Purely Advanced

2015 Edition

Know-how Makes KM **Technical Data Sheet**

KM Sterilized Nonwoven Wiper

Sterilized Nonwoven Sheet Wiper for Clean Environment

Product

Name	Description	Packaging
KM-6509	9" x 9"	10sh/10 I .bags/8 O.bags/box

Description

KM-6509 made of Polyester and Cellulose by high pressure water jet is excellent in hydrophile property and absorbs liquid well.
Even the cleaning on the rough surface is lint-free and it is a non-woven wiper that is excellent in contamination control.
KM-6509 sterilized with Gamma Ray is safe from Bacteria and Virus.

Feature

- Long time storage easiness with Gamma Ray sterilization
- High absorbency compared to light weight, thin thickness
- High absorption rate, quick absorption speed
- As Eco-friendly products, toxic gas generation control when incineration
- High absorption force compared to polyester & micro-denier fabric
- A solid structure, excellent durability of abrasion and resistant to physical shock and friction

Application

- Cleanroom, parts of assembly Line, equipment and floor for Cleaning
- Pre-cleaning of process equipment and parts for equipment
- Various equipment, an external surface of facilities and frame cleaning
- Access floor cleaning, parts, equipment and surface cleaning in Cleanroom

Product Environment

- Clean wipers produced in cleanroom
- Customers quality satisfaction through continuous cleanroom management
- Strict quality control based on ISO 9001:2008 quality standard
- Sterilization with Gamma Ray(cobalt-60) removes bacteria and virus
- Manages the Dosimetry range as 20~40kGy

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Know-how Makes KM **Specification**

KM Sterilized Nonwoven Wiper

Property	Unit	SPEC	Value	Test Method	Remarks
Material	-	-	-	Polyester + Cellulose	Polyeter 45% + Cellulose 55%
Length MD	Mm	230±10	230.6	JIS L 1096 8.3	-
Length TD					
Weight	g/sh	3.7±0.4	3.84	JIS L 1096 8.4	-
	g/㎡	70±7	72.28		-
Thickness	㎛	340±20	352.22	JIS L 1096 8.5	-
Horizontal Time to Sorption	sec/6ø	≤4	1.36	IEST-RP-CC004.2 7.2	-
Absorbency	ml/㎡	≥300	349.06	IEST-RP-CC004.2 7.1	-
	ml/g	≥4.3	4.82		-
NVR	Grade	≥B	A	IEST-RP-CC004.3 7.1.2	Dust Sport Method Grade : A > B > C
LPC	≥0.5㎛, ea/㎥	≤5.67 x 10^3	3.41 x 10^3	IEST-RP-CC004.3 6.1.3	Liquid Particle_ Orbital Shake Particle Channel_ 0.5~20㎛
Fiber	≥100㎛, ea/㎥	≤30	1.67	IEST-RP-CC004.3 6.2.2.2	-

KM is the Only Clean Products company to be ISO 9001:2008, 14001:2004, 13485:2003, and OHSAS 18001:2007 registered.

The Validation of final packaging materials

Shelf life “2Years” for Gamma Sterilization

“ Sterilized Non-Woven Wiper ”

2013-01-23

KM CORPORATION.

Document No : SLT-1214-01

SOYAGREENTEC
감마선멸균전문업체
(Contract Sterilizer)

Purely Advanced
KM CORPORATION.
(Manufacturer)

The Validation of final packaging materials shelf life for Gamma sterilization

Report No. : SLT-1214-01

- Product Name : “ Sterilized Non-Woven Wiper ”
- Manufacture : 주식회사 케이엠
  “ KM CORPORATION ”
- Contract sterilizer : “ SOYAGREENTEC Co., Ltd.”

2013년 1월 23일

Technology for better life!
SOYAGREENTEC
Contract Sterilizer

Purely Advanced
Manufacturer

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첨부1. – 감마선조사 성적서(Certificate of gamma irradiation)
첨부2. – 챔버계측기점검(Checking chamber meter)
첨부3. – 접합박리시험 보고서(Seal peel test report)
첨부4. – 무균시험 보고서(Sterility test report)
첨부5. – ㈜소야그린텍 인증서 및 등록 현황(Certificate of Soyagreentec Co., Ltd)
첨부6. – 교정 성적서(Certificate of calibration)
첨부7. – 방사선 안정성 재료선택을 위한 일반지침
(Inside radiation the general guideline for the malleability material selection.)

Summary of Result

* Product information

Product group	Sterilized Non-Woven Wiper	Picture
Product Name	Sterilized Non-Woven Wiper	
Model Name	KM-6612L	
Lot No	HH-20, HH-14, HH-04	
Package material	LDPE	

* Summary of Result

Test item	Standard	Result					
		criterion	Unit	Control	Accelerated test after 40kGy irradiation		
					No aging	12M	24M
Seal peel test	ASTM F88	Over 80% of Control	N / 15mm	10.82	11.64	11.34	8.93
Dye penetration test	ASTM F1929	OK	-	OK	OK	OK	OK
Burst test	ASTM F1140	Over 80% of Control	kgf/cm^2	0.1559	0.1513	0.1445	0.1467
Sterility test	ISO 11737-2	Negative	-	N/A	Negative	Negative	Negative
Estimation by stage of validity period				OK	OK	OK	OK
N/A = Not applied M= months							

* Conclusion

Conclusion(Validation of packages)	Result
It has been decided that the established validity period can be applied because no meaningful difference has been found in the packing material that passed through accelerated aging test after Gamma Irradiation according to ASTM and ISO.	OK 2yr (24months)

1. Introduction

Gamma sterilization can be available for sealing package material. Depending on packing material, there may be property change or functional loss. So it is required to assess package material according to the procedures of ISO, ASTM, etc.

This report is the data certifying the validity period established by SOYAGREENTEC Co.,Ltd after testing the safety of the package material. Therefore it is not permitted for the data to be disclosed to or copied by a third party for its own commercial purpose.

2. Objective

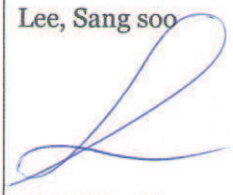
This test is to confirm the validity period of 2 years (24months) by comparing the property state and package state of the products and package material before and after accelerated aging test at a certain temperature according to related specs of ISO11607 and ASTM as well as the guideline of KFDA for the validity period and safety estimation of medical equipment.

3. Test Scope

This report will be applied to confirm the safety of package material by international standard tests with Gamma Test facility of SOYAGREENTEC for its sterilized and non-sterilized products. Samples were randomly chosen and provided by the client company. And this test result does not guarantee the safety of the products in all environments.

If there is any change in package material or production process, this report must be altered accordingly. Besides, it is highly important to make sure of the physical property and sterility state of the products as well as real-time packing state in accordance with the relevant standards.

4. Personnel & responsibilities

Class	Person	Facilities/Title	Related Field
Researcher	Lee, Sang soo  2013. 01. 23.	SOYAGREENTEC Co., Ltd. /Validation Team	Visual inspection Peel strength test Dye penetration test Burst test Sterility test
Reviewed By	Park, Jae Jeong  2013. 01. 23.	SOYAGREENTEC Co., Ltd. /Validation Team	
Approval	Lee, Kyou young  2013. 01. 23.	SOYAGREENTEC Co., Ltd. /Q.M.R.	Final report approval
Reviewed By		KM CORPORATION.	supervision institution "Testing and Research"
Approved By		KM CORPORATION.	supervision institution "Testing and Research"

5. 제품과 포장의 정보(Product & Package Information)

(1) 제품(Product)

품목군 (Product Group)	멸균 와이퍼 (Sterilized Wiper)	Device Grade
제품명 (Product Name)	멸균 논우븐 와이퍼 (Sterilized Non-Woven Wiper)	Class Ⅱ(FDA)
형 명 (Model Name)	KM-6612L	
제조번호 (Lot No.)	HH-20, HH-14, HH-04	
Raw materials or ingredients	Polyester 55% + Cellulose 45%	
크기 (Size)	9 inch x 9 inch	
사진 (Picture)		
Remark	-	

(2) 포장(Package)

구 성 (Composition)	포장재질 (Packaging material)	크 기 (Unit : mm)	Remark
1st Packaging	LOW-DENSITY POLYETHYLENE (LDPE)	255(W), 290(L), 5(H)	CAS Number (9002-88-4)
2nd Packaging	LOW-DENSITY POLYETHYLENE (LDPE)	320(W), 360(L), 35(H)	CAS Number (9002-88-4)
3rd Packaging	LOW-DENSITY POLYETHYLENE (LDPE)	345(W), 370(L), 35(H)	CAS Number (9002-88-4)

6. Sterilization method of product

According to the loading pattern planned in advance, products are loaded in totes by the operation team. In the totes, the products of the clients must be loaded in consecutively and must not be mingled with other products. Dosimeter has to be attached at ordinary supervisory point of the initial, mid, and final part in the series of totes. Before loading, attach Gamma Indicator on the exterior of equipment.

The totes in which products are loaded must be controlled separately from other products under survey, and must be controlled by the operator per cycle. All changes that may affect the absorption dose of the product in process such as variables of process, emergency stop of facility, source down, etc) must be recorded for preservation.

When the planned processing cycle is finished, collect Dosimeters attached to products so as to be read by Quality Control Team.

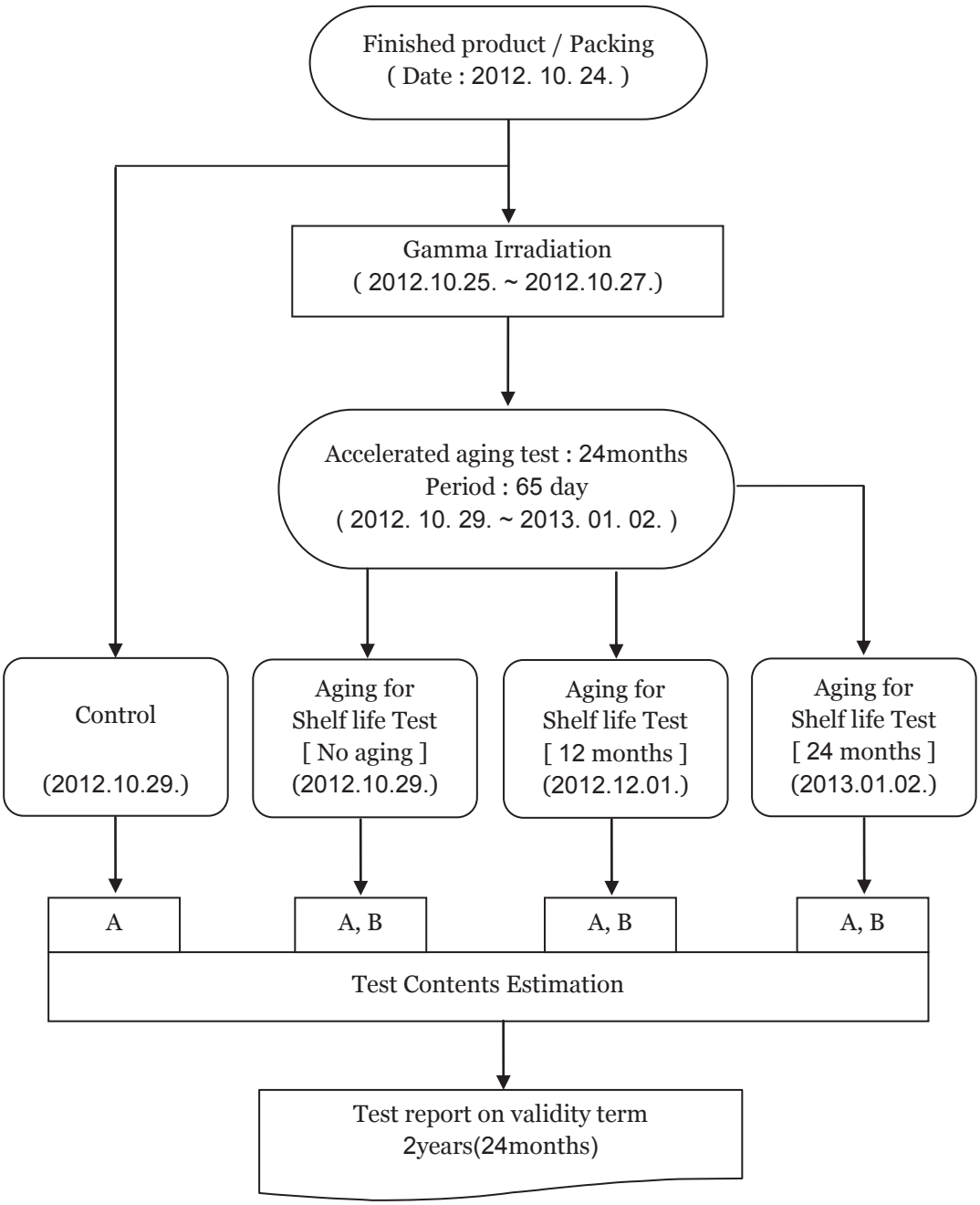
If survey has been made within required absorption dose range (25kGy ~ 40kGy) (that is, the minimum dose (sterility dose) of the tote to which the Dosimeter of the lowest value was attached is more than 25kGy, and the maximum absorption dose of the tote to which the Dosimeter of the maximum value was attached is not exceeding 40kGy), the process has been conducted successfully, and the product test process is finished.

The maximum absorption dose exceeds 40kGy, and the products loaded in the container must be treated as a failed process. So they must be treated according to the request of the client.

If the minimum absorption dose does not exceed 25kGy, it has to be treated as a failed process, and additional steps must be taken through the conference between managers of quality control team and operation team and the approval of the quality management representative. The additional steps must be treated by adjusting the process parameter within the range of required dose 25kGy and maximum absorption dose 40kGy. Here, the contents of additional steps must be recorded. The range of dose between 25~40kGy is wide, and additional survey is possible within the range not exceeding maximum absorption dose. In this case, as the additional steps are determined and conducted immediately after reading the dose (3~5 minutes), microbiological influence or product degradation by divided survey has been excluded from the estimation.

7. Protocol

(1) Test Plan



A : Visual inspection, Peel strength test
Dye penetration test, Burst test

B : Sterility test

(2) Test Period

Test item		Test Period	Remark
Total Period		2012. 10. 29. – 2013. 01. 17.	-
40kGy Gamma irradiation		2012. 10. 25. – 2012. 10. 27.	-
Accelerating aging test		2012. 10. 29. – 2013. 01. 02.	Aging for 24months
Visual inspection Peel strength test Dye penetration test Burst test Sterility test	1	2012. 10. 29. – 11. 13.	-
	2	2012. 10. 29. – 11. 13.	-
	3	2012. 12. 03. – 12. 18.	-
	4	2013. 01. 02. – 01. 17.	-

1 : Control group

2 : After 40kGy Gamma irradiation (No aging Test)

3 : After 40kGy Gamma irradiation (Aging for 12months)

4 : After 40kGy Gamma irradiation (Aging for 24months)

(3) Sample

	Temperature	Time	Product picture
Storage condition	(23 ± 2)℃	Over 40 hours before test	

(4) Test standard & Sample preparation

Test Type	Criteria	Sampling	Model / Std	Quantity (EA)
Visual inspection (packing)	ISO 11607	10ea per test point.(packaging)	Sealed packaging (120ea) + Finished product (36ea)	156
Gamma irradiation	ISO 11137	Gamma irradiation after checking sectional quantity. 40kGy(Based on maximum dose)		
Accelerated aging test	ASTM F1980-07	All samples except control group Prepare 90 samples (where 40kGy test is performed)		
Peel strength test	ASTM F88	10ea per test point. Cut to 15mm width.	Sealed packaging	40
Dye penetration test	ASTM F1929	10ea per test point.	Sealed packaging	40
Burst test	ASTM F1140	10ea per test point.	Sealed packaging	40
Sterility test	ISO 11737-1,2	Product 12ea per Accelerated test point.	Finished product	36
*The quantity includes spare samples as well.				

(5) Method & Procedure

1	Visual inspection
Purpose	Single out poor package to reduce error rate; make sure of the packing process when error rate is high.
Sample preparation	Prepare 10 samples randomly chosen.
Test system	Inspection stand Magnifying glass
Procedure	Inspect samples with a magnifying glass based on ISO11607 and mark poor samples.
Acceptance criteria	OK – If the sample is not poor.

2	Gamma irradiation test
Purpose	As Gamma sterility is applied to products, conduct test for samples with maximum dose which is expected to greatly affect the samples.
Sample preparation	Finished products : 36ea Sealed package material : 90ea
Test system	JS-10000 Gamma irradiation Dosimetry system (Measure absorbed dose)
Test Procedure	Put a sample box in tote for sterility [Tote: size (825mm*540mm*1500mm)] and attach Dosimeter to the position of maximum absorption dose to make sure of the dose.
Acceptance criteria	The range within +10% of ISO11137 is OK.

3	**Accelerated aging test**
Purpose	The test is to give extreme conditions to the finished products and sealed package which have passed Gamma Irradiation test with maximum absorption dose for the established valid period.
Sample preparation	Prepare the planned quantity of products (finished products and sealed package) after having passed maximum absorption dose test.
Test system	Constant humidity & temperature chamber

Procedure

The prescriptions of AAMI TIR17 and ASTM F 1980-07 as in the following are to calculate real-time equivalent (RTE) validity period on the basis of accelerated aging temperature (Taa) and accelerated aging time (AAT), and this test has applied the specification.

AAT = 730days/AAF

AAF= $Q_{10}^{(Taa-Trt)/10}$

Q_{10}= 2.0 or 1.8

AAT : Accelerated aging time
AAF : Accelerated aging factor
Taa : Accelerated aging temperature

Trt: Real-time temperature or ambient temperature. Normally the recommended storage temperature for the product is 20~25℃. In this test, the temperature was decided at 25℃ according to the condition proposed by the applicant.

Q_{10}: Aging quotient depending on the rise or fall of aging temperature by 10℃

Most industrial standard prescribes Q_{10}=2.0, and this test has been conducted at 2.0 according to the condition proposed by the applicant.

- If the package material is high polymer system, accelerated aging temperature not exceeding 60℃ is generally recommended, but in this test, 60±2℃ has been used according to the condition proposed by the applicant.
- As the valid period of the product is 2 years (24 months), the accelerated aging time is calculated as in the following :

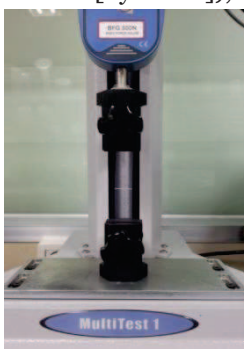
$AAF = 2.0^{(60-25)/10} = (2.0)^{3.5} \fallingdotseq 11.314$

AAT = 730days / 11.314 = 64.52days ≒ 65days(Accelerated aging time)

= 730 days (Real-time equivalent = 24months)

That is, if the accelerated aging time is longer than 65days under the 60±2℃ condition, the real-time equivalent validity period is over 2years. So in this test, the accelerated aging time is decided to be over 65days (real-time 2years) under the same temperature condition.

Acceptance criteria	OK – If there is no change in the package material.

4	**Seal peel test for packaging**
Purpose	Area of the thermal adhesive strength of the suture materials is measured.
Sample preparation	Prepare samples per section that have passed the control group and accelerated aging test. Sample : Cut to 15mm width.
Test system	Multi-tester, Push-pull gauge Vernier Calipers
Procedure	According to ASTM F88-07a(Technique B : Supported 90°[by Hand]), Eack tail of the specimen is secured in opposing grips and the seal remains hand-supported at a 90° perpendicular angle to the tails while the test is being conducted. Separate a grip at a rate of 200mm/min. Record the maximum seal force. 
Acceptance criteria	Should be maintain more than 80% of the average value of maximum seal force of the control group.

5	**Dye penetration test**
Purpose	This test method defines materials and a procedure that will detect and locate a leak equal or greater than a channel formed by a 50um (0.002in.) wire in package edge seals formed between a transparent film and a porous sheet material.
Sample preparation	Prepare 10ea per test point. The test specimen shall consist of a complete packaged device.
Test system	Small knife Dying liquid injector Magnifying glass
Procedure	< Dye agent > Wetting agent : Triton x 100 (0.5%) Indicator dye : Toluidine blue(0.05%) Inject sufficient dye penetrant into the package to cover the longest edge to a depth of approximately 5mm (0.25in.). Allow the dye penetrant solution to remain in contact with the seal edge for a minimum of 5 s and a maximum of 20. Channels will be detected within this time period but beyond 20 s, wicking of dye through the porous packaging will color the entire seal.
Acceptance criteria	There should be no Channels.

6	**Burst test**
Purpose	These test methods explain the procedure for determining the ability of packages to withstand internal pressurization.
Sample preparation	Prepare 10ea per test point. The test specimen shall consist of a complete packaged device.
Test system	Burst test System
Procedure	According to ASTM F1140-07(Test method A : Burst Test) Packages are tested in an apparatus that internally pressurizes the package until the package fails. The pneumatic supply and pressurization equipment need the capability to maintain an increasing pressure until the package bursts. The test measure is the maximum pressure detected before the package fails. 
Acceptance criteria	Should be maintain more than 80% of the average value of maximum pressure of the control group.

7	**Sterility test**
Purpose	To make sure about no bacteria in the sealed finished products.
Sample preparation	12ea(product) per accelerated test point of after sterilization.
Test system	Test tube, Incubation system, Clean room
Procedure	**Function test of culture medium** Inject 10~100 test strains or the equivalent strains, and culture them at the temperature for sterility test. The bacteria must grow within 5 days. **Microbiology growth inhibitory test** A. Inject 10~100 strains for cultural medium function test or the equivalent strains to cultural medium with a sample inside and control group cultural medium without any sample respectively. B. We cultured Soybean-casein digest broth for 7 days at 20~25℃ and checked bacterial growth at 30~35℃ of Thioglycollate Medium I and II. In case there is no bacterial growth, if the bacterial growth quantity is little or delayed compared to controlled group, it is judged to have bacteriostasis in the sample. In this case, either put an appropriate amount of inactivator that will not affect bacteria growth or increase the broth until there is no bacteriostasis. **Sterility test** A. As the sample is finished product that is nearly sterile, dissemble the sample after opening the container in the sterile condition. B. Sample was placed in Soybean-casein digest broth and Thioglycollate medium. Meidum where sample was not in has been treated as negative medium. C. We cultured Soybean-casein digest broth at 20~25℃ and Thioglycollate medium I, II at 30~35℃ for over 14 days. After checking once in 5^{th}~ 9^{th} days and observed bacterial growth twice on the final day. When reading was difficult due to unclear medium because of the sample, we transplanted to a new medium and observed for over 7 days at the same temperature.

Acceptance criteria	If bacterial growth is not detected at the test result, the medium is appropriate for sterility test, but if there are any bacteria, it is not appropriate for sterility test. If one of the following applies to the medium, void the test and start it again. ① When an error is detected in the course of test review ② Bacterial growth is recognized in the negative control group, ③ When an error is detected in the course of microbiological monitoring about sterile facility, ④ If the identified bacteria separated at a test is recognized to have come from the sterility test manipulation and material and if bacterial growth is not recognized at the retest, it is appropriate for sterility test. But if bacterial growth is recognized, it is not appropriate for sterility test.

8. Test results

1	**Visual inspection**				
Result					
Inspection items	Control	Accelerated test after 40kGy irradiation			Remark
		Aging for Shelf life Test (No aging)	Aging for Shelf life Test (12 months)	Aging for Shelf life Test (24 months)	
Sealing sutures	OK	OK	OK	OK	
Size	OK	OK	OK	OK	
Stain	OK	OK	OK	OK	
Foreign substance	OK	OK	OK	OK	
Tear	OK	OK	OK	OK	
Tiny hole	OK	OK	OK	OK	
Rupture	OK	OK	OK	OK	
Cracking	OK	OK	OK	OK	
Decision	It was confirmed that there was nearly no change when compared to the control group, and therefore the sample is recognized to be appropriate for a test sample.				
O K					

2	**Gamma irradiation test**			
Sample quantities	Sealing Packing : 90ea Finished product : 36ea			
Absorbed dose	ABS	Thickness(cm)	ABS/cm	Dose (kGy)
	1.056	0.318	3.32	42.1
Decision	As the dose is 40kGy +10%(Set dose: 40–44kGy), it is appropriate for the test.			
O K				
Attachments 1				

<table>
<tr><td>3</td><td colspan="3">Accelerated aging test</td></tr>
<tr><td>Accelerated aging test condition</td><td colspan="3">The temperature was set at 60±2℃ (humidity: 50%)
- As the validity period of the product is 2 years, the accelerated aging time can be calculated as in the following.
AAF = $2.0^{(60-25)/10} = (2.0)^{3.5} \fallingdotseq 11.314$
AAT = 730days/11.314 = 64.52days≒ 65days (Accelerated aging time)
= 730days (24 months)(Real-time equivalent)
That is, if the accelerated aging time is over 65days at 60±2℃, the real-time equivalent validity period is over 2 years (24 months). So in this test, we set the accelerated aging time more than 65days [real-time 2years (equivalent to 24 months)] at the same temperature.</td></tr>
<tr><td>Sample quantities</td><td colspan="3">Sealing Packing : 90ea
Finished product : 36ea
Becomes included extra.</td></tr>
<tr><td colspan="4">Packing condition</td></tr>
<tr><td rowspan="2">Control</td><td colspan="3">Accelerated test after 40kGy irradiation</td></tr>
<tr><td>Aging for Shelf life Test (No aging)</td><td>Aging for Shelf life Test (12 months)</td><td>Aging for Shelf life Test (24 months)</td></tr>
<tr><td>  </td><td>  </td><td>  </td><td>  </td></tr>
<tr><td>Decision
O K</td><td colspan="3">It was confirmed that there was nearly no change when compared to the control group, and therefore the sample is recognized to be appropriate for a test sample.</td></tr>
<tr><td colspan="4">Attachments 2</td></tr>
</table>

4	**Seal peel test for packaging**				
Result					
Criteria : Over 80% of control group					
No.	Unit : N/15mm				Remark
	Control	Accelerated test after 40kGy irradiation			
		Aging for Shelf life Test (No aging)	Aging for Shelf life Test (12 months)	Aging for Shelf life Test (24 months)	
1	11.0	12.2	11.3	8.7	
2	11.1	11.9	12.3	8.7	
3	11.3	10.2	10.7	8.9	
4	11.3	11.9	11.6	9.0	
5	10.9	12.5	12.5	8.9	
6	10.7	11.4	11.5	9.2	
7	10.5	11.7	11.0	8.9	
8	10.2	11.2	10.5	8.8	
9	10.5	11.4	11.1	9.3	
10	10.7	12.0	10.9	8.9	
Average	**10.82**	**11.64**	**11.34**	**8.93**	
Decision	The sample test value before and after accelerated aging test was over 80% of the value of control group, which means safety in the product control, and therefore, we judged it to be OK.				
O K					
Attachments 3					

5	**Dye penetration test**

Result

Criteria: There should be no Channels.

Lot No.	Control	Accelerated test after 40kGy irradiation			Remark
		Aging for Shelf life Test (No aging)	Aging for Shelf life Test (12 months)	Aging for Shelf life Test (24 months)	
1	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
2	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
3	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
4	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
5	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
6	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
7	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
8	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
9	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
10	Negative (-)	Negative (-)	Negative (-)	Negative (-)	
Not OK	NONE	NONE	NONE	NONE	

Channels : A small continuous open passage across the width of a package seal through which microorganisms could pass.
Negative : No leak of dye penetrant.
NONE : Nothing .

Decision	Judged to be suitable is because Dye leakage did not occur.
O K	

Attachments 4

6	**Burst test**				
Result					
Criteria : Over 80% of control group					
No.	Unit : kgf/cm^2				Remark
	Control	Accelerated test after 40kGy irradiation			
		Aging for Shelf life Test (No aging)	Aging for Shelf life Test (12 months)	Aging for Shelf life Test (24 months)	
1	0.147	0.148	0.140	0.137	
2	0.150	0.156	0.150	0.146	
3	0.161	0.138	0.139	0.146	
4	0.162	0.149	0.159	0.137	
5	0.154	0.157	0.148	0.155	
6	0.158	0.155	0.143	0.147	
7	0.153	0.137	0.138	0.153	
8	0.156	0.159	0.137	0.149	
9	0.157	0.154	0.136	0.140	
10	0.161	0.160	0.155	0.157	
Average	**0.1559**	**0.1513**	**0.1445**	**0.1467**	
Decision	The sample test value before and after accelerated aging test was over 80% of the value of control group, which means safety in the product control, and therefore, we judged it to be OK.				
O K					

7-1 Sterility test		Sample : Aging for Shelf life Test (No aging)		
		■ Direct method		
Cultural medium	Soybean-casein digest broth	Culturing condition	Aerophile bacteria/Fungi	22.5℃
	Thioglycollate medium I		Aerophile bacteria/Fungi	32.5℃

1. Function of medium

Strain & result / Medium	Test strains	Backteria growth
Thioglycollate medium I	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 9027) *Clostridium sporogenes* (ATCC 19404)	Yes
Soybean-casein digest broth	*Bacillus subtilis* (ATCC 6633) *Candida albicans* (ATCC 10231) *Aspergillus niger* (ATCC 16404)	

2. Bacteriostasis test

Medium	Test strains	Injection amount	Culturing	Sample medium	Control group medium	Decision
Thioglycollate medium I	*S. aureus*	10~100	At 32.5℃, aerophile culture, 7 days	G	G	No inhibiting material
	P. aeruginosa			G	G	No inhibiting material
	C. sporogenes			G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100	At 22.5℃, aerophile culture for 7 days	G	G	No inhibiting material
	Candida albicans			G	G	No inhibiting material
	Aspergillus niger			G	G	No inhibiting material

※ G: Growth. N.G.: No Growth.

3. Result of sterility test

Test method	Medium	Test start (2012.10.29.)	Middle check (2012.11.05.)	Final check (2012.11.13.)
Direct method	Thioglycollate medium I	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
	Soybean-casein digest broth	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.

4. Test result : The test result showed that sterility was maintained. Attachments 5

7-2 Sterility test		Sample : Aging for Shelf life Test (12months)		
		■ Direct method		
Cultural medium	Soybean-casein digest broth	Culturing condition	Aerophile bacteria/Fungi	22.5℃
	Thioglycollate medium I		Aerophile bacteria/Fungi	32.5℃

1. Function of medium

Strain & result / Medium	Test strains	Backteria growth
Thioglycollate medium I	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 9027) *Clostridium sporogenes* (ATCC 19404)	Yes
Soybean-casein digest broth	*Bacillus subtilis* (ATCC 6633) *Candida albicans* (ATCC 10231) *Aspergillus niger* (ATCC 16404)	

2. Bacteriostasis test

Medium	Test strains	Injection amount	Culturing	Sample medium	Control group medium	Decision
Thioglycollate medium I	*S. aureus*	10~100	At 32.5℃, aerophile culture, 7 days	G	G	No inhibiting material
	P. aeruginosa			G	G	No inhibiting material
	C. sporogenes			G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100	At 22.5℃, aerophile culture for 7 days	G	G	No inhibiting material
	Candida albicans			G	G	No inhibiting material
	Aspergillus niger			G	G	No inhibiting material

※ G: Growth. N.G.: No Growth.

3. Result of sterility test

Test method	Medium	Test start (2012.12.03.)	Middle check (2012.12.10.)	Final check (2012.12.18.)
Direct method	Thioglycollate medium I	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
	Soybean-casein digest broth	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.

4. Test result : The test result showed that sterility was maintained. Attachments 5

7-3 Sterility test		Sample : Aging for Shelf life Test (24months)		
		■ Direct method		
Cultural medium	Soybean-casein digest broth	Culturing condition	Aerophile bacteria/Fungi	22.5℃
	Thioglycollate medium I		Aerophile bacteria/Fungi	32.5℃

1. Function of medium

Strain & result / Medium	Test strains	Backteria growth
Thioglycollate medium I	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 9027) *Clostridium sporogenes* (ATCC 19404)	Yes
Soybean-casein digest broth	*Bacillus subtilis* (ATCC 6633) *Candida albicans* (ATCC 10231) *Aspergillus niger* (ATCC 16404)	

2. Bacteriostasis test

Medium	Test strains	Injection amount	Culturing	Sample medium	Control group medium	Decision
Thioglycollate medium I	*S. aureus*	10~100	At 32.5℃, aerophile culture, 7 days	G	G	No inhibiting material
	P. aeruginosa			G	G	No inhibiting material
	C. sporogenes			G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100	At 22.5℃, aerophile culture for 7 days	G	G	No inhibiting material
	Candida albicans			G	G	No inhibiting material
	Aspergillus niger			G	G	No inhibiting material

※ G: Growth. N.G.: No Growth.

3. Result of sterility test

Test method	Medium	Test start (2013.01.02.)	Middle check (2013.01.09.)	Final check (2013.01.17.)
Direct method	Thioglycollate medium I	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
	Soybean-casein digest broth	Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.
		Inoculation	N.G.	N.G.

4. Test result : The test result showed that sterility was maintained. Attachments 5

9. Estimation and conclusion of test result

☐ When calculated accelerated aging test at 60±2℃ (humidity 50%) and Q_{10}= 2.0 against the samples (package material sterilized by Gamma Irradiation) in order to figure out validity period of the material corresponding to the real-time validity period 2 years (24 months) according to the prescriptions of AAMI TIR17 and ASTM F 1980-07, the accelerated aging time of the package material corresponding to 2 years (24 months) of real-time validity period was 65 days.

☐ According to standard specifications, package material test, physical test, and sterility test was adopted considering the samples and manufacturing process which have to do with the checking items of the accelerated aging test

☐ At the test before and after the accelerated aging, there was almost no difference.

☐ On the basis of the test result, we can conclude the validity time of the sample is over 2 years (24 months)

☐ The foregoing conclusion came from the accelerated aging corresponding to the real-time validity period, and so the manufacturer will have to make sure real time in the future about the packing state, physical state, and sterility state of the package material.

10. Test institution and facilities

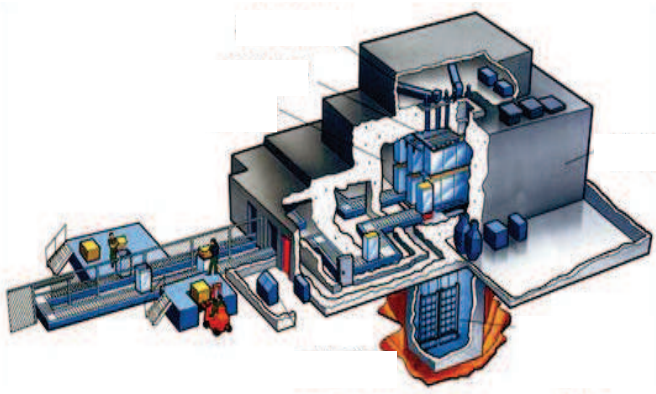
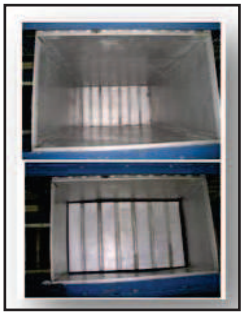
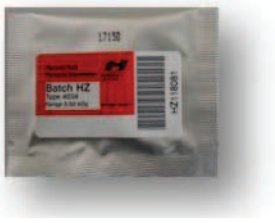
(1) Information of test institution & Facilities

Institution	Soyagreentec Co., Ltd			
Address	900-3 Sangsin-li, Hyangnam-eup, Whaseong-si, Gyeonggi-do			
Contact Number	TEL	031-353-6999	FAX	031-353-6979
Home page	www.soyagreentec.co.kr			
Facilities	Gamma irradiator JS10000			
	Constant humidity & temperature chamber			
	Multi-tester			
	Clean Room			
	Incubator			
	Bubble emission test system, Burst test system			

(2) Certificate & Calibration of SOYAGREENTEC

Item	Specification	Certified by	Reference
ISO9001:2008	Service of Sterilization by irradiation	TUV service	Attachments 6
EN ISO13485:2003	Provision of Irradiation Service of Medical Devices	TUV service	
EN ISO11137	Sterilization of healthcare product-Requirement of validation and routine Control – Radiation sterilization	TUV service	
US FDA Registration	Contract Sterilizer	US FDA Registration	
Certificate of GMP	We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices for the product(s) listed above.	*Korea Environment & Merchandise Testing Institute *Korea Food & Drug Administration	
Calibration	Constant humidity & temperature chamber	LBBFINE. Co.,Ltd.	Attachments 7
	Multi-tester	KTL	
	Gauge Pressure Gage	KTL	
	DIGITAL VERNIER CALIPER	KTL	
	HYGRO Thermometer	KTL	

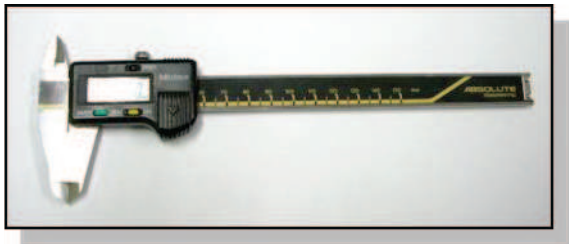
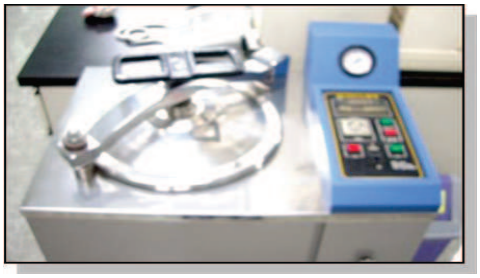
(3) Test institution & facility information

1. Introduction of SOYAGREENTEC			
Tester	Gamma Irradiator (High Performance Tote Type)		
Model	JS10000	Serial No.	IR-203
Installed company	MDS – Nordion (Canada)	Capacity	Co-60 3million Ci
Picture			
Tote	 		
Estimation of absorbed dose (Routine Dosimeter)	 Harwell Red  Amber Perspex type		

Material	Aluminum
Bore size (mm)	Width : 825 Length : 540 Height : 1500
Quantity	55
Maximum weight(kg)	360

2. Constant humidity & temperature chamber

Standard spec			
Model	FLT084S		
Function		**Standard**	
Test temperature range	0℃ - 80℃	Internal size	W800 * D600 * H850(mm)
Test humidity range	30% - 98%RH	External size	W920 * D1060 * H1840(mm)
Temperature calibration	± 0.3℃	Voltage	AC220V 60HZ 1PH
Humidity calibration	± 2.5%RH	Power	2.5KW
Temperature distribution	± 0.5℃	Weight	125kg
Humidity distribution	± 3%RH	-	-
Structure			
Internal & external material	Stainless Steel Plate(STS#304)		
Refrigerator	Completely sealed refrigerator		
Temperature Heater	Strip Wire Heater	Dehumidfier	Flat Fin Cooler
Humidity Heater	SUS#304 Pipe Heater	Water supplier	Automatic water supplier (gravitation type)
Safety device	Self-diagnosis(overheating, temperature sensor problem, low water level, overheating of heater)		
Picture			

3. DIGITAL VERNIER CALIPER			
Manufacturer	MITUTOYO	Model & Equipment No.	150mm / 0170226
Picture			
4. HYGRO Thermometer			
Manufacturer	China	Equipment No	071224A
Picture			
5. AUTOCLAVE			
Manufacturer	HANYOUNG	WATT	3KW
CAPACITY	60L	VOLT	220V 60HZ
Picture			

6-1. Multi-tester

Model	Multi Test 1
Picture	

MULTITEST 1 SPECIFICATIONS

Load capacity	1000N / 100kgf / 220lbf
Power consumption	60 watts (maximum)
Weight (stand only)	20kg (44lb)

CROSSHEAD MOTION

Travel range	500mm (19.68in)
Maximum daylight	630mm (24.80in)
Maximum headroom	510mm (20.08in)
Speed range	2.5 • 1000mm/min
Up and down settings	by toggle switch
Stand speed indicated	by potentiometer / graduated dial LED
Direction of travel indicated	LED
Limit switch repeatability	< 0.5mm (0.020in)
Over-run at top speed	< 2mm (0.08in)
Operating modes	Manual & single cycle with fast return
Reverse on alarm point	Yes, with AFG or AFTI cable
Reverse on sample break	Yes, with AFG or AFTI cable

ENVIRONMENTAL OPERATING CONDITIONS

Temperature range	5℃ to 40℃
Humidity	< 92.5%

STANDARD LOAD MEASUREMENT OPTIONS

Force Gauge and dovetail bracket	Yes
Anvil plate	Yes
S-beam loadcell, tension	
Block module & AFTI	Yes

SPECIAL OPTIONS

Increased crosshead travel	No
INCREASED CROSSHEAD DEPTH	Yes, reduced load capacity
Machine guard	Yes
Horizontal operation	Yes
Simple logging / platting PC software	Data Plot (See document M/501201)
Full computer control	Multi Test 1- i
Interoal storage of test programs	Multi Test 1- x

6-2. Push-Pull Gauge

Model	500N	Manufacturer	Mecmesin
Specification			

BFG Specification Table

Range & Resolution

Modle no	mN	N	kN	g-f	kg-f	oz-f	lb-f
BFG 50	50,000x10	50x0.01	-	5,000x1	5x0.001	180x0.05	11x0.002
BFG 200	-	200x0.05	-	20,000x5	20x0.005	720x0.2	44x0.01
BFG 500	-	500x0.1	-	50,000x10	50x0.01	1,800x0.5	110x0.02
BFG 1000	-	1,000x0.2	1x0.0002	-	100x0.02	3,500x1	220x0.05
BFG 2500	-	2,500x0.5	2.5x0.0005	-	250x0.05	9,000x2	550x0.1

Accuracy :

±0.25% of full-scale, ± least significant digit

Calibration temperature : 20℃ ± 2℃

Operating temperature : 10℃ - 35℃

Temperature shift at zero load : ±0.09% of full-scale / ℃

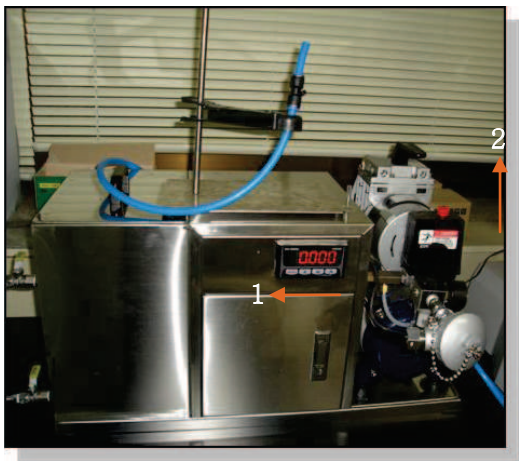
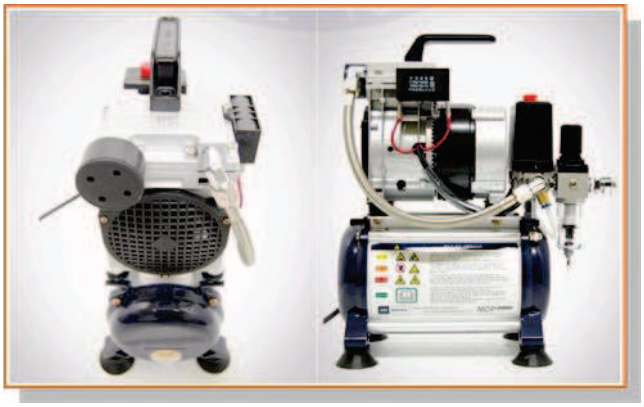
Output :

RS232-C ..... 8 data bits, 1 start bit, no parily

Digimatic [Mitutoyo] formal

Analogue ... • referenced to ground 1.5V at zero load , ±1V approx. for full-scale
Tension / compression

• referenced -to ve analogue output OV at zero load, ±1V approx. for full scale
Tension / compression

7. Burst test system **Bubble emission system**	
Composition	Picture
Burst test system **Bubble emission system**	
1. Digital compression **KN-2000W Series**	
2. Mult **Air Compressor**	

7-1. Digital compression indicator (Model : KN-2000W Series)

Series Name		KN-2000W Series
Power supply voltage		85 ~ 264VAC 47 ~ 63Hz / 24VAC 50Hz/60Hz(Options)
Power Consumption		Approximately 8VA (264VAC 60Hz)
How to Display		4 $\frac{1}{2}$line : 7Segment LED Display. Color : Red, green, orange Available.
Character Size		W 10mm x H 17mm (PV Show)
Input Specifications		RTD : JPT100Ω, DPT100Ω, DPT50Ω, CU50Ω, CU100Ω TC : K, J, E, T, L, N, U, R, S, B, C(w5), PL II Voltage Input : ±1.0000V, ±50.00mV, ±200.0mV, -1.000V ~ 10.000V Current input : 4.00 ~ 20.00mA, 0.00 ~ 20.00mA
Digital Input		Of three functions (Specify any ZERO, Disable alarm maintenance, PV hold function) Enabled by selecting one feature.
Auxiliary Output	Alarm Output	2 points: Relay contact capacity 250VAC 3A 1c 4 points: Relay contact capacity 250VAC 1A 1a
	Transport Output	ISOLATED DC4 ~ 20mA(PV Transport) Load resistance 600Ω Below
	Communication output	RS 485 modbus
Display Accuracy		[±0.2% F•S] ± 1Digit (25℃ ± 5℃) [±0.3% F•S] ± 1Digit (-10℃ ~ 20℃, 30℃ ~ 50℃) However, less than -100 ℃ thermocouple input [± 0.4% F • S] ± 1Digit ※ TC-T, TC-U at least ± 2.0 ℃
Setting method		Set using the front keys. Using 485communication.
Alarm Hysteresis		ON/OFF Set intervals (1~999Digit)
Input sampling cycle		Analog Input : 100ms. Temperature sensor input : 250ms
Function		Alarm, self-diagnostic function, peak hold function, digital input, input special function capability Enter the calibration, lock, display scale, output-scale features, the ability to change the display color.
The internal voltage		2000VAC 50/60Hz 1 minute (Between the input terminal and power terminal)
Internal vibration		5 ~ 55Hz (cycles 1 minute) Amplitude 0.75mm X, Y, Z Directions for two hours each.
Relay Life	2point	Mechanical : More than 10 million times, Electrical : More than 100,000 times (250VAC 3A resistive load)
	4point	Mechanical : More than 20 million times, Electrical : More than 500,000 times (250VAC 1A resistive load)
Insulation resistance		100M Ω or more (500VDC Per megabyte)
Internal noise		Square-wave noise by noise simulator (pulse-side 1us) ± 2KV
Compensation blackout		10 years (Approximately)
Ambient temperature using		-10 ~ 50℃ (Without freezing)
Storage Temperature		-20 ~ 60℃ (Without freezing)
Humidity using		35 ~ 85%RH
Weight		200g(Approximately)

7-2. Multi Air Compressor

Model : NCT011-T3 Manufacturer : Oillesscompressor Co., Ltd.

SPECIFICATIONS

Model	UNIT	SILVER	SILVER T3
Power	v	220	220
	Hz	60	60
Motor horsepower	hp	0.2	0.2
Power Consumption	kw	0.15	0.15
Air Production capacity	l/min	65	65
	CFM	2.28	2.28
MAX(8bar)	l/min	8	8
Displacement	CFM	2.28	2.28
Maximum Operating Pressure	Bar	7	7
	psi	100	100
Max.current	A	1.2	1.2
Tank Capacity	liter	-	3
	gallon	-	0.79
Weighy	Kg	5.51	8.52
	lbs	12	18.74
Size	mm	150/200/220	210/300/380
(W/L/H)	inch	5.9/7.87/8.66	8.26/11.8/14.9
Noise	dB(A)	67	67
Thermal	Thermal	OK	OK
Protechion	Protechion	OK	OK
Temperature	℃	0~40	0~40
	℉	32~104	32~104

Attachment 1.

Certificate of gamma irradiation.

CERTIFICATE

of gamma irradiation

Certificate No. : Soya-P 121029 1214-01

Customer : KM CORPORATION.

Item Specification	QTY(EA)	Lot No	Specified Dose	
			Dmin(kGy)	Dmax(kGy)
케이엠 부직포 멸균와이퍼 - 완제품 "Sterilized Non-Woven Wiper" finished product	36	HH-20 HI-14 HJ-04	40	44
케이엠 부직포 멸균와이퍼 - 포장재 "Sterilized Non-Woven Wiper" packing materials	90			
Total	126			

Irradiated Date : 24-Oct-12

Plant : Master Irradiation

Irradiation Container (Tote) No : 13 ~ -

Irradiator : Cobalt 60 gamma irradiator (JS-10000 High performance tote type)

Dosimeters for Monitoring (Batch No) : Harwell PMMA Dosimeter (Red 4034 JT)

Dosimetry Results (Dmin to Dmax) : - ~ 42.1 kGy

Date : 29-Oct-12

Approved : ki Hwan, Kim

Title : Q.M.R / Director

Signature

We hereby certify that the above specified goods have been duly irradiated by gamma-ray.

(상기에 명시된 제품은 정히 조사되었음을 확인합니다.)

Technology for better life!
SOYAGREENTEC

900-3, Sangsin-Ri, Hyangnam-Eup, Hwasung-Si, Kyoungki-Do, Korea

TEL : +82-31-353-6999 FAX : +82-31-353-6979 URL : http://www.soyagreentec.co.kr

ISO 9001 & EN ISO 13485
EN / ISO 11137-1:2006 Certified
NO. Q4N 11 01 50558 003

FDA
Contract sterilizer Registered
NO. 3004525100

Attachment 2.

Checking chamber meter

안정성 시험기 온도, 습도 기록서

(Safety Tester Temperature, Humidity documentation)

Oct. 2012.

점검자 (Recorder)	확인자 (Checker)	승인자 (Approval)
이상국	심현철	

모델(Model) : FLT-084S　　제조사(Manufacturer) : LABFINE, INC.

(Divide) 구분 / 날짜 (Date)	온도(Temperature) 기준(Standard) : 60±2℃ 1차 (Primary) AM 09:00	온도(Temperature) 기준(Standard) : 60±2℃ 2차 (Secondary) P.M. 04:00	습도(Humidity) 기준(Standard) : 50±5%Rh 1차 (Primary) AM 09:00	습도(Humidity) 기준(Standard) : 50±5%Rh 2차 (Secondary) P.M. 04:00	기록 (Record)	확인 (Check)	비고 (Remarks)
1	℃	℃	%	%			추석연휴
2	℃	℃	%	%			연휴
3	℃	℃	%	%			개천절
4	60 ℃	60 ℃	50 %	50 %			
5	60 ℃	60 ℃	50 %	50 %			
6	℃	℃	%	%			휴일
7	℃	℃	%	%			휴일
8	60 ℃	60 ℃	50.1 %	50 %			
9	60 ℃	60.1 ℃	50 %	50 %			
10	60 ℃	60 ℃	50 %	49.9 %			
11	60 ℃	60 ℃	50 %	50 %			
12	60 ℃	60 ℃	50 %	50 %			
13	℃	℃	%	%			휴일
14	℃	℃	%	%			휴일
15	60 ℃	60 ℃	50 %	50 %			
16	60 ℃	60 ℃	50 %	50.1 %			
17	60 ℃	60 ℃	50 %	50 %			
18	60 ℃	60 ℃	50 %	50 %			
19	60 ℃	60 ℃	50 %	50 %			
20	℃	℃	%	%			휴일
21	℃	℃	%	%			휴일
22	59.9 ℃	60 ℃	50 %	50 %			
23	60 ℃	60 ℃	50.1 %	50 %			
24	60 ℃	60 ℃	50 %	50 %			
25	60 ℃	60 ℃	50 %	50 %			
26	60 ℃	60 ℃	50 %	50 %			
27	℃	℃	%	%			휴일
28	℃	℃	%	%			휴일
29	60 ℃	60 ℃	50 %	50 %			
30	60 ℃	60 ℃	50 %	50 %			
31	60 ℃	60 ℃	50 %	50 %			

안정성 시험기 온도, 습도 기록서

(Safety Tester Temperature, Humidity documentation)

Nov. 2012.

점검자 (Recorder)	확인자 (Checker)	승인자 (Approval)

모델(Model) : FLT-084S

제조사(Manufacturer) : LABFINE, INC.

(Divide) 구분 / 날짜 (Date)	온도(Temperature) 기준(Standard) : 60±2℃ 1차 (Primary) AM 09:00	온도(Temperature) 기준(Standard) : 60±2℃ 2차 (Secondary) P.M. 04:00	습도(Humidity) 기준(Standard) : 50±5%Rh 1차 (Primary) AM 09:00	습도(Humidity) 기준(Standard) : 50±5%Rh 2차 (Secondary) P.M. 04:00	기록 (Record)	확인 (Check)	비고 (Remarks)
1	60 ℃	60 ℃	50 %	50 %			
2	60 ℃	60 ℃	50.1 %	50 %			
3	℃	℃	%	%			휴일
4	℃	℃	%	%			휴일
5	60 ℃	60 ℃	50 %	50 %			
6	60 ℃	60 ℃	50 %	50 %			
7	60 ℃	60 ℃	49.9 %	50 %			
8	60 ℃	59.9 ℃	50 %	50 %			
9	60 ℃	60 ℃	50 %	50 %			
10	℃	℃	%	%			휴일
11	℃	℃	%	%			휴일
12	60 ℃	60 ℃	50 %	50 %			
13	60.1 ℃	60 ℃	50 %	50 %			
14	60 ℃	60 ℃	50 %	50 %			
15	60 ℃	60 ℃	50 %	50.1 %			
16	60 ℃	60 ℃	50 %	50 %			
17	℃	℃	%	%			휴일
18	℃	℃	%	%			휴일
19	60 ℃	60 ℃	50 %	50 %			
20	60 ℃	60 ℃	50 %	50 %			
21	60 ℃	60 ℃	50 %	50 %			
22	60 ℃	60 ℃	50 %	50 %			
23	60 ℃	60 ℃	50 %	50.1 %			
24	℃	℃	%	%			휴일
25	℃	℃	%	%			휴일
26	60 ℃	60 ℃	49.9 %	50 %			
27	60 ℃	60 ℃	50 %	50 %			
28	60 ℃	60 ℃	50 %	50 %			
29	59.9 ℃	60 ℃	50 %	50 %			
30	60 ℃	60 ℃	50 %	50 %			

안정성 시험기 온도, 습도 기록서

(Safety Tester Temperature, Humidity documentation)

Dec. 2012.

점검자 (Recorder)	확인자 (Checker)	승인자 (Approval)
이성	김종천	

모델(Model) : FLT-084S

제조사(Manufacturer) : LABFINE, INC.

(Divide) 구분 / 날짜 (Date)	온도(Temperature) 기준(Standard) : 60±2℃ 1차 (Primary) AM 09:00	온도(Temperature) 기준(Standard) : 60±2℃ 2차 (Secondary) P.M. 04:00	습도(Humidity) 기준(Standard) : 50±5%Rh 1차 (Primary) AM 09:00	습도(Humidity) 기준(Standard) : 50±5%Rh 2차 (Secondary) P.M. 04:00	기록 (Record)	확인 (Check)	비고 (Remarks)
1	℃	℃	%	%			
2	℃	℃	%	%			
3	60 ℃	60 ℃	50 %	50 %			
4	60 ℃	60 ℃	50.1 %	50 %			
5	60 ℃	60 ℃	50 %	50 %			
6	60 ℃	60 ℃	50 %	50 %			
7	60.1 ℃	60 ℃	50 %	50 %			
8	℃	℃	%	%			
9	℃	℃	%	%			
10	60 ℃	60 ℃	50 %	49.9 %			
11	60 ℃	60 ℃	50 %	50 %			
12	60 ℃	60 ℃	50 %	50 %			
13	60 ℃	60 ℃	50.1 %	50 %			
14	60 ℃	60 ℃	50 %	50 %			
15	℃	℃	%	%			
16	℃	℃	%	%			
17	59.9 ℃	60 ℃	50.1 %	50 %			
18	60 ℃	60 ℃	50 %	50 %			
19	60 ℃	60 ℃	50 %	50 %			
20	60 ℃	60 ℃	50 %	50 %			
21	60 ℃	60 ℃	50 %	50 %			
22	℃	℃	%	%			
23	℃	℃	%	%			
24	60 ℃	60 ℃	50.1 %	50 %			
25	℃	℃	%	%			
26	60 ℃	60.1 ℃	50 %	50 %			
27	60 ℃	60 ℃	50 %	50 %			
28	60 ℃	60 ℃	50 %	49.9 %			
29	℃	℃	%	%			
30	℃	℃	%	%			
31	60 ℃	60 ℃	50 %	50 %			

안정성 시험기 온도, 습도 기록서

(Safety Tester Temperature, Humidity documentation)

Jan. 2013.

점검자 (Recorder)	확인자 (Checker)	승인자 (Approval)
이상숙	남원호	

모델(Model) : FLT-084S　　제조사(Manufacturer) : LABFINE, INC.

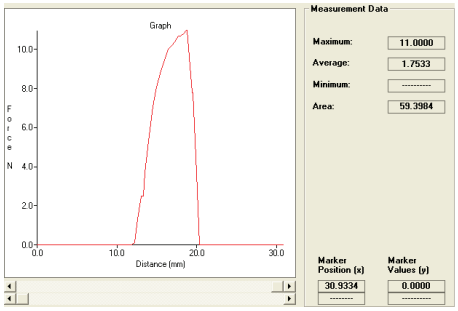
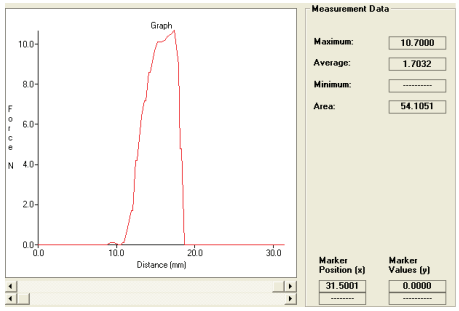
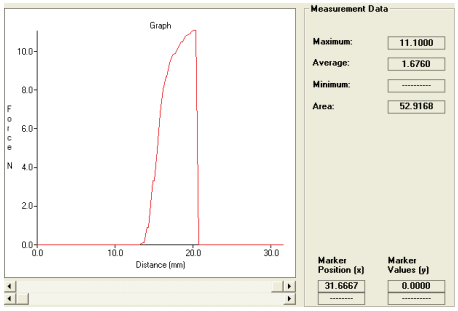
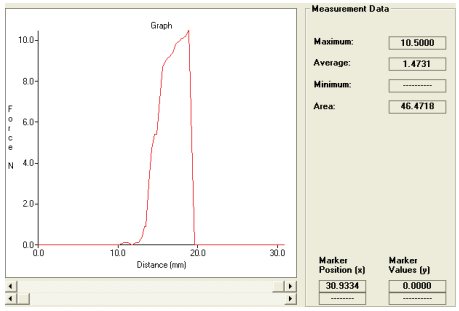
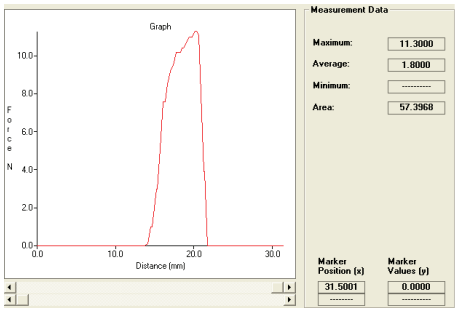
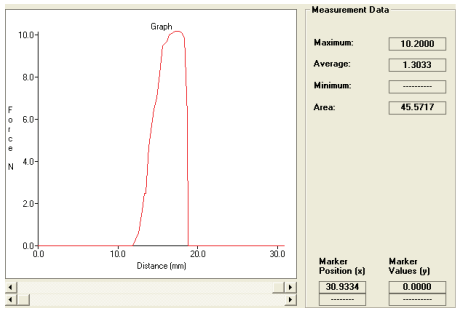
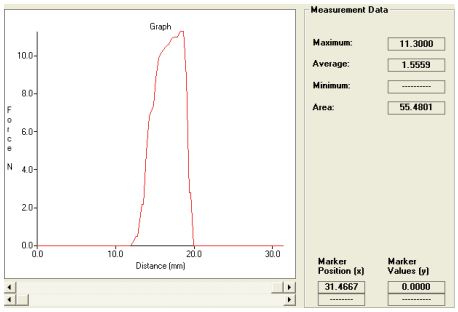
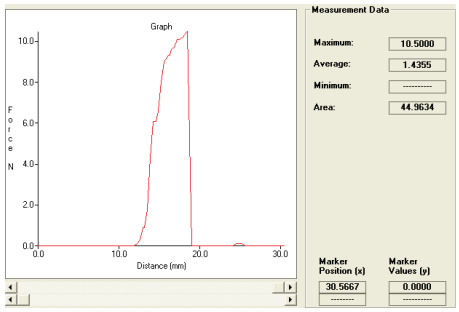
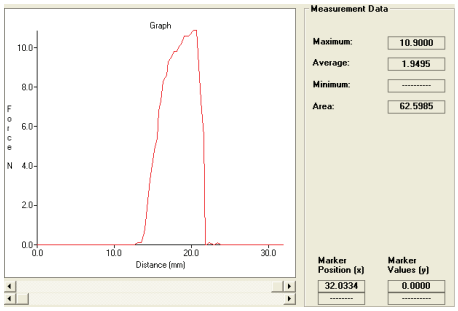
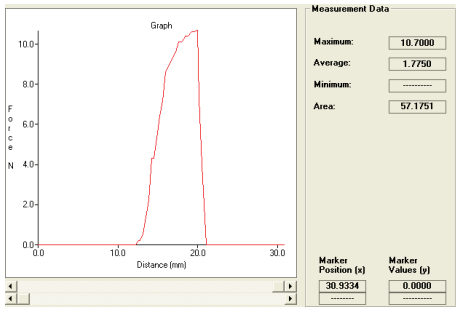
(Divide) 구분 / 날짜 (Date)	온도(Temperature) 기준(Standard) : 60±2℃ 1차 (Primary) AM 09:00	온도(Temperature) 기준(Standard) : 60±2℃ 2차 (Secondary) P.M. 04:00	습도(Humidity) 기준(Standard) : 50±5%Rh 1차 (Primary) AM 09:00	습도(Humidity) 기준(Standard) : 50±5%Rh 2차 (Secondary) P.M. 04:00	기록 (Record)	확인 (Check)	비고 (Remarks)
~~1~~	℃	℃	%	%			신정
2	60 ℃	60 ℃	50 %	50.1 %	이	남원호	
3	60 ℃	60 ℃	50 %	50 %	이	남원호	
4	60.1 ℃	60 ℃	50 %	50 %	이	남원호	
~~5~~	℃	℃	%	%			
~~6~~	℃	℃	%	%			
7	60 ℃	60 ℃	50 %	50 %	이	남원호	
8	60 ℃	60 ℃	49.9 %	50 %	이	남원호	
9	60 ℃	60 ℃	50 %	50 %	이	남원호	
10	60 ℃	60 ℃	50 %	50.1 %	이	남원호	
11	59.9 ℃	60 ℃	50 %	50 %	이	남원호	
~~12~~	℃	℃	%	%			
~~13~~	℃	℃	%	%			
14	60 ℃	60 ℃	50 %	50 %	이	남원호	
15	60 ℃	60 ℃	50.1 %	50 %	이	남원호	
16	60 ℃	60 ℃	50 %	50 %	이	남원호	
17	℃	℃	%	%			
18	℃	℃	%	%			
~~19~~	℃	℃	%	%			
~~20~~	℃	℃	%	%			
21	℃	℃	%	%			
22	℃	℃	%	%			
23	℃	℃	%	%			
24	℃	℃	%	%			
25	℃	℃	%	%			
~~26~~	℃	℃	%	%			
~~27~~	℃	℃	%	%			
28	℃	℃	%	%			
29	℃	℃	%	%			
30	℃	℃	%	%			
31	℃	℃	%	%			

Attachment 3.

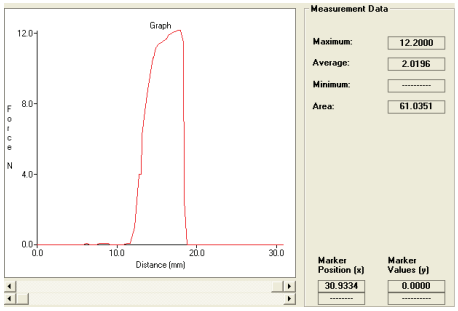
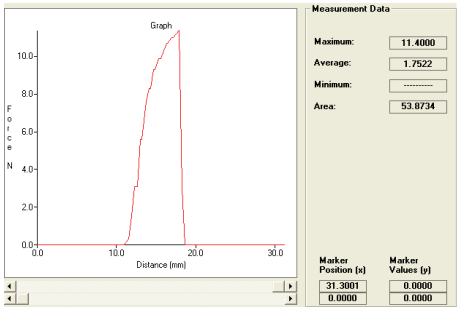
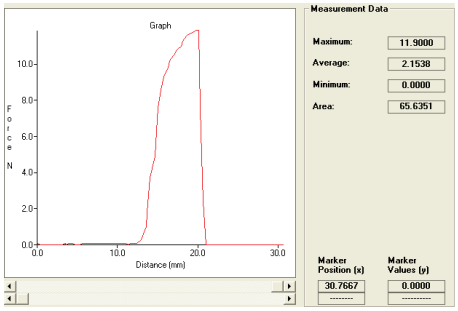
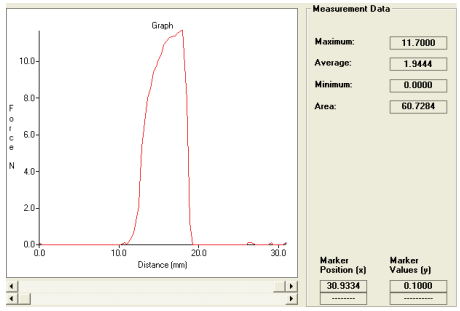
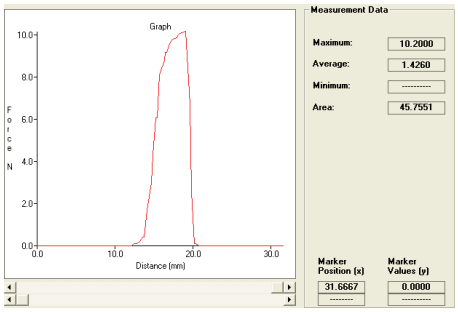
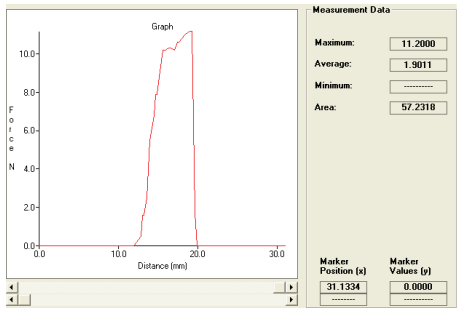
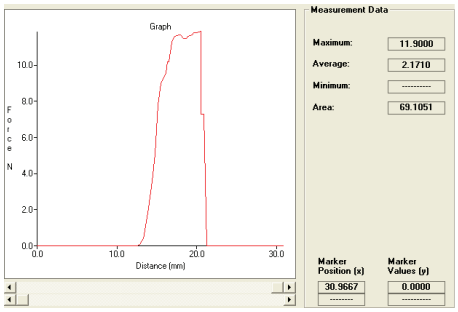
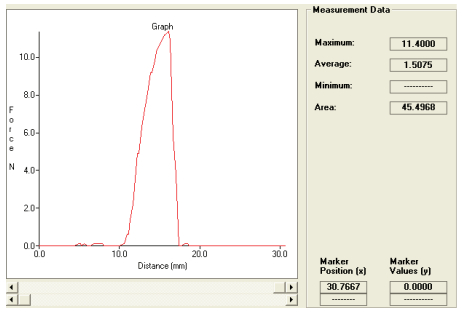
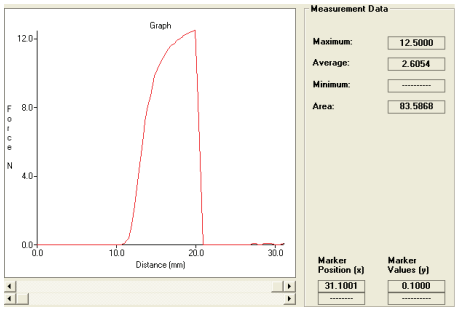
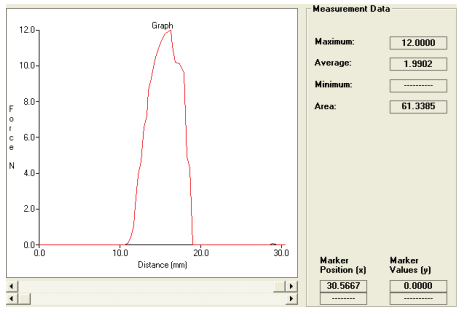
Seal peel test for packaging

* Seal peel test results pictures.

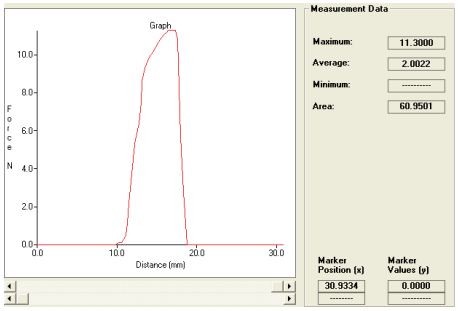
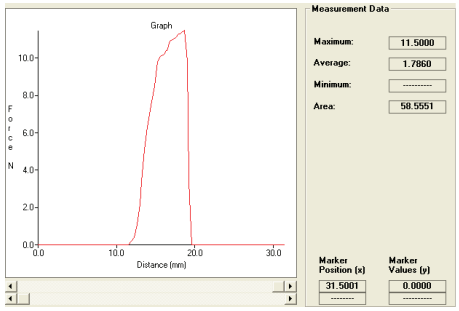
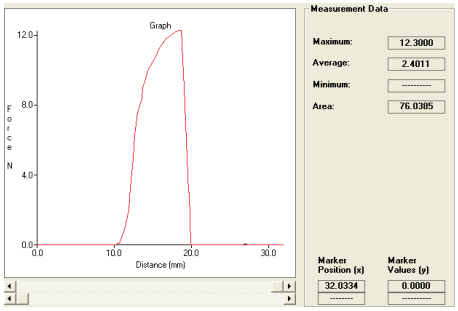
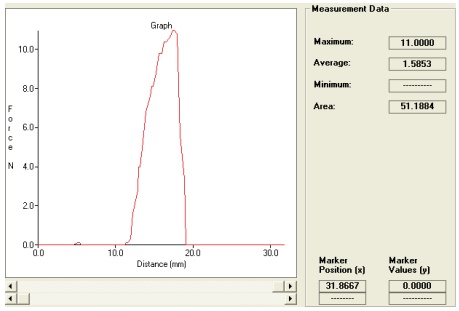
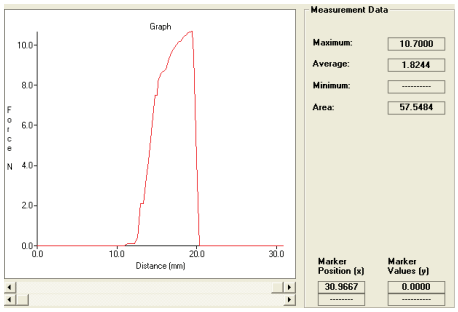
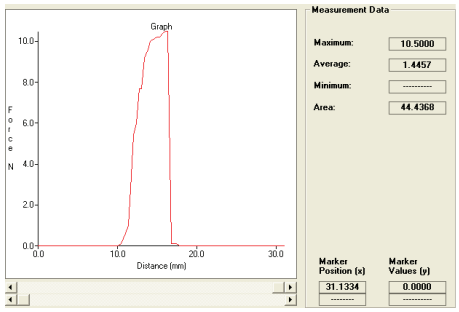
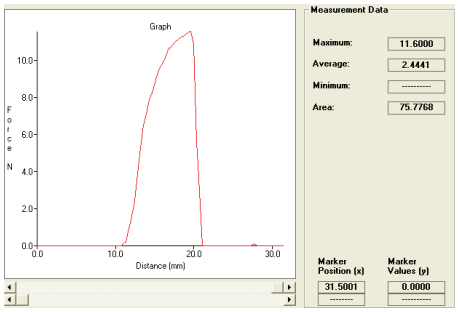
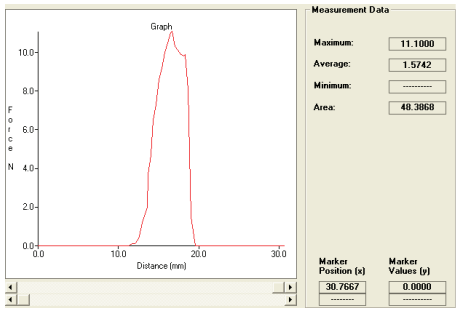
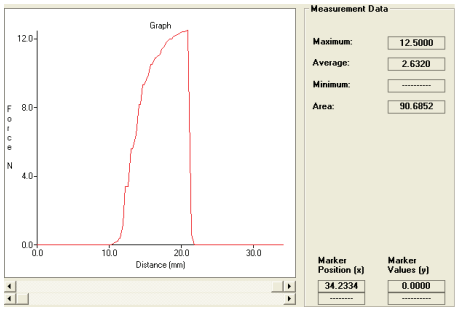
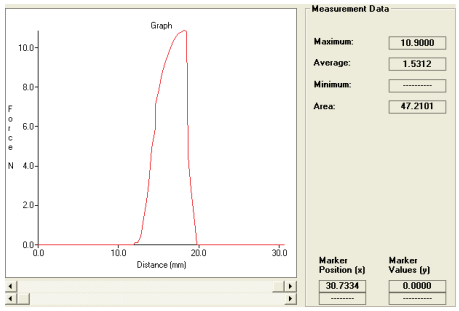
Before 40kGy irradiation : [Control]

No	Picture	No	Picture
1		6	
2		7	
3		8	
4		9	
5		10	

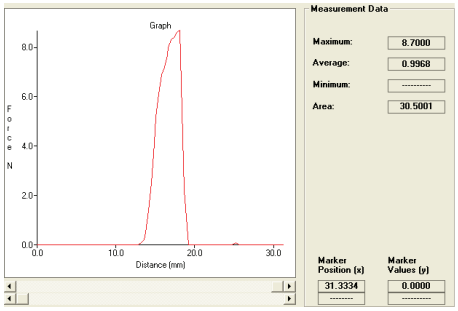
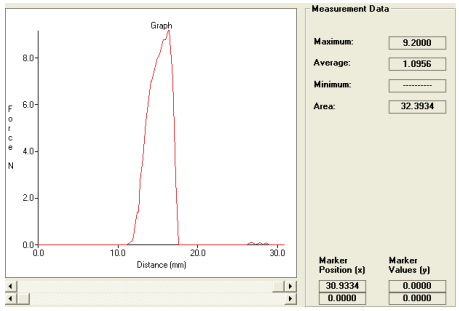
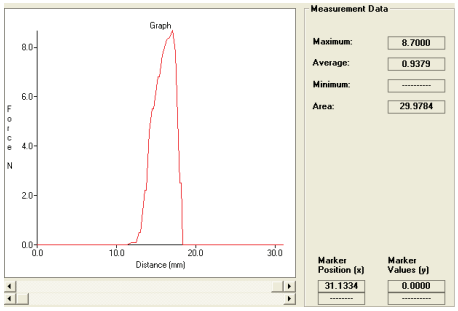
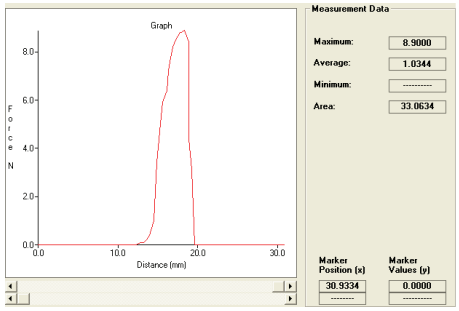
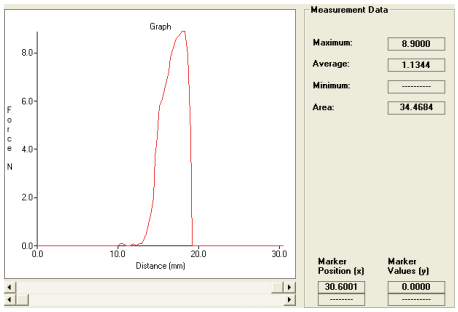
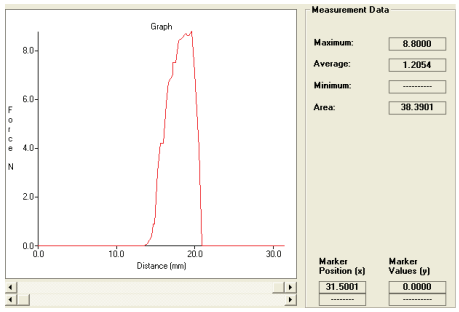
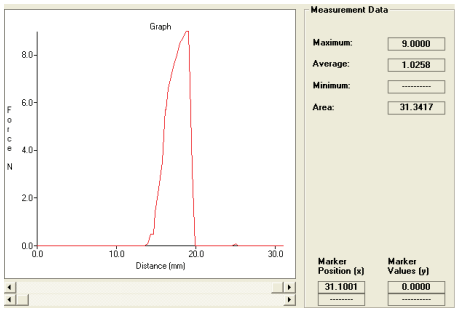
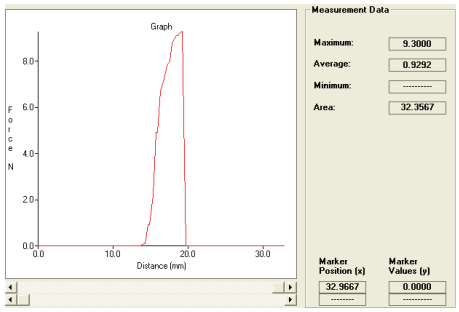
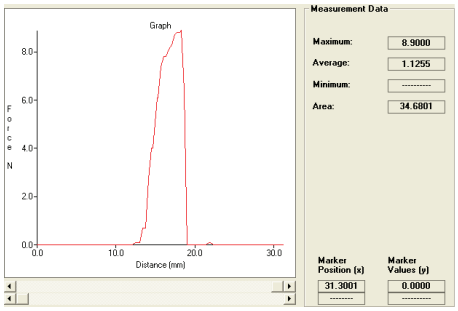
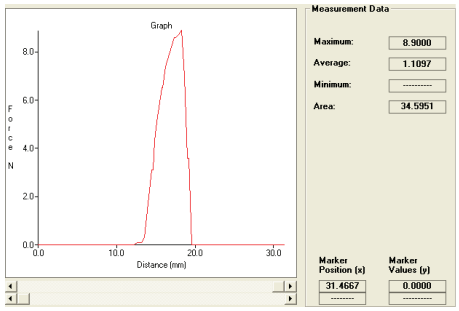
After 40kGy irradiation : Aging for Shelf life Test [No aging]

No	Picture	No	Picture
1		6	
2		7	
3		8	
4		9	
5		10	

After 40kGy irradiation : Aging for Shelf life Test [12 months]

No	No	No	No
1		6	
2		7	
3		8	
4		9	
5		10	

After 40kGy irradiation : Aging for Shelf life Test [24 months]

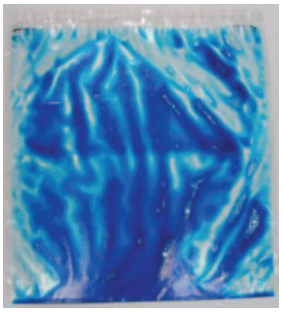
No	No	No	No
1		6	
2		7	
3		8	
4		9	
5		10	

Attachment 4.

Dye penetration test

* Dye penetration test results photos.

Before 40kGy irradiation : [Control]			
No	**Picture**	**No**	**Picture**
1		6	
2		7	
3		8	
4		9	
5		10	

After 40kGy irradiation : Aging for Shelf life Test [No aging]			
No	**Picture**	**No**	**Picture**
1		6	
2		7	
3		8	
4		9	
5		10	

After 40kGy irradiation : Aging for Shelf life Test [12 months]			
No	**No**	**No**	**No**
1		6	
2		7	
3		8	
4		9	
5		10	

After 40kGy irradiation : Aging for Shelf life Test [24 months]			
No	No	No	No
1		6	
2		7	
3		8	
4		9	
5		10	

Attachment 5.

Sterility test report

* Sterility test report.

* Media performance test documentation.

Sterility Test Report

SOYAGREENTEC Co., Ltd.
900-3 Sangsin-ri, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do
TEL : +82-31-353-6999
FAX : +82-31-353-6979

Sample Information	:	40kGy Irradiation (Aging for shelf life test - No aging)
Location	:	SOYAGREENTEC Lab.
Product	:	Sterilized Non-Woven Wiper
Lot No	:	HH-20, HH-14, HH-04
Period	:	Oct. 29. 2012. – Nov. 13. 2012.

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Sangsin-ri, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, SEOUL 445-937 KOREA,
TEL: (031)353-6999(代) FAX: (031)353-6979

Sterility Test Report

Requisition day : Oct. 29. 2012.

Sample Information	: 40kGy Irradiation (Aging for shelf life test - No aging)
Customer	: KM CORPORATION.
Address	: 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea.
Products Name	: Sterilized Non-Woven Wiper
Products Batch No.	: HH-20, HH-14, HH-04
Total test sample size	: 6ea

Test method	: ISO 11737-2 (E)	
Test period	: Oct. 29. 2012. – Nov. 13. 2012.	
Laboratory Condition	: Temperature 20.4 ℃, Humidity 41.7 %	
Media	Thioglycollate medium I	Tryptone soy Broth
Incubation Temperature	32.5 ℃	22.5 ℃
Incubation	: 14 day (336 hours)	

Result

Test Item	Positive(+)	Negative(-)
Sterility	0 unit	6 unit

*ATTACHMENTS : Post – sterilization count report
*USAGE : QUALITY CONTROL
*NOTE :
1. This test report shall be used within the purpose of its defined usage.
2. The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.

Nov. 13. 2012.

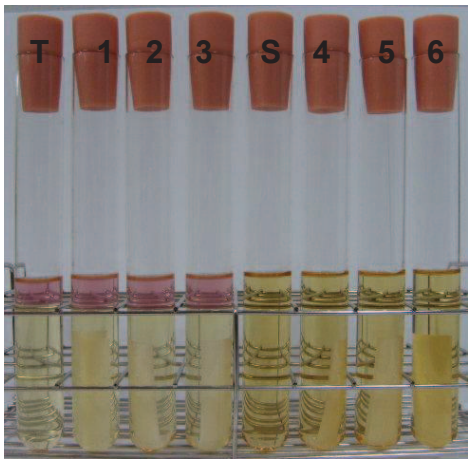
* Testing Personnel
이 상 수 (서 명)

* Approval Staff
박 재 정 (서 명)

Post-sterilization Count Report

Media	Thioglycollate medium I				Soybean-casein digest broth			
No.	T	1	2	3	S	4	5	6
Result	-	-	-	-	-	-	-	-

[T] = Thioglycollate medium I (Bank) // [S] = Soybean-casein digest broth (Bank)



Positive (+) assessment : 0 ea

Negative (-) assessment : 6 ea

** Photo of micro-organisms*

Bacteriostasis And Fungistasis Test Report

Test sample : 40kGy Irradiation (Aging for shelf life test – No aging)

Test method	: ISO11737-2
Test period	: Oct. 29. 2012. – Nov. 05. 2012.
Product Name	: Sterilized Non-Woven Wiper
Products Batch No	: HH-20, HH-14, HH-04
Total test sample size	: 6ea
Incubation	: 7 day 168 hours
Laboratory Condition	: Temperature 20.4 ℃, Humidity 41.7 %

Result

Media	Test Microorganisms	Inoculation amount	Culturing	**Sample medium**	**Control medium**	**Decision**
				A	**B**	
Thioglycollate medium I	*Staphylococcus aureus*	10~100cfu	32.5℃	G	G	No inhibiting material
	Pseudomonas aeruginosa	10~100cfu	32.5℃	G	G	No inhibiting material
	Clostridium sporogenes	10~100cfu	32.5℃	G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100cfu	22.5℃	G	G	No inhibiting material
	Candida albicans	10~100cfu	22.5℃	G	G	No inhibiting material
	Aspergillus niger	10~100cfu	22.5℃	G	G	No inhibiting material
※ G: Growth. N.G: No Growth.						

Nov. 05. 2012.

Testing Personnel: 이상수 (서명) Approval Staff: 박재정 (서명)

Sterility Test Report

SOYAGREENTEC Co., Ltd.
900-3 Sangsin-ri, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do
TEL : +82-31-353-6999
FAX : +82-31-353-6979

Sample Information	:	40kGy Irradiation (Aging for shelf life test–12months)
Location	:	SOYAGREENTEC Lab.
Product	:	Sterilized Non-Woven Wiper
Lot No	:	HH-20, HH-14, HH-04
Period	:	Dec. 03. 2012. – Dec. 18. 2012.

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Sangsin-ri, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, SEOUL 445-937 KOREA,
TEL: (031)353-6999(代) FAX: (031)353-6979

Sterility Test Report

Requisition day : Oct. 29. 2012.

Sample Information	: 40kGy Irradiation (Aging for shelf life test - 12months)
Customer	: KM CORPORATION.
Address	: 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea.
Products Name	: Sterilized Non-Woven Wiper
Products Batch No.	: HH-20, HH-14, HH-04
Total test sample size	: 6ea

Test method	: ISO 11737-2 (E)	
Test period	: Dec. 03. 2012. – Dec. 18. 2012.	
Laboratory Condition	: Temperature 20.2 ℃, Humidity 35.1 %	
Media	Thioglycollate medium I	Tryptone soy Broth
Incubation Temperature	32.5 ℃	22.5 ℃
Incubation	: 14 day (336 hours)	

Result

Test Item	Positive(+)	Negative(-)
Sterility	0 unit	6 unit

*ATTACHMENTS : Post – sterilization count report
*USAGE : QUALITY CONTROL
*NOTE :
1. This test report shall be used within the purpose of its defined usage.
2. The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.

Dec. 18. 2012.

* Testing Personnel
이 상 수 (서 명)

* Approval Staff
박 재 정 (서 명)

Post-sterilization Count Report

Media	Thioglycollate medium I				Soybean-casein digest broth			
No.	T	1	2	3	S	4	5	6
Result	-	-	-	-	-	-	-	-

[T] = Thioglycollate medium I (Bank) // [S] = Soybean-casein digest broth (Bank)

Positive (+) assessment : 0 ea

Negative (-) assessment : 6 ea

** Photo of micro-organisms*

Bacteriostasis And Fungistasis Test Report

Test sample : 40kGy Irradiation (Aging for shelf life test – 12months)

Test method	: ISO11737-2
Test period	: Dec. 03. 2012. – Dec. 10. 2012.
Product Name	: Sterilized Non-Woven Wiper
Products Batch No	: HH-20, HH-14, HH-04
Total test sample size	: 6ea
Incubation	: 7 day 168 hours
Laboratory Condition	: Temperature 20.2 ℃, Humidity 35.1 %

Result

Media	Test Microorganisms	Inoculation amount	Culturing	**Sample medium**	**Control medium**	**Decision**
				A	**B**	
Thioglycollate medium I	*Staphylococcus aureus*	10~100cfu	32.5℃	G	G	No inhibiting material
	Pseudomonas aeruginosa	10~100cfu	32.5℃	G	G	No inhibiting material
	Clostridium sporogenes	10~100cfu	32.5℃	G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100cfu	22.5℃	G	G	No inhibiting material
	Candida albicans	10~100cfu	22.5℃	G	G	No inhibiting material
	Aspergillus niger	10~100cfu	22.5℃	G	G	No inhibiting material
※ G: Growth. N.G: No Growth.						

Dec. 10. 2012.

Testing Personnel: 이상수 (서명) Approval Staff: 박재정 (서명)

Sterility Test Report

SOYAGREENTEC Co., Ltd.
900-3 Sangsin-ri, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do
TEL : +82-31-353-6999
FAX : +82-31-353-6979

Sample Information	:	40kGy Irradiation (Aging for shelf life test–24months)
Location	:	SOYAGREENTEC Lab.
Product	:	Sterilized Non-Woven Wiper
Lot No	:	HH-20, HH-14, HH-04
Period	:	Jan. 02. 2013. – Jan. 17. 2013.

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TEL: (031)353-6999(代) FAX: (031)353-6979

Sterility Test Report

Requisition day : Oct. 29. 2012.

Sample Information	: 40kGy Irradiation (Aging for shelf life test - 24months)
Customer	: KM CORPORATION.
Address	: 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea.
Products Name	: Sterilized Non-Woven Wiper
Products Batch No.	: HH-20, HH-14, HH-04
Total test sample size	: 6ea

Test method	: ISO 11737-2 (E)	
Test period	: Jan. 02. 2013. – Jan. 17. 2013.	
Laboratory Condition	: Temperature 19.9 ℃, Humidity 31.8 %	
Media	Thioglycollate medium I	Tryptone soy Broth
Incubation Temperature	32.5 ℃	22.5 ℃
Incubation	: 14 day (336 hours)	

Result

Test Item	Positive(+)	Negative(-)
Sterility	0 unit	6 unit

*ATTACHMENTS : Post – sterilization count report
*USAGE : QUALITY CONTROL
*NOTE :
1. This test report shall be used within the purpose of its defined usage.
2. The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.

Jan. 17. 2013.

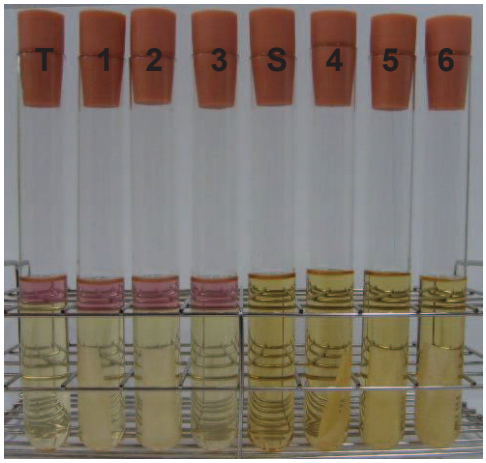
* Testing Personnel
이 상 수 (서 명)

* Approval Staff
박 재 정 (서 명)

Post-sterilization Count Report

Media	Thioglycollate medium I				Soybean-casein digest broth			
No.	T	1	2	3	S	4	5	6
Result	-	-	-	-	-	-	-	-

[T] = Thioglycollate medium I (Bank) // [S] = Soybean-casein digest broth (Bank)



Positive (+) assessment : 0 ea

Negative (-) assessment : 6 ea

** Photo of micro-organisms*

Bacteriostasis And Fungistasis Test Report

Test sample : 40kGy Irradiation (Aging for shelf life test – 24months)

Test method	: ISO11737-2
Test period	: Jan. 02. 2013. – Jan. 09. 2013.
Product Name	: Sterilized Non-Woven Wiper
Products Batch No	: HH-20, HH-14, HH-04
Total test sample size	: 6ea
Incubation	: 7 day 168 hours
Laboratory Condition	: Temperature 19.9 ℃, Humidity 31.8 %

Result

Media	Test Microorganisms	Inoculation amount	Culturing	**Sample medium**	**Control medium**	**Decision**
				A	**B**	
Thioglycollate medium I	*Staphylococcus aureus*	10~100cfu	32.5℃	G	G	No inhibiting material
	Pseudomonas aeruginosa	10~100cfu	32.5℃	G	G	No inhibiting material
	Clostridium sporogenes	10~100cfu	32.5℃	G	G	No inhibiting material
Soybean-casein digest broth	*Bacillus subtilis*	10~100cfu	22.5℃	G	G	No inhibiting material
	Candida albicans	10~100cfu	22.5℃	G	G	No inhibiting material
	Aspergillus niger	10~100cfu	22.5℃	G	G	No inhibiting material

※ G: Growth. N.G: No Growth.

Jan. 09. 2013.

Testing Personnel: 이상수 (서명) Approval Staff: 박재정 (서명)

Media performance test documentation
(배지성능시험 기록서)

Media (배지명)	: Fluid thioglycolate medium (액상티오글리콜산배지)		
Test Method (시험방법)	: The Korean Pharmacopoeia : Sterility test / ISO 11737-2:2009 / Direct		
Manufacturer (제조사)	MERCK	Batch No. (제조번호)	VM 242391
Manufacture date (제조일자)	2011.04.13.	Effective date (유효일자)	2016.02.10.
Purchase date (구입일자)	2011.08.17.	Open Date (개봉일자)	2012.07.06.
Incubation terms and incubation time (배양조건 및 배양시간)		**32.5℃, 3days** (2012.10.05. ~ 2012.10.08.)	

Microorganism (균주)	Test Standards (시험기준)	Results (결과)	Results photo (결과사진)
Negative control	No Growth	No Growth	
Staphylococcus aureus ATCC 6538	Growth	Growth	
Pseudomonas aeruginosa ATCC 9027	Growth	Growth	
Clostridium sporogenes ATCC 19404	Growth	Growth	
Remarks (비고)			

Result **(결과)**	**Result Date** **(결과일자)**	**Experimenter** **(시험자)**	**Checker** **(확인자)**
O.K.	2012.10.08.		

SOYAGREENTEC Co., Ltd

Certificate of Analysis

1.08191.5000 Fluid thioglycolate medium for microbiology

Batch VM242391

	Batch Values
Appearance	
clearness	clear
colour	yellowish
pH-value (25 °C)	7.2

Typical composition (g/litre): Peptone from casein 15.0; Yeast extract 5.0; D(+)Glucose 5.5; L-Cystine 0.5; Sodium chloride 2.5; Sodium thioglycolate 0.5; Resazurin sodium 0.001; Agar Agar 0.75.

Growth promotion test in accordance with ISO 11133 and the harmonised method of EP, USP and JP.

	Batch Values
Inoculum on reference medium	
Clostridium perfringens ATCC 13124	38
Clostridium sporogenes ATCC 11437	99
Clostridium sporogenes ATCC 19404	98
Bacillus subtilis ATCC 6633	26
Staphylococcus aureus ATCC 6538	41
Bacteroides vulgatus ATCC 8482	20
Kocuria rhizophila ATCC 9341	85
Pseudomonas aeruginosa ATCC 9027	35
Growth	
Clostridium perfringens ATCC 13124	+
Clostridium sporogenes ATCC 11437	+
Clostridium sporogenes ATCC 19404	+
Bacillus subtilis ATCC 6633	+
Staphylococcus aureus ATCC 6538	+
Bacteroides vulgatus ATCC 8482	+
Kocuria rhizophila ATCC 9341	+
Pseudomonas aeruginosa ATCC 9027	+

Incubation: up to 3 days; 30-35°C; aerobic; C. perfringens 24 hours; 37°C; aerobic

Date of release (DD.MM.YYYY): *13.04.2011*
Expiry date (DD.MM.YYYY): *10.02.2016*

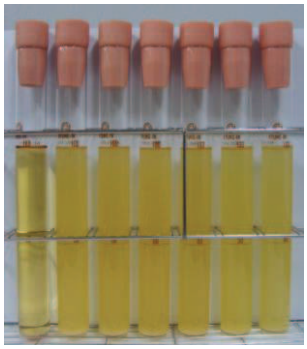
Dr. Christian Arndt

responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature

Media performance test documentation
(배지성능시험 기록서)

Media (배지명)	: Tryptic Soy Broth (대두카제인소화액체배지)		
Test Method (시험방법)	: The Korean Pharmacopoeia : Sterility test / ISO 11737-2:2009 / Direct		
Manufacturer (제조사)	BD	Batch No. (제조번호)	0286473
Manufacture date (제조일자)	2010.09.23.	Effective date (유효일자)	2015.09.30.
Purchase date (구입일자)	2011.08.17.	Open(Test)Date (개봉시험일자)	2012.10.05.
Incubation terms and incubation time (배양조건 및 배양시간)		**22.5℃, 5days** (2012.10.05. ~ 2012.10.10.)	

Microorganism (균주)	Test Standards (시험기준)	Results (결과)	Results photo (결과사진)
Negative control	No Growth	No Growth	
Bacillus subtilis ATCC 6633	Growth	Growth	
Candida albicans ATCC 10231	Growth	Growth	
Aspergillus niger ATCC 16404	Growth	Growth	
Remarks (비고)			

Result **(결과)**	**Result Date** **(결과일자)**	**Experimenter** **(시험자)**	**Checker** **(확인자)**
O.K.	2012.10.10.		

SOYAGREENTEC Co., Ltd

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE BACTO TSB CASEIN MED 500G
Catalog Number : 211825 **Manufacture Date :** 2010/09/23
Batch Number : 0286473
Expiration Date : 2015/09/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 3% solution, soluble in distilled or deionized water
03. Solution Appearance: Light amber, clear
04. Medium was tested per European (EP) and United States Pharmacopeia (USP) Growth Promotion requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for (*) organisms and gave cultural responses as indicated.

TEST ORGANISMS	ATCC®	RECOVERY	TEMPERATURE	INCUBATION
*Asperigillus brasiliensis	16404	growth	20-25˚C	Up to 5 days
Bacillus subtilis	6633	growth	30-35˚C,20-25˚C	Up to 3 days
*Candida albicans	10231	growth	20-25˚C	Up to 5 days
Escherichia coli	8739	growth	30-35˚C	Up to 3 days
Pseudomonas aeruginosa	9027	growth	30-35˚C	Up to 3 days
Salmonella typhimurium	14028	growth	30-35˚C	Up to 3 days
Staphylococcus aureus	6538	growth	30-35˚C	Up to 3 days

05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at the temperatures specified for 18-48 hours, or up to 72 hours if necessary.

TEST ORGANISMS	ATCC®	TEMPERATURE	RECOVERY
Neisseria meningitidis	13090	30-35˚C	fair to good
Staphylococcus epidermidis	12228	30-35˚C	good
Streptococcus pneumoniae	6305	30-35˚C	good
Streptococcus pyogenes	19615	30-35˚C	good

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Broth indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	LowLimit	HighLimit
Loss on Drying :	%	1	0	5
pH at 25˚C :		7.4	7.1	7.5
Bulk Lot Number :	-	0258422		

Creation Date: 2010/11/02 16:02:36

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE BACTO TSB CASEIN MED 500G
Catalog Number : 211825 **Manufacture Date :** 2010/09/23
Batch Number : 0286473
Expiration Date : 2015/09/30

Animal Source	Country of Origin	Tissue Category BIC	SIC	ABC
Porcine	USA	III	III	B
Bovine	Australia	IV	IV	C
Bovine	New Zealand	IV	IV	C
Porcine	Canada	III	III	B

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2008 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.

At the time the BDDS Certificate of Analysis is created and sent to the Internet website address at http://www.bd.com/regdocs/, the animal origin information as provided to BDDS by its suppliers is pulled into the certificate as it is created by the BDDS automated certificate system.

At times, suppliers notify BDDS of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BDDS. When this situation occurs, BDDS updates the animal origin information in the automated certificate system, recreates the affected finished product COAs for batches within expiration date, and sends them to the Internet website where they replace the prior certificate and are immediately available to customers.

Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name	: BOTTLE BACTO TSB CASEIN MED 500G		
Catalog Number	: 211825	**Manufacture Date :**	2010/09/23
Batch Number	: 0286473		
Expiration Date	: 2015/09/30		

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at http://www.bd.com/regdocs/.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2010/11/02

Attachment 6.

Certificate

Item	Specification	Certified by
ISO9001: 2008	Service of Sterilization by irradiation	*TUV service
EN ISO13485:2003 / AC: 2009	Provision of Irradiation Service of Medical Devices	*TUV service
EN ISO 11137 : 2006	Sterilization of healthcare product- Requirement of validation and routine Control – Radiation sterilization	*TUV service
US FDA Registration	Contract Sterilizer	*US FDA Registration
Ministry of Health, Labour and Welfare (JAPAN)	It is certified that the above manufacturer is certificated foreign medical device manufacturer pursuant to Article 13-3 of the Pharmaceutical Affairs Act.	* Minister of health. labour and welfare (JAPAN)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Asia Pacific TÜV SÜD Group

certifies that

Technology for better life!
SOYAGREENTEC

SOYAGREENTEC Co., Ltd.

900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si Gyeonggi-Do, 445-922, Korea

has established and applies
a Quality Management System for

Provision of Irradiation Service of Medical Devices
Design, Development, Production and Distribution of Sterile Blood Collection Tubes

An audit was performed, Report No. **20041555**

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled. The certificate is valid from **2011-03-01** until **2014-02-28**

Certificate Registration No. **TUV100 01 1501**

2011-03-28

Kim, Du IN

Certification Body
of TÜV SÜD Asia Pacific
TÜV SÜD Group

JAS-ANZ

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Accreditation by the Joint Accreditation System
of Australia and New Zealand, URL
www.jas-anz.org/register

ISO 9001

TÜV SÜD Korea Ltd. ● 12F, "KLI63" Bldg., #60, Yoido-Dong, Youngdeungpo-Gu ● 150-763 Seoul ● Korea

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q4N 11 01 50558 003

Holder of Certificate: **SOYAGREENTEC Co., Ltd.**
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do 445-922
REPUBLIC OF KOREA

Facility(ies):
SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup, Hwaseong-Si, Gyeonggi-Do
445-922, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Provision of Gamma Sterilization of Medical Devices**

Applied Standard(s): **EN ISO 13485:2003/AC:2009**
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74926742

Valid from: 2011-03-01
Valid until: 2013-02-28

Date, 2011-02-25

Hans-Heiner Junker

355065

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Supplement to Quality System Certificate Q4N 11 01 50558 003

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2011-03-01

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do
445-922, KOREA

for the facility

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do
445-922, KOREA

The quality system certified as stated above additionally fulfills the applicable requirements of **EN / ISO 11137:2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. 74926742.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Munich, 2011-03-01

TÜV SÜD KOREA LTD. TÜV SÜD

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

US FDA Registered (Contract Sterilizer)

Establishment Registration Database

1 registered establishments meeting your search criteria returned - **Establishment Registration Name :** *soya*

New Search			Help | Download Files | More About Registration & Listing
Name	**State/ Country**	**Registration Number**	**Current Registration Yr**
SOYA CO., LTD.	KOREA, REPUBLIC OF	3004525100	2011
• BANDAGE, ELASTIC -			Contract Manufacturer
• TAPE AND BANDAGE, ADHESIVE -			Contract Sterilizer
• BONE GRAFTING MATERIAL, SYNTHETIC - OSTEON			Contract Sterilizer

Establishment:
SOYA CO., LTD.
900-3 Sangsin-Ri
Hyangnam-Myun, Hwasung-Gun
Kyunggi-Do, KOREA, REPUBLIC OF
Registration Number: 3004525100
Status: Active
Date Of Registration Status: 2011

Owner/Operator:
SOYA CO., LTD.
900-3 Sangsin-Ri
Hyangnam-Myun, Hwasung-Gun
Kyunggi-Do, KOREA, REPUBLIC OF
Owner/Operator Number: 9062715

Official Correspondent:
John H Choi
PISCIUM INTERNATIONAL, INC.
779 Granite Ave.
Langhorne, PA 19047
Phone: 267-2109365

US Agent:
Peter
GQ America
300 Atwood St. Pittsburgh
Oakland, PA 15213
Phone: 412 5128802 Ext
Fax: 412 6873976
Email: Pittcmi@Hotmail.Com

認定番号 BG10300069
Number of accreditation

医療機器 外国製造業者認定証

Accreditation certificate of foreign medical devicemanufacturer

氏名又は名称 Name(Name of corporation)	Soyagreentec Co.,Ltd.
製造所の名称 Name of the manufacturing establishment	Soyagreentec Co.,Ltd.
製造所の所在地 Location of the manufacturing establishment	900-3,Sangsin-Ri Hyangnam-Eup Hwaseong-Si Gyeonggi -Do,445-746,Korea
認定の区分 Accreditation categories	医療機器 滅菌医療機器(Sterile Medical devices)

薬事法第１３条の３の規定により認定された 医療機器外国製造業者であることを証明する。

It is certified that the above manufacturer is certificated foreign medical device manufacturer pursuant to Article 13-3 of the Pharmaceutical Affairs Act.

平成 24年 10月 12日
2012 Year Month Day

厚生労働大臣 三井 辨雄
Minister of Health, Labour and Welfare Wakio Mitsui

有効期間 平成 24年 9月 6日から
Valid period From 2012 Year Month Day
平成 29年 9月 5日まで
until 2017 Year Month Day

5122477019030

Attachment 7.

Certificate of calibration

*Multi-tester

*Digital Vernier Calipers

*Digital Thermo-Hygrometer

* Pressure gauges, gage

* Constant humidity & temperature chamber

교정성적서
CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

성적서 번호 : 12-049550-03-2
Certificate No.

1. 의 뢰 자 (Client)

기 관 명 (Name) : SOYAGREENTEC CO.,LTD.

주 소 (Address) : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : Push-Pull Gauge

제작회사 및 형식(Manufacturer and Model Name) : Mecmesin / BFG 500N

기기번호 (Serial Number) : 05-0223-08

3. 교 정 일 자 (Date of Calibration) : 22 August 2012

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (22.3 ± 0.1) ℃ 습 도 (Humidity) : (52 ± 1) % R.H.

교정장소 (Location) : ▣ 고정표준실 (KTL Lab.) ☐ 이동교정 (Mobile Lab.) ☐ 현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

The above instrument is calibrated as per standard calibration procedure(CP801-20206-1,KTL) for Push-Pull Gauge and by standards traceabled to National Metrology Institude.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Weights	Dae-kyung Engineering / -	03-36-6N	2013. 03. 09	KTL

6. 교 정 결 과 (Calibration Results) : Refer to the attached calibration results

7. 측정불확도 (Measurement Uncertainty) : Refer to the attached calibration results

확인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : Cho Jeong Rae	직 위 (Title) : Technical Supervisor 성 명 (Name) : Chung Chan-Heung

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA)

22 August 2012

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장
Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다
(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is key to affect the validity of the calibration

FP812-03-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 결 과

CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu,
Ansan-si, Gyeonggi-do, KOREA
Tel : +82-31-500-0217 , Fax : +82-31-500-0389
E-mail : standard@ktl.re.kr

성적서 번호 : 12-049550-03-2
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME
KOLAS
CALIBRATION NO.028

◇ Description : Push-Pull Gauge
◇ Manufacturer : Mecmesin
◇ Type : BFG 500N
◇ Serial Number : 05-0223-08

Tension

Calibration Load (N)	Value of the Indication Load (N)				Relative Accuracy Error (%)	Relative Expanded Uncertainty (%)
	Run1	Run2	Run3	Average		
0	0.0	0.0	0.0	0.0	-	-
200	97.6	97.7	97.7	97.7	-51.15	0.15
400	195.2	195.3	195.3	195.3	-51.18	0.08
600	292.9	293.0	293.0	293.0	-51.17	0.05
800	390.7	390.8	390.7	390.7	-51.16	0.04
1150	488.6	488.7	488.7	488.7	-57.50	0.03
0	0.0	0.0	0.0	0.0	-	-

(Confidence Level ≒ 95 %, k = 2.87)

Compression

Calibration Load (N)	Value of the Indication Load (N)				Relative Accuracy Error (%)	Relative Expanded Uncertainty (%)
	Run1	Run2	Run3	Average		
0	0.0	0.0	0.0	0.0	-	-
100	98.7	98.8	98.7	98.7	-1.30	0.15
200	196.6	196.6	196.6	196.6	-1.70	0.03
300	294.4	294.4	294.4	294.4	-1.87	0.03
400	392.1	392.1	392.1	392.1	-1.97	0.02
500	489.8	489.7	489.8	489.8	-2.04	0.03
0	0.0	0.0	0.0	0.0	-	-

(Confidence Level ≒ 95 %, k = 2.87)

* There are wide differences between the output of your gauge and that of our calibration machine. We recommend that you must use it very carefully.

* 1 Division : 0.1 (N)
* Resolution : 0.1 (N)

The end.

※ Recommend Recal. Term : 12 months

FP812-04-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 성 적 서
CALIBRATION CERTIFICATE

Korea Testing Laboratory
723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-5000-246 FAX : +82-31-5000-244

성적서 번호 : 11-2522-1509-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)
   기 관 명 (Name) : SOYAGREENTEC CO.,LTD.
   주 소 (Address) : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. 측 정 기 (Calibration Subject)
   기 기 명 (Description) : Digital Calipers
   제작회사 및 형식 (Manufacturer and Model Name) : S.TOOLS / (0 ~ 150, 0.01) mm
   기 기 번 호 (Serial Number) : F413916

3. 교 정 일 자 (Date of Calibration) : 29 November 2011

4. 교 정 환 경 (Environment)
   온 도 (Temperature) : (20.2 ± 0.1) °C 상대습도 (Relative Humidity) : (50 ± 1) % R.H.
   교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)
   교정방법 및 소급성 서술 (Calibration method and/or brief description) :
   The above instrument is calibrated as per standard calibration procedure(CP801-10605-1, KTL) for Internal·Outside Calipers and by standards traceabled to National Metrology Institude.

   교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Gauge Block	PTW / 103 pcs, 0 Grade	77647	2013. 10. 15.	KTL
Caliper Tester	Mitutoyo / 360 mm	430127	2012. 07. 09.	KTL

6. 교 정 결 과 (Calibration Results) : Refer to the attached calibration results

7. 측정불확도 (Measurement Uncertainty) : Refer to the attached calibration results

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : Park Sang-Wook 상욱	직 위 (Title) : Technical Supervisor 성 명 (Name) : Noh Hyeon-Soo 노현수

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.
(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

29 November 2011

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장
Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.
This Certification is invalid under sudden change of voltage, temperature, humidity that affect subjected instrument precision.

교 정 결 과

CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-5000-246 FAX : +82-31-5000-244
E-mail : leegs@ktl.re.kr

성적서 번호 : 11-2522-1509-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME
KOLAS
CALIBRATION NO.028

* Description : Digital Calipers
* Manufacturer : S.TOOLS
* Serial No. : F413916

1. Outside measurement hour scaled accuracy

Nominal Size (㎜)	Correction Value (㎜)	Measurement Uncertainty (㎜) (CL about 95 %, k=2)
0	0.00	-
50	-0.03	0.01
100	-0.07	0.01
150	0.05	0.01

2. The inside measurement hour scaled accuracy

Nominal Size (㎜)	Correction Value (㎜)	Measurement Uncertainty (㎜) (CL about 95 %, k=2)
0	-	-
50	0.02	0.01
100	0.01	0.01
150	0.09	0.01

* Calibration Value = Nominal Size + Correction Value The end.

CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

Certificate No. : 12-065940-02-2

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO. KC01-028

1. Client

Name : SOYAGREENTEC CO.,LTD.

Address : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. Calibration Subject

Description : Calipers, inside/outside

Manufacturer & Model Name : S.TOOLS / (0 ~ 150 / 0.01) mm

Serial Number : F413916

3. Date of Calibration : 04 December 2012

4. Environment

Temperature : (20.0 ± 0.1) ℃ Humidity : (47 ± 1) % R.H.

Location : ▣ KTL Lab. ☐ Mobile Lab. ☐ On Site Calibration

5. Traceability

Calibration method and/or brief description :

The above instrument is calibrated as per standard calibration procedure(CP801-10605-1,KTL) for Calipers, inside/outside and by standards traceabled to National Metrology Institute.

List of used standards/specifications

Description	Manufacturer and Model Name	Serial Number	Calibration valid until	Calibration Laboratory
Gauge Blocks	Mitutoyo / 103 pcs.	77647	2013. 10. 15	KTL
Step gauges	Mitutoyo / 515-585	430127	2014. 07. 09	KTL

6. Calibration Results : Refer to the attached calibration results

7. Measurement Uncertainty : Refer to the attached calibration results

Affirmation	Measurements performed by	Approved by
	Name : Kim Sung-Joong	Title : Technical Supervisor
		Name : Noh Hyeon-Soo

The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.

04 December 2012

Korea Testing Laboratory
Accredited by KOLAS, Republic of KOREA

(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is likely to affect the validity of the calibration.

FP812-03-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 결 과

CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
Tel : +82-31-500-0217, Fax : +82-31-500-0389
E-mail : standard@ktl.re.kr

성적서 번호 : 12-065940-02-2
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME
KOLAS
CALIBRATION NO. KC01-028

* Description : Calipers, inside/outside
* Manufacturer : S.TOOLS
* Serial No. : F413916

1. Outside measurement hour scaled accuracy

Nominal Size (mm)	Correction Value (mm)	Measurement Uncertainty (mm) (CL about 95 %, k=2)
0	0.00	-
50	0.00	0.01
100	0.00	0.01
150	0.00	0.01

2. The inside measurement hour scaled accuracy

Nominal Size (mm)	Correction Value (mm)	Measurement Uncertainty (mm) (CL about 95 %, k=2)
0	-	-
50	0.07	0.01
100	0.06	0.01
150	0.07	0.01

Note) Calibration Value = Nominal Size + Correction Value

The end.

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 성 적 서

CALIBRATION CERTIFICATE

KOREA TESTING LABORATORY

1271-12, Sa-dong, Sangrok-gu, Ansan-si, Gyeonggi-do, Korea

TEL : 82-31-500-0298 FAX : 82-31-500-0297

성적서번호: 11-2564-943-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : SOYAGREENTEC CO.,LTD.

주 소 (Address) : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : Digital Hygrometers

제 작 회 사 및 형식 (Manufacturer and Model Name TESTO / 608-H2

기기번호 (Serial Number) : 3003581

3. 교정일자 (Date of Calibration) : 24 November 2011

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

The above instruments is calibrated as per standard calibration procedure (CP801-50204-2, KTL) for Digital Hygrometers and by standards traceabled to National Metrology Institute.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Dewpoint Hygrometer	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	KTL
Thermometer Bridge	HART / 1529	A38474	2011. 12. 13.	KTL
Constant Temperature and Humidity Chamber	espec / PL-3KP	14010007	2012. 03. 11.	KTL

6. 교 정 결 과 (Calibration Results) : Refer to the attached calibration results

7. 측정불확도 (Measurement Uncertainty) : Refer to the attached calibration results

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : Hwang Sung	직 위 (Title) : Technical Supervisor 성 명 (Name) : Ji, Jin-hwan

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

24 November 2011

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.
This Certification is invalid under sudden change of voltage, temperature, humidity that affect subjected instrument precision.

교 정 결 과
CALIBRATION RESULTS

1271-12, Sa-dong, Sangrok-gu, Ansan-si, Gyeonggi-do, Korea
TEL : 82-31-500-0298 FAX : 82-31-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-943-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

◇ Description : Digital Hygrometers
◇ Manufacturer and Model Name : TESTO / 608-H2
◇ Seiral Number : 3003581

1. 온 도 (TEMPERATURE)

Reference Val. (℃)	Indicated Val.(℃)	Uncertainty (℃)
10.0	10.1	0.8
20.0	20.1	0.8
30.0	30.2	0.6

Uncertainty (Confidence Level 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

Reference Val. (% R.H.)	Indicated Val. (% R.H.)	Uncertainty (% R.H.)
39.5	33.8	2.7
59.9	53.2	3.7
79.7	71.3	3.9

Uncertainty (Confidence Level 95 %, k=2)

The end.

◇ Refer to clause 41 of the operation of national calibration laboratories designation system, calibration period : 12 Months.

CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

Certificate No. : 12-065940-02-3

1. Client

Name : SOYAGREENTEC CO.,LTD.

Address : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. Calibration Subject

Description : Digital Hygrometers

Manufacturer & Model Name : NONE / NONE

Serial Number : 071224A

3. Date of Calibration : 11 December 2012

4. Environment

Temperature : (23.2 ± 0.4) ℃ Humidity : (48 ± 2) % R.H.

Location : ▣ KTL Lab. ☐ Mobile Lab. ☐ On Site Calibration

5. Traceability

Calibration method and/or brief description :

The above instrument is calibrated as per standard calibration procedure(CP801-50204-2.KTL) for Digital Hygrometers and by standards traceabled to National Metrology Institude.

List of used standards/specifications

Description	Manufacturer and Model Name	Serial Number	Calibration valid until	Calibration Laboratory
Constant Temerature & Humidity Generator	ESPEC / PL-3KP	1401007	2013. 01. 30	KTL
Dew Point Hygrometer	G. E. / M-2 PLUS	0930504	2013. 06. 27	KTL
Digital Thermometer	HART / 1529	A38474	2013. 11. 30	KTL

6. Calibration Results : Refer to the attached calibration results

7. Measurement Uncertainty : Refer to the attached calibration results

Affirmation	Measurements performed by	Approved by
	Name : Hwang Sung-Ho	Title : Technical Supervisor Name : Ji Jin-Whan

The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.

11 December 2012

Korea Testing Laboratory
Accredited by KOLAS, Republic of KOREA

(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is likely to affect the validity of the calibration.

FP812-03-00

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교 정 결 과
CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL :+82-31-500-0217 FAX :+82-31-500-0389
E-mail :standard@ktl.re.kr

성적서번호 : 12-065940-02-3
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO. KC01-028

◇ Description : Digital Thermo-hygrometer
◇ Manufacturer and Model Name : NONE / NONE
◇ Seiral Number : 071224A

1. 온 도 (TEMPERATURE)

SENSOR;OUT

Reference (℃)	Indication (℃)	Uncertainty (℃)
10.0	9.5	0.5
20.1	20.3	0.5
30.2	30.6	0.6

Uncertainty (Confidence Level 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

Reference (% R.H.)	Indication (% R.H.)	Uncertainty (% R.H.)
40.6	39	4
59.6	61	4
79.3	81	5

Uncertainty (Confidence Level 95 %, k=2)

The end.

◇ Refer to clause 41 of the operation of national calibration laboratories designation system, calibration period : 12 Months.

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교정성적서
CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

성적서 번호 : 12-049550-03-3
Certificate No.

1. 의 뢰 자 (Client)

기 관 명 (Name) : SOYAGREENTEC CO.,LTD.

주 소 (Address) : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : Pressure gauges, gage

제작회사 및 형식(Manufacturer and Model Name) : KONICS / TPS20&KN-2000W

기기번호 (Serial Number) : IE0278

3. 교 정 일 자 (Date of Calibration) : 28 August 2012

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (20.5 ± 0.5) ℃ 습 도 (Humidity) : (50 ± 5) % R.H.

교정장소 (Location) : ▣ 고정표준실 (KTL Lab.) ☐ 이동교정 (Mobile Lab.) ☐ 현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

The above instrument is calibrated as per standard calibration procedure(CP801-20413-1,KTL) for Pressure gauges, gage and by standards traceabled to National Metrology Institute.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Pressure Calibrator	DH INSTRUMENT INC / PPC3	309	2012. 09. 14	KTL

6. 교 정 결 과 (Calibration Results) : Refer to the attached calibration results

7. 측정불확도 (Measurement Uncertainty) : Refer to the attached calibration results

확인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : Chang jinseok	직 위 (Title) : Technical Supervisor 성 명 (Name) : Chung Heung-Hwan

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA)

28 August 2012

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장
Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다
(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is key to affect the validity of the calibration

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 결 과
CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
Tel : +82-31-500-0217 , Fax : +82-31-500-0389
E-mail : standard@ktl.re.kr

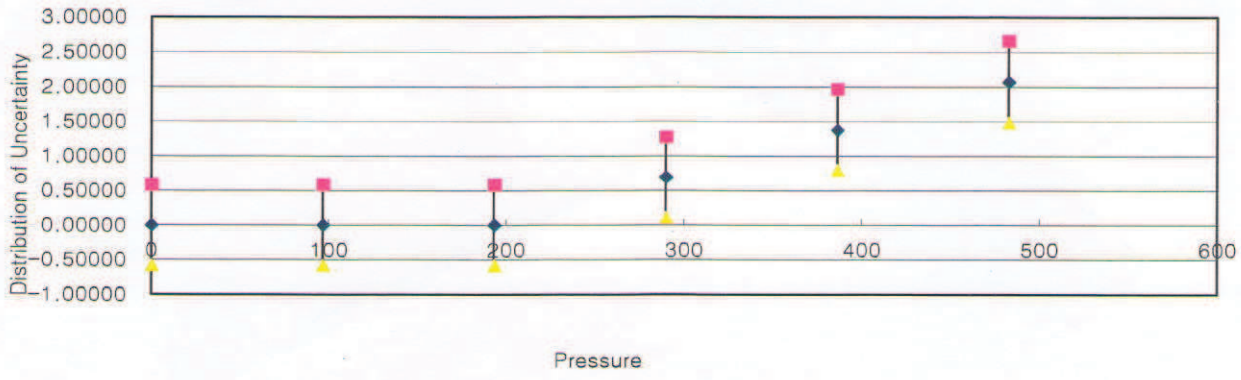
성적서 번호 : 12-049550-03-3
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO. 28

This assigned expanded uncertainty corresponds to a coverage probability of approximately 95%.

No.	Standard Value	Indication Value	Correction Value	Expanded Uncertainty (k=2)	Accuracy
	kPa	kPa	kPa	kPa	kPa
1	0.0	0	0	1	1
2	96.5	97	0	1	1
3	193.1	193	0	1	1
4	289.6	290	0	1	1
5	386.1	387	-1	1	2
6	482.6	485	-2	1	3

Distribution chart of Uncertainty



※ Correction Value = Standard Value − Indication Value
※ Accuracy=|Correction Value|+|Expanded Uncertainty|
※ Unit conversion : 1kPa=0.145037psi

"End"

※ Accreditation system of national calibration laboratories, clause 41 : 12 Months.

FP812-04-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

Stability Test Chamber Validation
(안정성시험기 Validation)

Experiment Date 시험일자	: 2012.03.07 ~ 08
Experimental Machine 시험기기	: Stability Test Chamber
Manufacturer 제조사	: LABFINE, INC.
Model 모델	: FLT-084S

Signature (서명)	Experimenter (시험자)	Checker (확인자)	Approver (승인자)
	이상주		

SOYAGREENTEC Co., Ltd.

(주) 소 야 그 린 텍

STABILITY TEST CHAMBER VALIDATION
(안정성시험기 VALIDATION)

Date (일자)	: 2012. 03. 07. ~ 08.
Purpose (목적)	: To ensure the reliability of the product set as the storage conditions are maintained to verify. (제품의 안정성을 확인하기 위해 설정된 보관조건대로 유지되는지 검증한다.)
Target (대상)	STABILITY TEST CHAMBER (안정성시험기) Model(모델) : FLT - 084S Manufacturer (제조회사) : LABFINE, INC. Manufacturing number (제조번호) : 080324
Item (항목)	: Temperature and humidity distribution test (온도, 습도 분포 시험) Measuring Machines (측정기기) : TR320 (DICKSON) Verification and correction date (확인 및 정정일자) : 2011.12.26. Next Verification and correction date (차기 검·교정일자): 2012.12.25.
Result (결론)	: The Stability Test Chamber has been proven to be working well. (안정성시험기가 잘 작동됨이 증명되었다.) - Temperature distribution : Set temperature of ± 2 ℃ (온도분포 : 설정온도의 ±2℃) - Humidity Distribution : Set humidity of ± 5% Rh (습도분포 : 설정온도의 ±5%Rh)
Attachments (첨부)	: Stability Test Chamber Validation data (안정성시험기 밸리데이션 자료) TR320 Verification and correction certificate (TR320 의 검·교정 성적서)
Remarks (비고)	: Operation, temperature and humidity distribution uniformity of Stability Test Chamber has been confirmed. (안정성시험기의 작동 및 온도, 습도 분포의 균일성이 확인되었다.

Result (결과)	Experimenter (시험자)	Checker (확인자)	Person in charge (책임자)
O.K.	이상국	문천수	

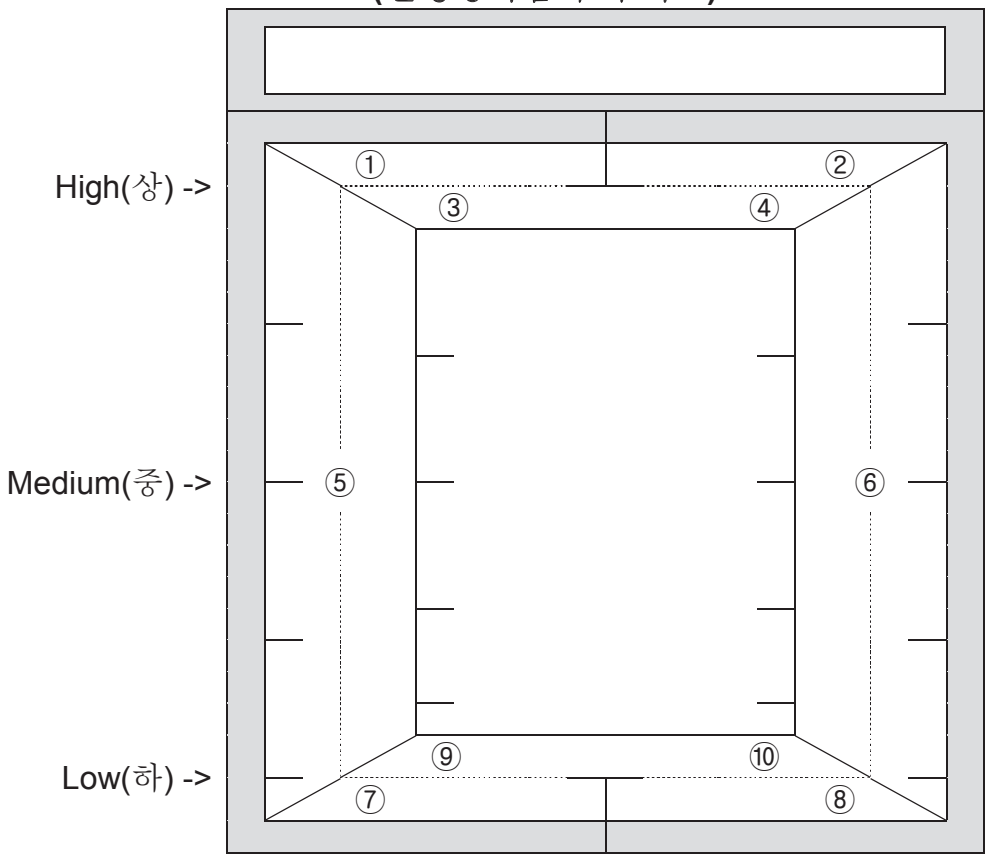
SOYAGREENTEC Co., Ltd.

(주) 소 야 그 린 텍

< Measurement location and measurement equipment >
(측정위치 및 측정기기)

NO. (번 호)	Measurement location (측 정 위 치)	measurement equipment (측 정 기 기)
< High(상) >		
①	Front Left(전면 좌)	TR320 / 07157157
②	Front Right(전면 우)	TR320 / 07157158
③	Rear Left(후면 좌)	TR320 / 07157160
④	Rear Right(후면 우)	TR320 / 07157161
< Medium(중) >		
⑤	Middle left(중면 좌)	TR320 / 07157171
⑥	Middle Righ(중면 우)	TR320 / 07164138
< Low(하) >		
⑦	Front Left(전면 좌)	TR320 / 07164143
⑧	Front Right(전면 우)	TR320 / 07164144
⑨	Rear Left(후면 좌)	TR320 / 07164146
⑩	Rear Right(후면 우)	TR320 / 07164147

< Stability Test Chamber Perspective drawing >
(안정성시험기 투시도)



Temperature distribution test documentation 1
(안정성시험기 온도 분포시험 기록서 1)

Experimental Machine (기기 종류)	Stability Test Chamber - TR320 (안정성시험기 – TR320)
Installation Location (설치장소)	Q.C. Laboratory (품질관리부, 연구실)
Set status (상태 설정)	55℃, 50%Rh
Test Date (시험 일자)	2012. 03. 07.

온도분포 시험 및 결과 (Temperature distribution test Result)

○ Temperature Distribution Standard (온도분포 기준)

-> 5 hours, temperature Set(±2℃) (5시간 동안 설정온도의 ±2℃ 이하)

Unit(단위) : ℃

Location (위치)	Experimental Machine (측정기기)	Minimum (최소값)	Maximum (최대값)	Error : 55℃ (오차 : 55℃)		Deviation (편차)	Decision (판정)
				Minimum (최소값)	Maximum (최대값)		
①	TR320 / 07157157	54.5	55.1	-0.5	+0.1	-0.4	O.K.
②	TR320 / 07157158	54.6	55.5	-0.4	+0.5	0.1	O.K.
③	TR320 / 07157160	54.4	55.6	-0.6	+0.6	0.0	O.K.
④	TR320 / 07164161	54.5	55.3	-0.5	+0.3	-0.2	O.K.
⑤	TR320 / 07157171	54.6	55.2	-0.4	+0.2	-0.2	O.K.
⑥	TR320 / 07164138	54.8	55.4	-0.2	+0.4	0.2	O.K.
⑦	TR320 / 07164143	54.8	55.7	-0.2	+0.7	0.5	O.K.
⑧	TR320 / 07164144	54.6	55.4	-0.4	+0.4	0.0	O.K.
⑨	TR320 / 07164146	54.7	55.1	-0.3	+0.1	-0.2	O.K.
⑩	TR320 / 07164147	54.5	55.5	-0.5	+0.5	0.0	O.K.

○ Attachments data (첨부자료)

TR320 10 different test results were attached.

(TR320 10 개의 시험결과를 첨부했다.)

1. Temperature and humidity data : temperature, humidity distribution)

(작동시간 동안의 온도, 습도 데이터 : 온도, 습도 분포))

○ Uniqueness(특이사항)

Decision (판정)	Experimenter (시험자)	Creation Date (작성일자)	Checker (확인자)	Person in charge (책임자)
O.K.	이상욱	2012.03.09.	윤현욱	

Humidity Distribution test documentation 1
(안정성시험기 습도 분포시험 기록서 1)

Experimental Machine (기기 종류)	Stability Test Chamber - TR320 (안정성시험기 – TR320)
Installation Location (설치장소)	Q.C. Laboratory (품질관리부, 연구실)
Set status (상태 설정)	55℃, 50%Rh
Test Date (시험 일자)	2012. 03. 07.

습도분포 시험 및 결과 (Humidity Distribution test Result)

○ Humidity Distribution Standard (습도분포 기준)

-> 5 hours, Humidity Set(±5%Rh (5시간 동안 설정습도의 ±5%Rh 이하)

Unit(단위) : ℃

Location (위치)	Experimental Machine (측정기기)	Minimum (최소값)	Maximum (최대값)	Error : 50%Rh) (오차 : 50%Rh)		Deviation (편차)	Decision (판정)
				Minimum (최소값)	Maximum (최대값)		
①	TR320 / 07157157	49.2	52.6	-0.8	+2.6	1.8	O.K.
②	TR320 / 07157158	48.8	51.4	-1.2	+1.4	0.2	O.K.
③	TR320 / 07157160	48.1	52.5	-1.9	+2.5	0.6	O.K.
④	TR320 / 07164161	47.9	50.8	-2.1	+0.8	-1.3	O.K.
⑤	TR320 / 07157171	48.2	51.2	-1.8	+1.2	-0.6	O.K.
⑥	TR320 / 07164138	48.2	51.4	-1.8	+1.4	-0.4	O.K.
⑦	TR320 / 07164143	48.1	52.2	-1.9	+2.2	0.3	O.K.
⑧	TR320 / 07164144	48.7	52.6	-1.3	+2.6	1.3	O.K.
⑨	TR320 / 07164146	48.3	51.1	-1.7	+1.1	-0.6	O.K.
⑩	TR320 / 07164147	49.1	52.4	-0.9	+2.4	1.5	O.K.

○ Attachments data (첨부자료)

TR320 10 different test results were attached.

(TR320 10 개의 시험결과를 첨부했다.)

1. Temperature and humidity data : temperature, humidity distribution)

(작동시간 동안의 온도, 습도 데이터 : 온도, 습도 분포))

○ Uniqueness(특이사항)

Decision (판정)	Experimenter (시험자)	Creation Date (작성일자)	Checker (확인자)	Person in charge (책임자)
O.K.	이상석	2012. 03. 09.		

Temperature distribution test documentation 2
(안정성시험기 온도 분포시험 기록서 2)

Experimental Machine (기기 종류)	Stability Test Chamber - TR320 (안정성시험기 – TR320)
Installation Location (설치장소)	Q.C. Laboratory (품질관리부, 연구실)
Set status (상태 설정)	60℃, 55%Rh
Test Date (시험 일자)	2012. 03. 08.

온도분포 시험 및 결과 (Temperature distribution test Result)

○ Temperature Distribution Standard (온도분포 기준)

-> 5 hours, temperature Set(±2℃) (5시간 동안 설정온도의 ±2℃ 이하)

Unit(단위) : ℃

Location (위치)	Experimental Machine (측정기기)	Minimum (최소값)	Maximum (최대값)	Error : 60℃ (오차 : 60℃)		Deviation (편차)	Decision (판정)
				Minimum (최소값)	Maximum (최대값)		
①	TR320 / 07157157	59.7	60.2	-0.3	+0.2	-0.1	O.K.
②	TR320 / 07157158	59.6	60.8	-0.4	+0.8	0.4	O.K.
③	TR320 / 07157160	59.4	60.6	-0.6	+0.6	0.0	O.K.
④	TR320 / 07164161	59.6	60.5	-0.4	+0.5	0.1	O.K.
⑤	TR320 / 07157171	59.7	60.3	-0.3	+0.3	0.0	O.K.
⑥	TR320 / 07164138	59.2	60.7	-0.8	+0.7	-0.1	O.K.
⑦	TR320 / 07164143	59.3	60.2	-0.7	+0.2	-0.5	O.K.
⑧	TR320 / 07164144	59.5	60.4	-0.5	+0.4	-0.1	O.K.
⑨	TR320 / 07164146	59.8	60.7	-0.2	+0.7	0.5	O.K.
⑩	TR320 / 07164147	59.6	60.5	-0.4	+0.5	0.1	O.K.

○ Attachments data (첨부자료)

TR320 10 different test results were attached.

(TR320 10 개의 시험결과를 첨부했다.)

1. Temperature and humidity data : temperature, humidity distribution)

(작동시간 동안의 온도, 습도 데이터 : 온도, 습도 분포))

○ Uniqueness(특이사항)

Decision (판정)	Experimenter (시험자)	Creation Date (작성일자)	Checker (확인자)	Person in charge (책임자)
O.K.	이상수	2012.03.09.		

Humidity Distribution test documentation 2
(안정성시험기 습도 분포시험 기록서 2)

Experimental Machine (기기 종류)	Stability Test Chamber - TR320 (안정성시험기 – TR320)
Installation Location (설치장소)	Q.C. Laboratory (품질관리부, 연구실)
Set status (상태 설정)	60℃, 55%Rh
Test Date (시험 일자)	2012. 03. 08.

습도분포 시험 및 결과 (Humidity Distribution test Result)

○ Humidity Distribution Standard (습도분포 기준)

-> 5 hours, Humidity Set(±5%Rh (5시간 동안 설정습도의 ±5%Rh 이하)

Unit(단위) : ℃

Location (위치)	Experimental Machine (측정기기)	Minimum (최소값)	Maximum (최대값)	Error : 55%Rh) (오차 : 55%Rh)		Deviation (편차)	Decision (판정)
				Minimum (최소값)	Maximum (최대값)		
①	TR320 / 07157157	54.4	56.3	-0.6	+1.3	0.7	O.K.
②	TR320 / 07157158	54.5	57.2	-0.5	+2.2	1.7	O.K.
③	TR320 / 07157160	53.8	56.5	-1.2	+1.5	0.3	O.K.
④	TR320 / 07164161	54.5	56.4	-0.5	+1.4	0.9	O.K.
⑤	TR320 / 07157171	53.8	55.8	-1.2	+0.8	-0.4	O.K.
⑥	TR320 / 07164138	54.6	56.3	-0.4	+1.3	0.9	O.K.
⑦	TR320 / 07164143	54.0	56.8	-1.0	+1.8	0.8	O.K.
⑧	TR320 / 07164144	53.9	56.6	-1.1	+1.6	0.5	O.K.
⑨	TR320 / 07164146	54.3	56.4	-0.7	+1.4	0.7	O.K.
⑩	TR320 / 07164147	54.1	57.1	-0.9	+2.1	1.2	O.K.

○ Attachments data (첨부자료)

TR320 10 different test results were attached.

(TR320 10 개의 시험결과를 첨부했다.)

1. Temperature and humidity data : temperature, humidity distribution)

(작동시간 동안의 온도, 습도 데이터 : 온도, 습도 분포))

○ Uniqueness(특이사항)

Decision (판정)	Experimenter (시험자)	Creation Date (작성일자)	Checker (확인자)	Person in charge (책임자)
O.K.	이상수	2012. 03. 09.		

SI-A-025

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07157157

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-1
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07157157

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	39	4
59.0	60	5
79.7	81	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-2
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07157158

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-2
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07157158

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	33	4
59.0	52	5
79.7	71	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-4
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)
   기 관 명 (Name) : (주)한국파마
   주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)
   기 기 명 (Description) : 디지털 온습도계
   제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320
   기기번호 (Serial Number) : 07157160

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)
   온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.
   교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)
   교정방법 및 소급성 서술 (Calibration method and/or brief description) :
   위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

   교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-4
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07157160

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	11	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	41	4
59.0	62	5
79.7	84	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-3
Certificate No.

1. 의 뢰 자 (Client)
   - 기 관 명 (Name) : (주)한국파마
   - 주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8
2. 측 정 기 (Calibration Subject)
   - 기 기 명 (Description) : 디지털 온습도계
   - 제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320
   - 기기번호 (Serial Number) : 07157161
3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일
4. 교 정 환 경 (Environment)
   - 온 도 (Temperature) : (23.4 ± 0.4) ℃
   - 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.
   - 교정장소 (Location) : ■고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)
5. 측정표준의 소급성 (Traceability)

   교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조
7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-3
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07157161

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	41	4
59.0	62	5
79.7	84	5

측정불확도 (신뢰수준 약 95 %, k=2) 끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-5
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07157171

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정

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한국산업기술시험원장

Korea Testing Laboratory

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교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-5
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07157171

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	31	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	39	4
59.0	60	5
79.7	80	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-6
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.026

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07164138

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-6
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07164138

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	11	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	40	4
59.0	60	5
79.7	82	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-7
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07164143

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ■고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 디지털 온습도계의 표준교정절차(CP801-50204-2, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 12 월 26 일

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

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교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-7
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07164143

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	30	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	40	4
59.0	61	5
79.7	82	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-8
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07164144

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ■고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

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교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
온도브리지	HART / 1529	A38474	2012. 12. 09.	한국산업기술시험원
항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과 참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

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2011 년 12 월 26 일

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Korea Testing Laboratory

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TEL : 031-500-0298 FAX : 031-500-0297
Email : h9610@ktl.re.kr

성적서번호 : 11-2564-1037-8
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07164144

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	31	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	39	4
59.0	61	5
79.7	83	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

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TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-9
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07164146

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정 (Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

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노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
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항온항습기	espec / PL-3KP	14010007	2012. 03. 11.	한국산업기술시험원

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	성 명 (Name) : 황 성 호	직 위 (Title) : 기술책임자 성 명 (Name) : 지 진 환

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2011 년 12 월 26 일

한국인정기구 인정

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성적서번호 : 11-2564-1037-9
Certificate No.

◇ 기 기 명 : 디지털 온습도계
◇ 제작회사 및 형식 : DICKSON / TR320
◇ 기 기 번 호 : 07164146

1. 온 도 (TEMPERATURE)

기 준 값 (℃)	지 시 값(℃)	불 확 도 (℃)
10.0	10	2
20.0	20	2
30.0	31	2

측정불확도 (신뢰수준 약 95 %, k=2)

2. 습 도 (HUMIDITY) (at 20 ℃)

기 준 값 (% R.H.)	지 시 값 (% R.H.)	불 확 도 (% R.H.)
39.0	38	4
59.0	59	5
79.7	81	5

측정불확도 (신뢰수준 약 95 %, k=2)

끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

교 정 성 적 서

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TEL : 031-500-0298 FAX : 031-500-0297

성적서번호: 11-2564-1037-10
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.026

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)한국파마

주 소 (Address) : 경기도 화성시 향남읍 상신리 907-8

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : 디지털 온습도계

제 작 회 사 및 형식 (Manufacturer and Model Name DICKSON / TR320

기기번호 (Serial Number) : 07164147

3. 교정일자 (Date of Calibration) : 2011 년 12 월 26 일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.4 ± 0.4) ℃ 상 대 습 도 (Relative Humidity) : (51 ± 2) % R.H.

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노점 습도계	G. E. / M2-Plus, 1211H	0930504	2012. 06. 27.	한국산업기술시험원
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2011 년 12 월 26 일

한국인정기구 인정

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2. 습 도 (HUMIDITY) (at 20 ℃)

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측정불확도 (신뢰수준 약 95 %, k=2)

끝.

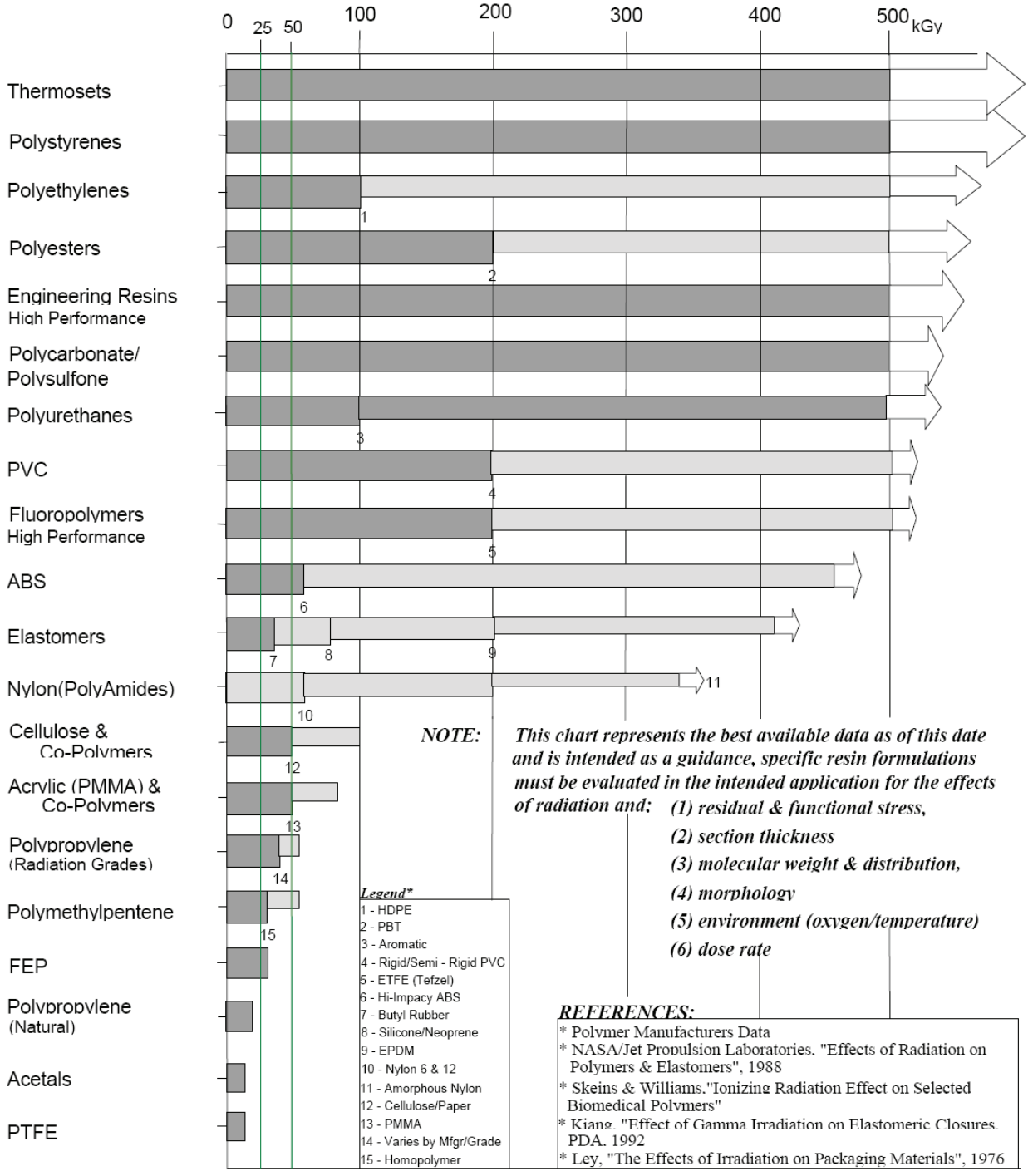
◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 12개월

Attachment 8.

Inside radiation the general guideline for
the malleability material selection.

Table 1 - Relative Radiation Stability of Medical Polymer "Families"

Dose (Kilogray) in Ambient Air at which Elongation Decreases by 25%

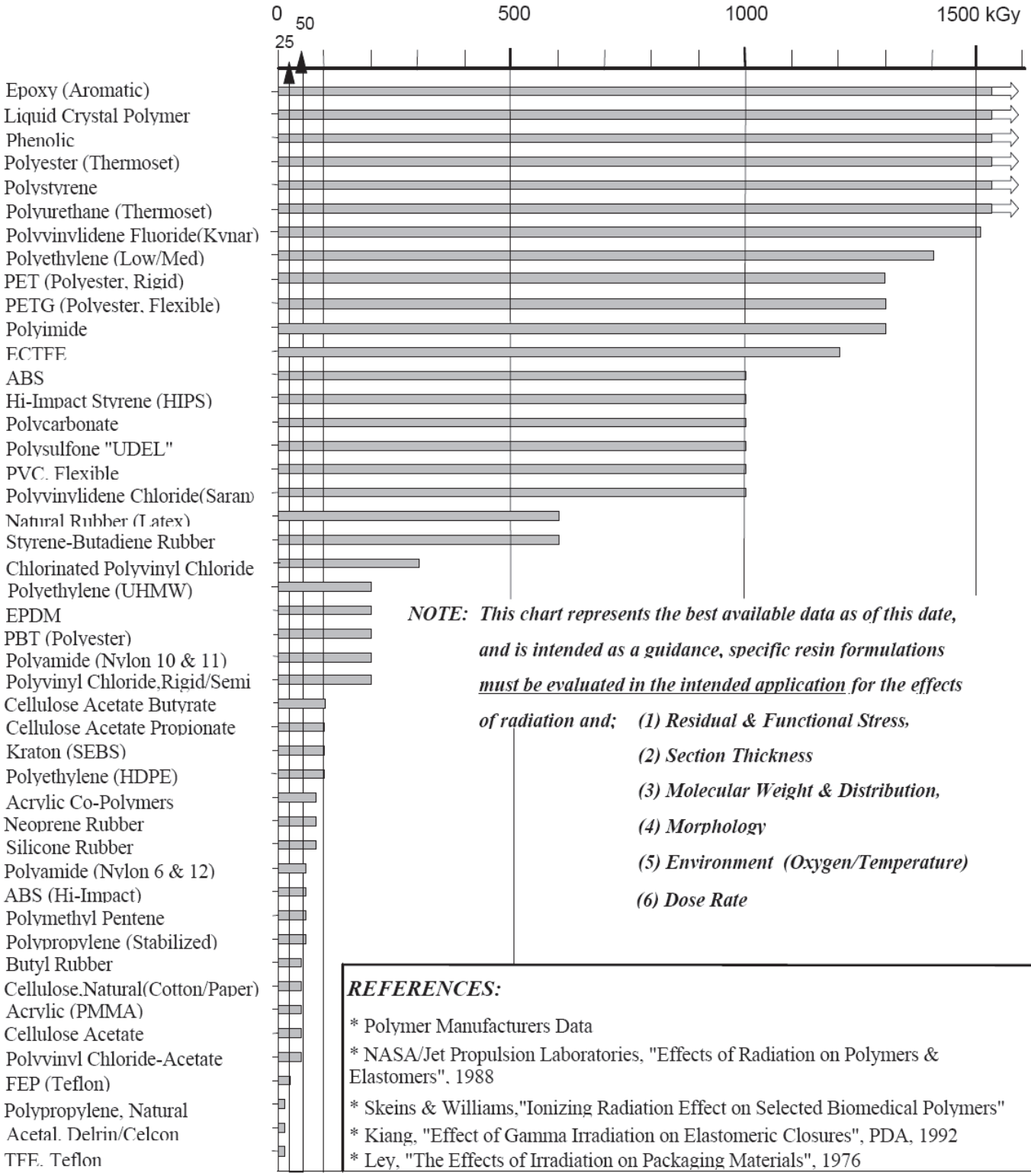


* - Within each family is a range of radiation stabilities, the "steps" are intended to show significant family members

Courtesy of Karl J. Hemmerich, Ageless ProcessingTechnologies

Table 2 - Relative Radiation Stability of Medical Polymers

Dose (KiloGray) in Ambient Air at Which Elongation Decreases by 25%



NOTE: ***This chart represents the best available data as of this date, and is intended as a guidance, specific resin formulations must be evaluated in the intended application for the effects of radiation and;***

(1) Residual & Functional Stress,

(2) Section Thickness

(3) Molecular Weight & Distribution,

(4) Morphology

(5) Environment (Oxygen/Temperature)

(6) Dose Rate

REFERENCES:

* Polymer Manufacturers Data
* NASA/Jet Propulsion Laboratories, "Effects of Radiation on Polymers & Elastomers", 1988
* Skeins & Williams,"Ionizing Radiation Effect on Selected Biomedical Polymers"
* Kiang, "Effect of Gamma Irradiation on Elastomeric Closures", PDA, 1992
* Ley, "The Effects of Irradiation on Packaging Materials", 1976

Courtesy of Karl J. Hemmerich, Ageless ProcessingTechnologies

Table 3—General guide to radiation stability of materials

MATERIALS	RADIATION STABILITY	COMMENTS
Thermoplastics		
ABS	Good	High impact grades are not as radiation resistant as standard impact grades.
Acrylics (PMMA)	Fair–Good	
Cellulosics		Esters degrade less than does cellulose.
Esters	Fair	
Cellulose acetate propionate	Fair	
Cellulose acetate butyrate	Good–Fair	
Cellulose, paper, cardboard	Fair–Good	
Fluoropolymers		When irradiated, PTFE and PFA are significantly damaged. The others show better stability. Some are excellent.
Polytetrafluoroethylene (PTFE)	Poor	
Perfluoro Alkoxy (PFA)	Poor	
Polychlorotrifluoroethylene (PCTFE)	Good–Excellent	
Polyinyl fluoride (PVF)	Good–Excellent	
Polyvinylidene fluoride (PVDF)	Good–Excellent	
Ethylene-Tetrafluoroethylene (ETFE)	Good	
Fluorinated ethylene propylene (FEP)	Fair	
Liquid Crystal Polymer (LCP)	Excellent	Commercial LCPs; Natural LCPs not stable.
Polyacetals	Poor	Irradiation causes embrittlement. Color changes have been noted (yellow to green).
Polyamides (Nylon)	Good	Nylon 10,11,12,6-6, more stable than 6. Nylon film and fiber are less resistant.
Polycarbonate	Good–Excellent	Yellows—mechanical properties not greatly affected; color-corrected radiation formulations are available.
Polyesters	Good–Excellent	PBT not as radiation stable as PET resins.
Polyethylene, various density	Good–Excellent	HD not as stable as MD and LD.
Polyimides	Excellent	
Polyphenylene sulfide	Excellent	
Polypropylene, natural Polypropylene, stabilized	Poor–Fair	Physical properties greatly reduced when irradiated. Radiation stabilized grades, utilizing high Mw and co-polymerized and alloyed with polyethylene, should be used in most radiation applications; High dose rate electron beam may reduce oxidative degradation.
Polystyrene	Excellent	
Polysulfone	Excellent	Natural material is yellow.
Polyurethane	Excellent–Good	Aromatic discolors; polyesters more stable than esters. Retains physical properties.
Polyvinylchloride (PVC)	Good	Yellows—antioxidants and stabilizers prevent yellowing. High molecular weight organotin stabilizers improve radiation stability: color-corrected radiation formulations available.
Polyvinylchloride-Polyvinylacetate	Good	Less resistant than PVC.
Polyvinylidene dichloride (Saran)	Good	Less resistant than PVC.
Styrene/Acrylonitrile (SAN)	Good–Excellent	

Table 3—General guide to radiation stability of materials (continued)

MATERIALS	RADIATION STABILITY	COMMENTS
Elastomers		
Butyl	Poor	Friable, sheds particulate.
Chlorosulfonated polyethylene	Poor	
EPDM	Excellent	
Natural rubber	Good–Excellent	
Nitrile	Good–Excellent	Discolors.
Polyacrylic	Poor	
Polychloroprene (neoprene)	Good	Discolors; the addition of aromatic plasticizers renders the material more stable to irradiation.
Silicone	Good	Phenyl-methyl silicones are more stable than are methyl silicones. Platinum cured silicones are superior to peroxide cured silicones. Full cure during manufacture can eliminate most post-irradiation effects.
Styrene-butadiene	Good	
Urethane	Excellent	
Thermosets		
Allyl diglycol carbonate (Polyester)	Excellent	Maintains its excellent optical properties after irradiation.
Epoxies	Excellent	All curing systems.
Phenolics	Excellent	Includes the addition of mineral fillers.
Polyesters	Excellent	Includes the addition of mineral or glass fibers.
Polyurethanes Aliphatic Aromatic	 Excellent Good–Excellent	 Darkening can occur. Possible breakdown products could be derived.

Primary source: INTERNATIONAL ATOMIC ENERGY AGENCY. *Guidelines for industrial radiation sterilization of disposable medical products, Co 60 gamma irradiation.* TEC DOC-539. Vienna: IAEA, 1990.

Validation Report of "Sterilized Non-Woven Wiper" for Gamma Sterilization

Validation English Ver.

2012-12-28

KM CORPORATION

Document No : SYVP-1234

(Contract Sterilizer)

KM CORPORATION
(Manufacturer)

Validation Report for gamma sterilization

English Ver.

- Product Name : Sterilized Non-Woven Wiper
- Manufacturer : KM CORPORATION
- Contract sterilizer : SOYAGREENTEC Co., Ltd.

- Document No : SYVP-1234

Prepared By _____ Date : Dec. 28. 2012.
H C Sim (Soyagreentec Co., Ltd. Validation Team)

Reviewed By _____ Date : Dec. 28. 2012.
J J Park (Soyagreentec Co., Ltd. Q. A Manager)

Reviewed By Chris Shin _____ Date : Jan. 03. 2013
(KM CORPORATION)

Approved By Alaska Han _____ Date : Jan. 04. 2013
(KM CORPORATION)

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Attachment

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1. Introduction

The manufacturer must supply the product in the process of sterilization of medical devices for the possibility of microbial contamination should be minimized.

Produced before the sterilization, some microorganisms are more likely to be contaminated, the contaminated microbes may be fewer. In this sense, sterilization of medical devices that have been contaminated by bacteria disabled, non-sterile products are sterilized product to change.

Microorganisms associated with a particular sterilization process, the bacterial viability and resistance levels, and sterilization of microbial survival during the period is determined by the environment.

Medical device design / development, production, installation and service standards for quality management are presented in the ISO 13485. ISO 13485 and the subsequent inspection and testing process to determine the final outcome cannot be sufficiently specific manufacturing process, a "special process" is defined as. Therefore, the sterilization process, product inspection and testing process to determine the efficacy, because the process that corresponds to the special process is one example. For this reason, sterilization process to go through a verification process before use and regularly monitor performance • to oversee the process at the same time, and related equipment will also continue to be maintained. In addition, the input of raw materials and / or component level of microbial reproduction (viable), the subsequent storage conditions, and product manufacturing, assembly and packaging, including environmental control unit for numerous elements and care must be taken care of.

This information, EN ISO11137: 2006 validated by the standards of performance will be evaluated and irradiated companies [SOYAGREENTEC CO., LTD(EN ISO11137, ISO9001, ISO13485 certified and registered with the FDA, Ministry of Health, Labour and Welfare(JAPAN) to be sterilized in business units.)].

2. Purpose & Scope

The research data for medical products **KM CORPORATION**, Gamma sterilization of cutting instruments and ISO 9001:2008 & ISO 13485:2003, EN ISO 11137:2006 standard radiation sterilization and validation requirements according to the regulations (SYS-PQ-101), and daily management of radiation sterilization Regulations (SYS-PP-101) based on radiation sterilization of medical devices for the purpose of verification is a process.

This research coverage of gamma-sterilization of medical equipment verification, process control and supervisory standards for work-related regulations are detailed. Through the mechanism of irradiation devices using Co^{-60} radioactive isotope used in the continuous and batch type gamma irradiator model JS-10000 has been applied for.

This study validated data for radiation sterilization, and pre-production steps to control and quality assurance system is not about technology. In addition, work processes and related research facilities for radiation protection standards are not addressed.

This report is not available to the customer in addition to sales

3. Personnel

Test the validity of this information is in charge of the sterilization from an international certification authority gamma sterilization, quality and validity of the test EN ISO11137-1: 2006 accredited international specifications (SOYAGREENTEC Co., Ltd.) repeated in the practice and theory, appropriate training was made up characters.

4. References

1) ISO 9001 : 2008, Quality System – Model for quality assurance in design, development, production, installation and servicing.

2) ISO 13485 : 2003, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

3) ISO 11137-1, 2, 3 Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization.

- *ISO 11137-1 :* Sterilization of health care products Radiation
  Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices
- *ISO 11137-2 :* Sterilization of health care products Radiation
  Part 2 : Establishing the sterilization dose
- *ISO 11137-3 :* Sterilization of health care products Radiation
  Part 3 : Guidance on dosimetric aspects

4) ISO 11737-1, 2 Sterilization of medical devices – Microbiological

- ISO 11737-1(2006) : Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
- ISO 11737-2(2009) : Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

5) The Korean Pharmacopoeia : Sterility Test

5. Definitions

5.1. Absorbed dose

1) Dose : Quantity of ionizing radiation energy imparted per unit mass of a specified material

*NOTE 1. The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 J/kg.

*NOTE 2. For the purposes of this part of ISO 11137, the term dose is used to mean "absorbed dose".

5.2. Bioburden : population of viable microorganisms on or in the product and/or sterile barrier system

5.3. Biological Indicator : test system containing viable microorganisms providing a defined resistance to a specified sterilization process

5.4. Calibration : set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. [VIM:1993, definition 6.11]

5.5. Change Control : assessment and determination of the appropriateness of a proposed alteration to product or procedure [ISO/TS 11139:2006]

5.6. Correction : action to eliminate a detected nonconformity

*NOTE 1. A correction can be made in conjunction with corrective action (3.7).

[ISO 9000:2005]

5.7. Corrective Action : action to eliminate the cause of a detected nonconformity or other undesirable situation

*NOTE 1. There can be more than one cause for a nonconformity.

*NOTE 2. Corrective action is taken to prevent recurrence whereas "preventive action" (3.24) is taken to prevent occurrence.

*NOTE 3. There is a distinction between correction and corrective action. [ISO 9000:2005]

5.8. *D* value : *D*10 **value** time or radiation dose required to achieve inactivation of 90 % of a population of the test microorganism under stated conditions

*NOTE 1. For the purpose of the ISO 11137 series, the *D* value refers to the radiation dose necessary to achieve the 90 % reduction. [ISO/TS 11139:2006]

5.9. Development : act of elaborating a specification [ISO/TS 11139:2006]

5.10. Dose Mapping : measurement of dose distribution and variability in material irradiated under defined conditions

5.11. Dosimeter : device having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system [ISO/TS 11139:2006]

5.12. Dosimetry : measurement of absorbed dose by the use of dosimeters

5.13. Establish : determine by theoretical evaluation and confirm by experimentation [ISO/TS 11139:2006]

5.14. Fault : one or more of the process parameters lying outside of its/their specified tolerance(s) [ISO/TS 11139:2006]

5.15. Health Care Product(s) : medical device(s), including *in vitro* diagnostic medical device(s), or medicinal product(s), including biopharmaceutical(s) [ISO/TS 11139:2006]

5.16. Installation Qualification (IQ) : process of obtaining and documenting evidence that equipment has been provided and installed in
accordance with its specification [ISO/TS 11139:2006]

5.17. Irradiation Container : holder in which product is transported through the irradiator

*NOTE 1. The holder can be a carrier, cart, tray, product carton, pallet or other container.

5.18. Irradiator Operator : company or body responsible for irradiation of product

5.19. Maximum Acceptable Dose : dose given in the process specification as the highest dose that can be applied to a defined product without compromising safety, quality or performance

5.20. Specification : approved document stipulating requirements

5.21. Specify : stipulate in detail within an approved document [ISO/TS 11139:2006]

5.22. Sterile : free from viable microorganisms [ISO/TS 11139:2006]

5.23. Sterility : state of being free from viable microorganisms

*NOTE 1. In practice, no such absolute statement regarding the absence of microorganisms can be proven (see **sterilization**) 3.39. [ISO/TS 11139:2006]

5.24. Sterility Assurance Level (SAL) : probability of a single viable microorganism occurring on an item after sterilization

*NOTE 1. The term SAL takes a quantitative value, generally 10^{-6} or 10^{-3}. When applying this quantitative value to assurance of sterility, an SAL of 10–6 has a lower value but provides greater assurance of sterility than an SAL of 10^{-3}.

[ISO/TS 11139:2006]

5.25. Sterilization : validated process used to render product free from viable microorganisms

*NOTE 1. In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number it can never be reduced to zero

[see **"sterility assurance level"** (3.38)]. [ISO/TS 11139:2006]

5.26. Sterilization Dose : minimum dose to achieve the specified requirements for sterility

5.27. Sterilization Process : series of actions or operations needed to achieve the specified requirements for sterility

6. Product Qualification

6.1. General

6.1.1. Product Name : Sterilized Non-Woven Wiper

6.1.2. Model Name : KM-6612L

6.1.3. Device Grade : Class II

6.1.4. SAL : 10^{-6}

6.2. Evaluation of Device materials

*Raw materials

No.	Name	Raw material	Note
1	Polyester	Polyester 55%	-
2	Cellulose	Cellulose 45%	-

Attachment 1 : Product information

6.3. Evaluation of Sterile Barrier

Composition	Contents		Picture
1st Packaging	Material	: LOW-DENSITY POLYETHYLENE(LDPE)	
	Dimension	: 255 mm(W), 290 mm(L), 5 mm(H)	
	Package Type	: 10 ea	
	Weight	: 14.8 g	
2nd Packaging	Material	: LOW-DENSITY POLYETHYLENE(LDPE)	
	Dimension	: 320 mm(W), 360 mm(L), 35 mm(H)	
	Package Type	: 25 ea	
	Weight	: 25.0 g	
3rd Packaging	Material	: LOW-DENSITY POLYETHYLENE(LDPE)	
	Dimension	: 345 mm(W), 370 mm(L), 35 mm(H)	
	Package Type	: 100 ea	
	Weight	: 26.5 g	

6.3.1. Carton Packaging

Material	: Paper	Picture
Dimension	: 340 mm(W), 315 mm(L), 320 mm(H)	
Package Type	: 8 outer bags / ctn	
Weight	: 5,300 (g)	
Density	: 0.155 g/cm^3	

6.4. Establishment of Maximum dose

	Contents	Test method
Establishment of Maximum dose	Maximum acceptable dose	40 kGy Radiation Source : Co^{-60}
Result	Manufacturer's(**KM CORPORATION**) product safety evaluation of the material up to 40 kGy dose of radiation is not affected by packaging material, and the set was evaluated for validity *Consultation : Evaluation of gamma sterilization for shelf life of 36 months Gamma irradiation for sterilization can't mark a change in the quality, safety and performance of the materials. So, they can be used in most sterile device applications according to table of Appendix A. "Examples & Guidance of radiation stable material(in sterilizing dose range)" in AAMI TIR 17	

* Technical Information Report. AAMI TIR 17 : 2008 - Compatibility of materials subject to sterilization

Attachment 2 : Guideline for selection of Device and packaging materials

6.5. Establishment of Sterilization dose

6.5.1. Sterility assurance level : SAL

Value : SAL 10^{-6}

6.5.2. Product to represent a product family

- ● the master product
- ○ an equivalent product
- ○ a simulated product
- ○ product rejected

(see ISO 11137-2:2006 4.3, 5.3.2)

6.5.3. Sample item portion: SIP

- ● an entire product : SIP=1
- ○ a selected portion of product (SIP :)

Value : The entire product was used testing.

6.5.4. The selecting method for determining the sterilization dose

- ○ Method 1 : dose setting using bioburden information
- ● Method VD_{max}^{25} : Substantiation of 25 kGy as the sterilization dose
  - ■ multiple production batches
  - □ single production batch

6.5.5. Micro-biological testing method

*Test of biobuden : ISO 11737-1

*Test of sterility : ISO 11737-2

6.5.6. VD_{max}^{25} substantiation : SIP ≤ 1.0

6.5.6.1. Stage 1 : Number of product items

Value : 40

10 from each of 3 batches for bioburden determination plus 10 for verification dose experiment.

6.5.6.2. Overall SIP average bioburden

Value : 6.0

SIP bioburdens of 5.7, 4.9 and 7.4 were observed for the three batches tested for an overall SIP average bioburden of 6.0.

6.5.6.3. Stage 2 : Overall average bioburden

Value : 9.72

*Correction factor : 1.62 (recovery efficiency)

The average bioburden for the entire product of each of the batches is calculated:

9.23	/1	=	9.23
7.94	/1	=	7.94
11.99	/1	=	11.99

The overall average bioburden is 9.72. None of the individual batch average bioburdens was twice the overall average bioburden of 9.72, therefore the overall average bioburden is used to calculate the verification dose.

Attachment 3 : Bioburden test report

6.5.6.4. Stage 3 : Verification dose

Value : 7.1 kGy

Use table 9 to obtain the verification dose. A bioburden of 9.72 is not listed in the table, so the next higher bioburden of 10.0 is used. The VD_{max}^{25} dose for an SIP of 1 is calculated using the following equation.

SIP VD_{max}^{25} = (SIP = 1,0 VD_{max}^{25}) + (SIP dose reduction factor × log SIP) [Equation (10)]

SIP verification dose = 7.1 kGy + (3.57 × log1) = 7.1 kGy

6.5.6.5. Stage 4 : Perform Verification dose experiment

Select 10 product items from a single batch of product. The 10 product items for the performance of Stage 4 may be selected from one of the batches for which a bioburden determination was carried out in Stage 4 may be selected from a fourth batch manufactured under conditions that are representative of normal production.

6.5.6.6. Verification dose acceptance criteria

The highest dose to the measured dose may not exceed $VDmax^{25}$ by more than 10%. If the arithmetic mean of the highest and lowest doses of measured doses is < 90% of $VDmax^{25}$, the verification dose experiment may be repeated. If this mean dose is < 90% of $VDmax^{25}$ and, on performance of the test of sterility, acceptable results are observed, the verification experiment need not be repeated.

Value : 7.20 kGy(min) ~ 7.29 kGy(max)

Verification dose	Dose range	Specified Dose		Dosimetry Results	
7.1 kGy	± 10 %	D_{min}(kGy)	6.39	D_{min}(kGy)	7.20
		D_{max}(kGy)	7.81	D_{max}(kGy)	7.29

Attachment 4 : Gamma Irradiation for Verification Experiment

6.5.6.6. Stage 5 : Sterility testing

Value : 0 Positive

Result	Purview	Interpretation of result
0	0 or 1 positive	substantiate 25 kGy as the sterilization dose
	2 positive	Confirmatory verification dose experiment : the verification dose experiment shall be repeated.(stage 3, 4, 5)
	More than two positive	Do not accept verification if there are than two positive tests of sterility.

Subject the product items(Stage 4) individually to a test of sterility in accordance with ISO 11737-2:2009 and record the number of positive tests of sterility.

Accept verification if there is no more than one positive test of sterility from the 10 tests carried out and there by substantiate 25 kGy as the sterilization dose.

Attachment 5 : Sterility test report

6.6. Specifying the maximum acceptable dose and the sterilization dose

Value : 25 kGy ~ 40 kGy

The higher the dose deviation of the maximum allowable dose in case, the product dose mapping results are up to the value of the absorbed dose values were less than 40 kGy. Therefore, the safety of products and materials identified to determine the maximum dose of 40 kGy

ISO 11737-1 the average determined by means of microbial contamination (9.72 CFU / unit), and 7.1 kGy dose is about this verification. Sterility test samples as determined by test dose (10ea) after gamma irradiation and sterility test results were all negative results ISO 11137-2: 2006 (E) in the Substantiation of 25 kGy as a sterilization dose [AAMI TIR 27: $VDmax^{25}$ Method (verification experiment performed on ten samples at $SAL10^{-6}$) is proved along.

7. Installation Qualification

7.1. Contract sterilizer information

7.1.1. Contract Sterilizer : SOYAGREENTEC CO., LTD.

7.1.2. Address : 900-3, Sangsin-Ri, Hyangnam-Eup, Hwasung-Si, Kyoengki-Do, Korea.

7.1.3. Certificate

ISO 9001 & ISO 13485 Quality System

EN ISO 11137 Sterilization of healthcare product-Requirement of validation and routine Control – Radiation sterilization

FDA Registration

Korea Food & Drug Administration, Certificate of GMP

Ministry of Health, Labour and Welfare(JAPAN)

Attachment 6 : Certificate of Soyagreentec Co., Ltd.

7.1.4. Responsibilities

Was stipulated at the Agreement for contract sterilization

7.2. Information of gamma irradiation

7.2.1. Irradiator specifications and characteristics

* Model : JS-10000 (High Performance Tote Irradiator)
* Serial No. : IR203
* Manufacture of Gamma irradiation : MDS-Nordion International INC.
* Date of manufacture : 2000. 1

Attachment 7 : JS-10000 Brochure

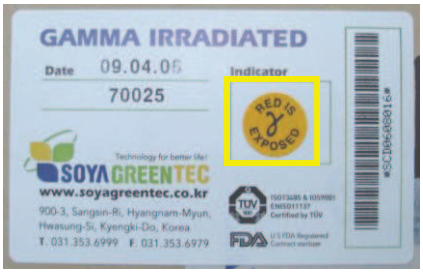
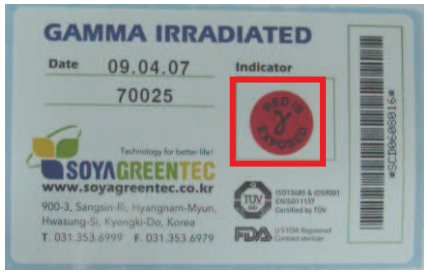
7.2.2. Distinction control of sterilized products

Description of premises in Soyagreentec Irradiation Facility, products to be irradiated are loaded at right side and irradiated products are loaded at left side from direction of irradiation room and its products are separated from each other by barrier.

Attachment 7 : Fig. 1. JS-10000 Lay out, Fig. 2. Factory Layout

*Distinction methods between sterilized and non-sterilized product

*Chemical indicator : dots – sticker type

Yellow → Red color change	
Non-Irradiated	Irradiated
	

Attachment 8 : Certificate of Self-adhesive Gamma indicator

7.2.3. The construction and operation of any associated conveyor system

*Source Pass

All of the 44 running tote are located at right and left, upper and lower position around Co^{-60} source. Each tote orbited to keep movement through 44 positions in order to increase the absorbed dose uniformity. Irradiation will begin when loaded tote enter into irradiation room by conveyer and first entered continuously like this order. All of these operation are controlled by PLC.

Attachment 7 : Source pass (fig. 3-1, 3-2)

* Timer and set

-Master timer

Irradiation time will decide by soured strength and density of product to be irradiated in order to irradiate optimum dose. Irradiation time could be adjusted by Master Time Set. Master time is from beginning time of source pass to next beginning time of source pass.

-Over dose timer

Over Dose Timer will set automatically 10 sec. long by Master time setting. Overdose timer will operate if source pass did not work when Master time elapsed 10 sec. So that source will down and operation will stop to prevent over irradiation of product.

7.2.4. Irradiation container (Tote)

Tote made of specific aluminum which hold adequate gamma ray penetration and its dimension is 830mm × 530mm ×1,500mm(width, length, height) and available up to 380kg loading

Attachment 7 : Tote - Irradiation container (Fig. 5-1, 5-2)

7.2.5. Load and Unload

At loading position, tot will up by foot switch and load safely. Product loading procedure will handle by loading pattern with attachment of dosimeter at certified minimum absorbed dose position which was recertified by dose mapping and will attach more dosimeter at appropriate for tote interval when different items will irradiate continuously and evaluate the

Attachment 7 : Fig. 4. load and Unload area

7.2.6. Research Loop

Research Loop is used to determine the optimum dose of each item before mass irradiation.

Attachment 7 : Fig. 5-3. Research Loop

7.2.7. Source verify daily strength and Source capsule for position

*Source information

-Radioactive Source : Cobalt-60

- Manufacture & Model : MDS-Nordion (C-188)

-1.17Mev 100%, 1.33Mev 100%

- Half –life : 5.26year

- Designed capacity : 3,000,000 Ci

* Source and Source rack

Irradiation room have 2 of source rack, 12 module installed at one rack and 42 source installed at one module. Active area of one source rack is 1.55m × 1.83m and its will be located at center of tote loaded in irradiation room when facility is running.

Attachment 7 : Fig. 6. Source and Source rack

7.2.8. Manner of operating the irradiator

7.2.9. Operation by the licensed personal

Radiation supervised operator(RSO), Authorized Operators.

7.2.10. Normal Start-up

In the equipment room, At the control console, In the radiation room.

7.2.11. Means to identify disorder : Alarm system, Video Display.

7.2.12. Maintenance frequency

weekly, monthly, quarterly, yearly regularly inspection and record.

8. Operational Qualification

8.1. Standard Operation Procedure

* Radiation driving instructions (SYS-IP-103)
* Radiation Facility inspection standards (SYS-SP-104)

8.2. Standard Process

Procedure of irradiation sterilization : Radiation sterilization and routine administrative regulations (SYS-PP-101)

8.3. Equipment calibration

8.3.1. Dosimetry system

8.3.2. Cycle setting-timer for irradiation

Sources the strength of the mind set to periodically change

Attachment 9 : Certificate of calibration

8.4. Irradiator Dose Mapping

8.4.1. Dose mapping for OQ is carried out to characterize the irradiator with respect to the distribution and reproducibility of dose and to establish the effect of process interruption on dose. Dose mapping should be performed by placing dosimeters in an irradiation container filled to its design limits with material of homogeneous density. This density should be within the density range for which the irradiator is to be used. At least two dose mapping exercises should be carried out, one with material close to the lower limit of the density range for which the irradiator is intended to be used and another with material close to the upper limit of this range.

8.4.2. A sufficient number of irradiation containers (at least three) should be dose mapped at each chosen density to allow determination of variability of dose and dose distribution between containers. The detail and number of replicate dose mapping exercises required will be influenced by the amount of knowledge gained from previous OQ dose mapping exercises on the same or similar irradiators. This means that a greater number of replicate exercises might be required for a new installation than for qualification dose mapping exercises after replenishment of sources.

8.4.3. Writing dose table or calculating transitdose must be performed for verification

influence of process stopping. It should be confirmed dose measurement whether carried-dose calculation is suitable. Effect of process stopping evaluate compare writing result of dose table at normality process condition. In order to accurately assess must be made several times to process stopping

8.4.4. Information for material of homogeneous density

Material	Corrugated Cardboard		
Size(W*L*H) mm	815*0.7*1,525	Radiation room Temperature(℃)	
		15.0	
Unit weight (kg)	1	Radiation room Humidity(%)	
		25.0	
Loading quantity (ea)	70	Master time(min)	4 m 37sec
Loading weight (kg)	70		
Loading density (g/cm^3)	0.1	Source Activity(Ci)	371,063
Dosimeter Type	Harwell Red	Dosimeter Lot No	4034JT

Material	Starch		
Size(W*L*H) mm	815*0.7*1,525	Radiation room Temperature(℃)	
		12.0	
Unit weight (kg)	20	Radiation room Humidity(%)	
		23.5	
Loading quantity (ea)	10	Master time(min)	4 m 37 sec
Loading weight (kg)	200		
Loading density (g/cm^3)	0.3	Source Activity(Ci)	371,063
Dosimeter Type	Harwell Red	Dosimeter Lot No	4034JT

8.4.5. Information for material of Process stopping

Material	Corrugated Cardboard		
Size(W*L*H) mm	815*0.7*1,525	Radiation room Temperature(℃)	
		15.0	
Unit weight (kg)	1	Radiation room Humidity(%)	
		25.0	
Loading quantity (ea)	70	Master time(min)	4 m 37sec
Loading weight (kg)	70		
Loading density (g/cm3)	0.1	Source Activity(Ci)	371,063
Dosimeter Type	Harwell Red	Dosimeter Lot No	4034JT

Material	Starch		
Size(W*L*H) mm	815*0.7*1,525	Radiation room Temperature(℃)	
		12.0	
Unit weight (kg)	20	Radiation room Humidity(%)	
		23.5	
Loading quantity (ea)	10	Master time(min)	4 m 37 sec
Loading weight (kg)	200		
Loading density (g/cm3)	0.3	Source Activity(Ci)	371,063
Dosimeter Type	Harwell Red	Dosimeter Lot No	4034JT

8.4.6. Result for Irradiator Dose Mapping

Distribution Dose : Fitness

Source before and after increasing the dose did not show any significant difference in the distribution.

Attachment 10 : Irradiator Dose Mapping Report

9. Performance Qualification

9.1. Product Loading Pattern

Loading of the product the way the size of the product determined in accordance with the size and the Tote, and according to the density of the product by considering the uniformity of the absorbed dose, radiation dose and working up to the minimum dose is loaded to be included in the category of

Material	: Paper	Picture
Dimension	: 340 mm(W), 315 mm(L), 320 mm(H)	
Package Type	: 8 outer bags / ctn	
Weight	: 5,300 (g)	
Loading Density	: 0.155 g/cm^3	

* Products direction : 8 C/T loading(direction : no connection)

*Products Loading Pattern : **Attachment 11 : Master Process Specification**

* TOTE Size : **Attachment 7**

* Irradiation container (Tote)

Tote made of specific aluminum which hold adequate gamma ray penetration and its dimension is 830mm × 530mm ×1,500mm(width, length, height) and available up to 380kg loading

9.2. Product Dose mapping Study

Replicate dose mapping exercises are carried out in order to obtain information on variability of doses caused by irradiator variation, product variation and dosimeter uncertainty. A minimum of three exercises – each done using a separate irradiation container – is recommended in order to obtain statistically valid data; confidence in the measured values is, however, increased by using a larger number of exercises. For replicate dose mapping exercises, it could be sufficient to place dosimeters only in areas of dose extremes, rather than carry out a full dose mapping exercise.

9.2.1. The expected min/max dose zone

* min dose zone : 26.0 kGy (M5)
* max dose zone : 32.8 kGy (M8)

9.2.2. Product dose mapping

The data from dose mapping can be analyzed to calculate the ratios of minimum dose to dose to dose at the monitoring position and maximum dose to dose at the monitoring position for each exercise. A calculation of the respective mean values, together with their standard deviations, can then be made. The mean minimum to monitor dose ratio and its uncertainty, combined with the uncertainty of the dosimeter system, can be used to select a monitor dose that will ensure that, in subsequent processing, the minimum dose exceeds the sterilization dose with a defined confidence level.

***Result**

Dose Measurement						
Specified Dose(kGy)		Product dose mapping of Totes (Location)				Location
		Dose Map 1	Dose Map 2	Dose Map 3	Average	
D_{Min}	25	25.9	25.9	26.1	26.0	M5
D_{Max}	40	32.6	32.8	33.0	32.8	M8
Decision		Passed	Passed	Passed	Passed	-

6.2.3. Routine Monitorin1g Position

* D_{Min} Dose : M-5 (Location)
* D_{Max} Dose : M-8 (Location)

Attachment 12 : Product dose mapping Report

10. Review and approval of validation

10.1. Product

Material	: Paper	Picture
Dimension	: 340 mm(W), 315 mm(L), 320 mm(H)	
Package Type	: 8 outer bags / ctn	
Weight	: 5,300 (g)	
Density	: 0.155 g/cm^3	

10.2. Master Process Specification

1 Tote : 8 Carton

10.3. Maximum acceptable dose

40 kGy

10.4. Sterilization dose

25 kGy

10.5. For product that support microbial growth, the maximal interval of time between manufacture and completion of irradiation. The growth of the microbe is not an occurrence possibility and the set of time interval between manufacture and irradiation completing is not meaning.

10.6. Routine dosimeter monitoring positions

M-5 (minimum dose)

(9.2.3 see)

11. Routine monitoring and control

11.1. Warehousing of Products

Management department confirm the same as product quantity and those recorded in that from the customer "Request for Gamma irradiation". Product loaded into inspection waiting areas. Receive the approval of Quality control supervisor.

11.2. Incoming inspection

Write the Product checklist, after packaging, quantity, weight, and contents are examine. Product move to non-irradiation area and storage after Receive the approval of Quality control supervisor. In such cases, broken and the information of the contents is incorrect, move to unsuitable area. And process after discussion with customer.

11.3. Sterilization process control

11.3.1. Check lists

11.3.1.1. Product of sterilization request

1) Product size and loading quantity in tote are confirm to Master Process Specification.
2) Confirm to Product package
3) Confirm to Absorbed dose.
4) Chemical indicator attach to product final package(Yellow).
5) Measure the Weight of stocked product and write to Master record for gamma irradiation process.

11.3.2. Facility check and start a facility

1) Activate Air compressor
2) Use a key and start a facility

11.3.3. Loading product and irradiation preparation

11.3.3.1. Product load to lift at load area.

11.3.3.2. Products are loaded to lift loads safely in a tote.

1) Load to Product package won't be damaged or modify
2) Load to tote not swollen.
3) Do not expose the product outside the Tote.
4) Confirm to product density(product weight(kg) / Tote volume(630 ℓ))

11.3.3.3. Dosimeter attach to expected location(center of Tote)

11.3.3.4. Write to master record after load to product

11.3.3.5. "maintenance auto mode" use to Tote(loaded product) in position.

11.3.4. Timer setting, source activate and sterilization process

11.3.4.1. Timer is set make use of table 1(offer Mds-Nordion)

11.3.4.2. Source intensity change is calculate which make use of table 2(offer Mds-Nordion).

11.3.4.3. Source rack up and carry sterilization process out

1) Use the master key and eliminate Fault

2) Confirm to all indicator.

3) Confirm to Timer setting.

4) Depending on the access procedure go into irradiate room

5) Confirm to Facility normality.

6) Use the master key and operate start-up key

7) 90 sec delay Timer, the alarm that the listening and go out irradiation room

8) Safety chain of Source valve hang up the control room door

9) Close the control room door.

10) Use the master key, and source rack up.

11.3.4.4. Confirm to source pass of tote, put the tote into the irradiation room.

11.3.5. Dose evaluation and finish the sterilization process

11.3.5.1. Confirm to chemical indicator and dosimeter is evaluated when the Tote(sterilized) come out to unload area.

1) Warming up the spectrophotometer minimum 30 minute ago.

2) Set the wavelength.(Red: 640nm, Amber: 651 nm)

3) Set the zero(zero is blank value)

4) Evaluated Absorbed dose

5) Use to digital caliper and Evaluated Dosimeter thickness

6) Calibrated Table use to absorbed dose evaluation

7) Confirm to absorbed dose and write to master record for gamma irradiation process

11.3.5.2. When measured appropriate absorbed dose, unload to product. And product is stored “irradiated area”.

11.3.5.3. If dose caught short, carry out additional irradiation. And sterilization process finished.

11.3.5.4. When process finished, write to Master record for gamma irradiation process and notify to Quality control team.

11.4. Sterilization acceptance

After Evaluate dosimeter and write Master record for Gamma irradiation process, approved sterilization process suitability. After confirm Product effectivity, ‘certificate of irradiation’ will be issued, provide to customer.

Attachment 15 : Certificate of gamma sterilization

11.5. Release and storage

11.5.1. Operator is storage and control irradiated product not mixed other product. When long-term storage handling, storage and delivery in accordance with administrative regulations.

11.5.2. Operator is irradiation, according to the time of use not release to FIFO(first-in, first-out) principle and the quantity not release product management in the intestine, the customer pays record.

11.6. Occurrence notification of inconsistence product

11.6.1. When In irradiation the discovery of nonconforming product or problem occurs, finder immediately operator shall notify its contents to a suitable product is handled in accordance with administrative regulations.

11.6.2. Operator is to identification control and storage which unsuitable product, record to customer provide management register and notified immediately to sales manager

11.6.3. Sales manager is notified and discuss what customer unsuitable product

11.6.4. Miss, damage and loss in respect of customer product consultation with the customer in accordance with are decide

11.7. Control of non-irradiated product, irradiating product

Do not mix with other products, only products of customer load. The beginning and middle of the Tote, continuous, routine monitoring for the last three locations where the Tote should be attached to the Dosimeter. Chemical indicator attach to Product before product loading.

11.6.1. Non-irradiated and irradiated product shall be segregated.

Product load area of irradiated product and non-irradiated product is strictly segregated and moving of product impossible. After irradiate product move to irradiated area.

11.8. Absorbed dose of KM CORPORATION product evaluation and product release

Customer ask for dose is 25 ~ 40 kGy. When Minimum dose(sterilization dose) value is greater than 25 kGy and Maximum dose value is lower than 40 kGy, process is successful.

11.9. Irradiated product suitable evaluation.

If the value exceeds the maximum dose 40 kGy, products and processes to handle failure. If you do not exceed the minimum dose value 25 kGy, products and processes to handle failure and carry out additional irradiation. Additional irradiation is demand dose of the product is in excess of 25 kGy, Additional processing to adjust the Process Parameter does not exceed the maximum dose in the range. As this time, for additional irradiation information, record and preserve. Product demand dose is wide range(25 ~ 40 kGy), does not exceed the maximum dose is enough to Additional irradiation the extent. Additional irradiation is immediately decide and carry out after dose evaluation(3 ~ 5 minute), not evaluated segregated irradiation for microbiological effects or deterioration of the product.

“Process(to incoming from outgoing) is record and control by Master Record for Gamma irradiation Process.”

12. Maintenance of validation

12.1. General

The continued effectiveness of the established sterilization dose shall be demonstrated through the conduct of determinations of bioburden to monitor the number of microorganisms present on product in relation to a defined bioburden specification, and sterilization dose audits to monitor the radiation resistance of the bioburden on product.

12.2. Frequency of sterilization dose audits

12.2.1. For product of average bioburden greater than or equal to 1.5, the maximum interval of time between determinations of bioburden shall be three months.

12.2.2. For product of average bioburden less than 1.5 and for which a sterilization dose of 15 kGy has been selected, the maximum interval of time between determinations of bioburden shall be three months.

12.2.3. If the interval of time between the manufacture of batches of product is more than either one month or three months, as applicable, determinations of bioburden shall be performed on each production batch.

12.2.4. If the outcome of determinations of bioburden exceeds the specified limit, an investigation in accordance with ISO 11737-1 shall be performed. If a sterilization dose of 25 kGy has been selected and substantiated using Method VD_{max}^{25} and the average bioburden is less than 1,000, the sterilization dose audit frequency currently used shall be continued.

12.3. Sterilization dose audits

12.3.1. Dose audit period

* The first every three months → suitable case every six months → suitable case every twelve months

The maximum interval of time between performance of sterilization dose audits shall be twelve months.

* Sterilization dose auditing guidelines (SYS-SQ-105)

12.3.2. Obtain samples of product

Select at least 20 product items from a single batch of product

12.3.3. Determination average bioburden

*Products 10 ea test

12.3.4. Perform verification dose experiment

* 7.1 kGy

12.3.5. Sterility test

*1 positive or 0 positive : Accept the sterilization dose audit

*2 positive : Perform a confirmatory sterilization dose audit

*3 ~ 6 positive : Augmented Sterilization dose (25 kGy + Augmented value)

*More then 7 positive : Reestablishment of using another method

13. Recalibration

Table A.1 — Guidance on qualification of changes to a gamma irradiator

Irradiator change	Installation qualification	Operational qualification			
	Installation testing and equipment documentation	Equipment testing	Equipment calibration	Irradiator dose mapping	Type of dose mapping
Addition, removal or reconfiguration of/to radionuclide	○			○	Homogeneous material to design limits
Carrier/irradiation container redesign	○	○		○	Homogeneous material to design limits
Removal or relocation of overhead conveyor inside irradiation cell	○	○		○	Homogeneous material to design limits
Removal or relocation of stop units in the critical product path	○	○		○	Homogeneous material to design limits
Removal or relocation of stop units outside of the critical product path	○	○			
Replacement of source cables	○	○			
Redesign of the source drive system	○			○	Transit dose
Redesign that affects the source to product distance	○	○		○	Homogeneous material to design limits Transit dose
Redesign of the source rack system	○	○		○	Homogeneous material to design limits Transit dose
Changes to type of irradiator cycle timer	○	○	○		
Changes to type of irradiator radiation safety monitoring devices	○	○	○		
Changes to type of irradiator pool water monitoring devices	○	○	○ (if applicable)		
NOTE 1. Addition of radionuclide without reconfiguration of the source geometry might only require that part of the homogeneous dose mapping study be performed to confirm the results of mathematical modelling or modification objectives. Whereas addition of radionuclide with change of source geometry might require that all homogeneous dose maps be repeated in addition to some of the ancillary studies such as centre loading or partial load. NOTE 2. Pending results of operational testing (e.g. verification of source position), irradiator dose mapping may be required after source cable replacement. NOTE 3. OQ dose mapping results may lead to a repeat of PQ.					

*ISO 11137-1 : 2006 - Sterilization of health care products Radiation

Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

13.1. calibration

13.2. Maintenance of equipment

During the review of the maintenance records, the maintenance schedule and procedures should be revised as necessary to address information learned about the equipment.

13.3. Requalification of equipment

The intervals for requalification of the irradiator should be chosen to provide assurance that the irradiator is consistently operating within specifications. For gamma irradiators, the requalification is typically carried out in connection with replenishment of sources. For electron beam and X-ray irradiators, requalification is typically carried out on an annual cycle, with specific parts of requalification at shorter time intervals within this cycle. If requalification measurements show that the IQ and/or OQ status of the irradiator has changed, then PQ might have to be repeated.

13.4. Assessment of change

For gamma irradiators, examples of when OQ should be performed after a change include:
replenishment of the source;
changes in source geometry and position;
changes to the conveyor;
a change in product path;
a change in irradiation container.

The extent of the OQ will depend on the type and degree of the change (see Table A.1).

Determination of Sterilization Dose
[VD_{max}^{25} substantiation (SIP=1.0) VD_{max}^{25}]

Term	Value	Comment
Stage 1		
SAL	10^{-6}	This method substantiates only a 10^{-6} SAL at 25 kGy
SIP	1	The entire product unit was used for resistance group verification
Stage 2		
SIP bioburden estimate	6.0	SIP bioburden estimate results of 5.7, 4.9 and 7.4 were observed from the Three batches tested, for an average SIP bioburden estimate of 6.0.
Average bioburden estimate	9.72	The bioburden for the estimate product unit was calculated as follows. 9.23/1 = 9.23 7.94/1 = 7.94 11.99/1 = 11.99 The overall average bioburden is 9.72. None of the individual batch average bioburden was twice the overall average bioburden of 9.72, therefore the overall average bioburden is used to calculate the verification dose.
Stage 3		
Verification dose	7.1 kGy	Use ISO 11137-2:2006 table 9 to obtain the verification dose. A bioburden of 9.72 is not listed in the table 9, so the next higher biburden of 10.0 is used. The $VDmax^{25}$ dose for and SIP of 1 is calculated using the following equation. SIP verification dose = 7.1 kGy + (3.57 × log1) = 7.1 kGy
Stage 4		
Sterility results	0 positive	The verification dose was within the specified dose range. (±10%) At 6.39 ~ 7.81 kGy / (7.20 ~ 7.29 kGy)
Stage 5		
Sterilization Dose for 10^{-6} SAL	25 kGy	The sterility test results were acceptable(0≤ 1 positives). There fore, 25 kGy has been substantiated to achieve at least a 10^{-6} SAL.

Attachment 1.

Product information

Purely Advanced

2015 Edition

Know-how Makes KM **Technical Data Sheet**

KM Sterilized Nonwoven Wiper

Sterilized Nonwoven Sheet Wiper
for Clean Environment

Description

KM-6509는 Polyester와 Cellulose 수압직조법으로 생산하여 친수성이 뛰어나 습식 Cleaning시 액체를 잘 흡수하며, 거친면 Cleaning에도 표면의 보푸라기가 일어나지 않아 오염제어에 탁월함. 감마선(Gamma Ray)으로 멸균처리하여 박테리아 및 세균으로부터 안전한 멸균 Wiper임.

Feature

- 감마선(Gamma Ray) 멸균으로 장기간 보관 용이
- 저 중량, 얇은 두께 대비 고흡수성
- 높은 흡수율, 빠른 흡수속도
- 환경친화적 제품으로 사용 후 소각시 유독가스 발생 억제
- Polyester & Microdenier 원단 대비 고흡수력
- 뛰어난 조직결합을 통한 견고한 구조로 내마모성 및 물리적 충격과 마찰에 강함

Product

Name	Description	Packaging
KM-6509	9″ x 9″	100sh/bag, 8bag/box

Application

- Cleanroom, Assembly Line의 부품, 장비 및 바닥 Cleaning용
- 공정 장비 및 설비용 부품류의 전세정(Pre-cleaning)
- 각종 장비 및 설비의 외면, 프레임 청소
- Cleanroom내 Access Floor 청소 및 부품, 장비, 표면 Cleaning

Product Environment

- Cleanroom 환경에서 생산한 Clean Wiper
- 지속적인 Cleanroom 관리를 통한 고객 품질 만족
- ISO 9001:2008 품질규격에 입각한 엄격한 품질 검사
- 감마(cobalt-60)멸균 처리하여 세균 및 미생물 박멸
- Dosimetry Range를 20~40kGy로 관리 적용

Office	348-1 Bocheri Miyang Anseong Gyeonggi	**Tel** 031-678-8800	**Fax** 031-678-8899
Factory1	269-2 Gyereuk Miyang Anseong Gyeonggi	**Tel** 031-678-8900	**Fax** 031-678-8960
Factory2	306-3 Gusuri Miyang Anseong Gyeonggi	**Tel** 031-678-3400	**Fax** 031-678-3499
Factory3	516-5 Jujinri Pyrongchan Gangwon	**Tel** 033-333-6660	**Fax** 033-332-9287

KM

www. kmbiz.com

Purely Advanced

Know-how Makes KM **Specification**

KM Sterilized Nonwoven Wiper

Property	Unit	SPEC	Value	Test Method	Remarks
Material	-	-	-	Polyester + Cellulose	Polyeter 45% + Cellulose 55%
Length (MD / TD)	Mm	230±10	230.6	JIS L 1096 8.3	-
Weight	g/sh	3.7±0.4	3.84	JIS L 1096 8.4	-
	g/㎡	70±7	72.28		-
Thickness	㎛	340±20	352.22	JIS L 1096 8.5	-
Horizontal Time to Sorption	sec/6ø	≤4	1.36	IEST-RP-CC004.2 7.2	-
Absorbency	ml/㎡	≥300	349.06	IEST-RP-CC004.2 7.1	-
	ml/g	≥4.3	4.82		-
NVR	Grade	≥B	A	IEST-RP-CC004.3 7.1.2	비색법 Grade : A > B > C
LPC	≥0.5㎛, ea/㎠	≤5.67 x 10^3	3.41 x 10^3	IEST-RP-CC004.3 6.1.3	Liquid Particle_ Orbital Shake Particle Channel_ 0.5~20㎛
Fiber	≥100㎛, ea/㎠	≤30	1.67	IEST-RP-CC004.3 6.2.2.2	-

KM is the Only Clean Products company to be ISO 9001:2008, 14001:2004, 13485:2003, and OHSAS 18001:2007 registered.

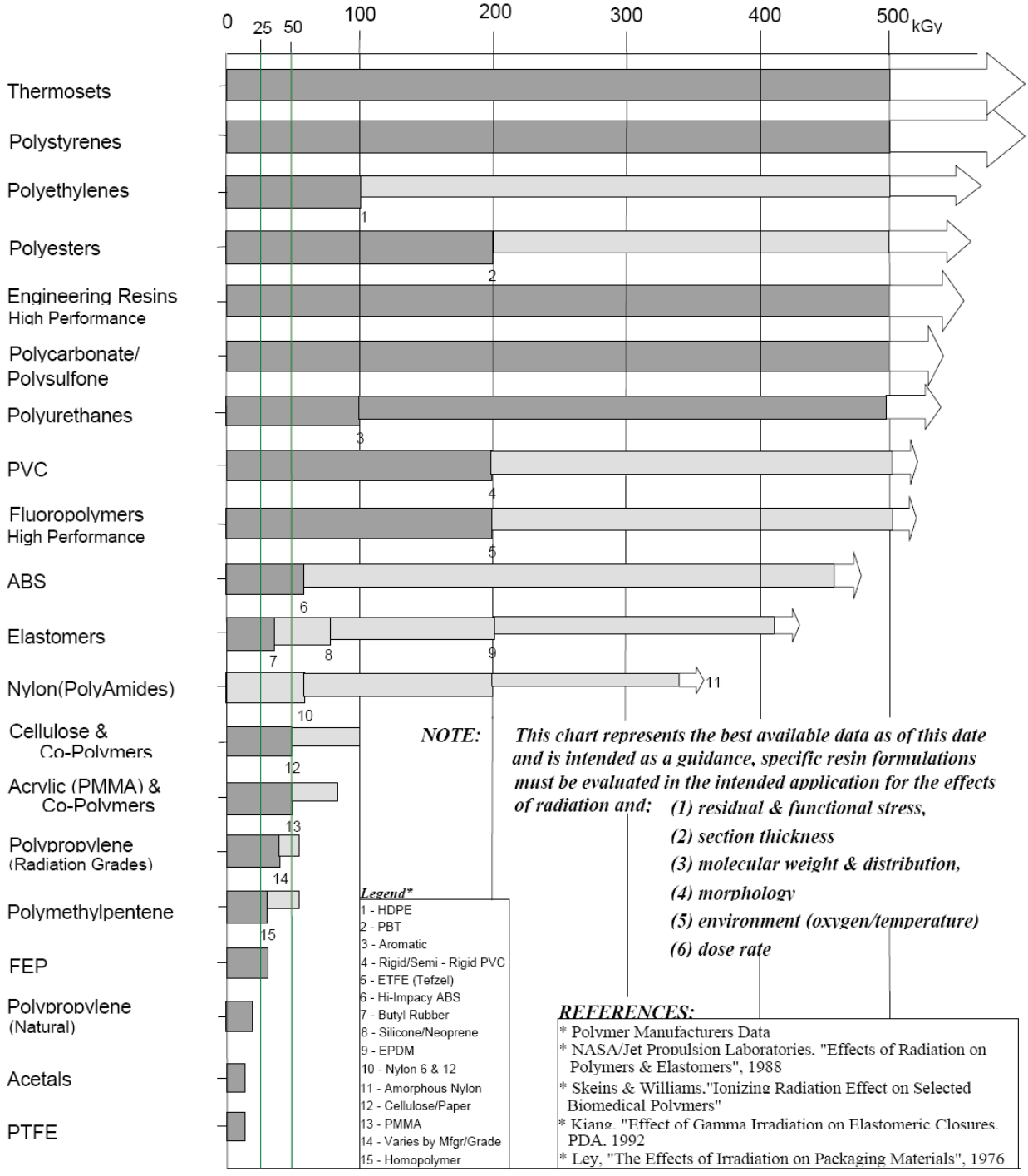
Attachment 2.

Guideline for selection of device

and packaging materials

Table 1 - Relative Radiation Stability of Medical Polymer "Families"

Dose (Kilogray) in Ambient Air at which Elongation Decreases by 25%

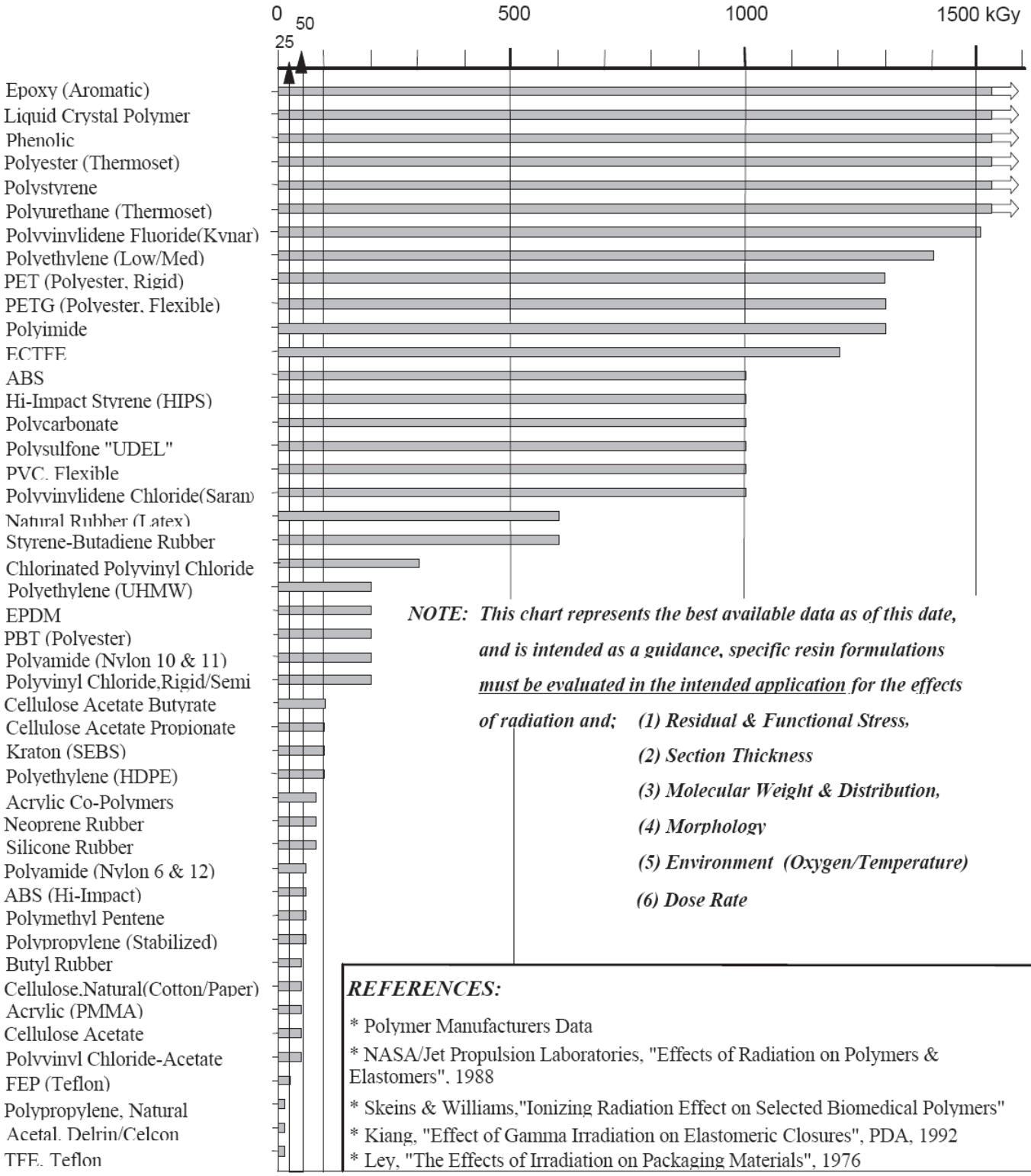


* - Within each family is a range of radiation stabilities, the "steps" are intended to show significant family members

Courtesy of Karl J. Hemmerich, Ageless ProcessingTechnologies

Table 2 - Relative Radiation Stability of Medical Polymers

Dose (KiloGray) in Ambient Air at Which Elongation Decreases by 25%



NOTE: ***This chart represents the best available data as of this date, and is intended as a guidance, specific resin formulations must be evaluated in the intended application for the effects of radiation and;***

(1) Residual & Functional Stress,

(2) Section Thickness

(3) Molecular Weight & Distribution,

(4) Morphology

(5) Environment (Oxygen/Temperature)

(6) Dose Rate

REFERENCES:

* Polymer Manufacturers Data
* NASA/Jet Propulsion Laboratories, "Effects of Radiation on Polymers & Elastomers", 1988
* Skeins & Williams,"Ionizing Radiation Effect on Selected Biomedical Polymers"
* Kiang, "Effect of Gamma Irradiation on Elastomeric Closures", PDA, 1992
* Ley, "The Effects of Irradiation on Packaging Materials", 1976

Courtesy of Karl J. Hemmerich, Ageless ProcessingTechnologies

Table 3—General guide to radiation stability of materials

MATERIALS	RADIATION STABILITY	COMMENTS
Thermoplastics		
ABS	Good	High impact grades are not as radiation resistant as standard impact grades.
Acrylics (PMMA)	Fair–Good	
Cellulosics		Esters degrade less than does cellulose.
Esters	Fair	
Cellulose acetate propionate	Fair	
Cellulose acetate butyrate	Good–Fair	
Cellulose, paper, cardboard	Fair–Good	
Fluoropolymers		When irradiated, PTFE and PFA are significantly damaged. The others show better stability. Some are excellent.
Polytetrafluoroethylene (PTFE)	Poor	
Perfluoro Alkoxy (PFA)	Poor	
Polychlorotrifluoroethylene (PCTFE)	Good–Excellent	
Polyinyl fluoride (PVF)	Good–Excellent	
Polyvinylidene fluoride (PVDF)	Good–Excellent	
Ethylene-Tetrafluoroethylene (ETFE)	Good	
Fluorinated ethylene propylene (FEP)	Fair	
Liquid Crystal Polymer (LCP)	Excellent	Commercial LCPs; Natural LCPs not stable.
Polyacetals	Poor	Irradiation causes embrittlement. Color changes have been noted (yellow to green).
Polyamides (Nylon)	Good	Nylon 10,11,12,6-6, more stable than 6. Nylon film and fiber are less resistant.
Polycarbonate	Good–Excellent	Yellows—mechanical properties not greatly affected; color-corrected radiation formulations are available.
Polyesters	Good–Excellent	PBT not as radiation stable as PET resins.
Polyethylene, various density	Good–Excellent	HD not as stable as MD and LD.
Polyimides	Excellent	
Polyphenylene sulfide	Excellent	
Polypropylene, natural Polypropylene, stabilized	Poor–Fair	Physical properties greatly reduced when irradiated. Radiation stabilized grades, utilizing high Mw and co-polymerized and alloyed with polyethylene, should be used in most radiation applications; High dose rate electron beam may reduce oxidative degradation.
Polystyrene	Excellent	
Polysulfone	Excellent	Natural material is yellow.
Polyurethane	Excellent–Good	Aromatic discolors; polyesters more stable than esters. Retains physical properties.
Polyvinylchloride (PVC)	Good	Yellows—antioxidants and stabilizers prevent yellowing. High molecular weight organotin stabilizers improve radiation stability: color-corrected radiation formulations available.
Polyvinylchloride-Polyvinylacetate	Good	Less resistant than PVC.
Polyvinylidene dichloride (Saran)	Good	Less resistant than PVC.
Styrene/Acrylonitrile (SAN)	Good–Excellent	

Table 3—General guide to radiation stability of materials (continued)

MATERIALS	RADIATION STABILITY	COMMENTS
Elastomers		
Butyl	Poor	Friable, sheds particulate.
Chlorosulfonated polyethylene	Poor	
EPDM	Excellent	
Natural rubber	Good–Excellent	
Nitrile	Good–Excellent	Discolors.
Polyacrylic	Poor	
Polychloroprene (neoprene)	Good	Discolors; the addition of aromatic plasticizers renders the material more stable to irradiation.
Silicone	Good	Phenyl-methyl silicones are more stable than are methyl silicones. Platinum cured silicones are superior to peroxide cured silicones. Full cure during manufacture can eliminate most post-irradiation effects.
Styrene-butadiene	Good	
Urethane	Excellent	
Thermosets		
Allyl diglycol carbonate (Polyester)	Excellent	Maintains its excellent optical properties after irradiation.
Epoxies	Excellent	All curing systems.
Phenolics	Excellent	Includes the addition of mineral fillers.
Polyesters	Excellent	Includes the addition of mineral or glass fibers.
Polyurethanes Aliphatic Aromatic	 Excellent Good–Excellent	 Darkening can occur. Possible breakdown products could be derived.

Primary source: INTERNATIONAL ATOMIC ENERGY AGENCY. *Guidelines for industrial radiation sterilization of disposable medical products, Co 60 gamma irradiation.* TEC DOC-539. Vienna: IAEA, 1990.

Attachment 3.

Bioburden test report

*Test Report for Sterility & Growth Promotion of Culture Media
*Validation of technique for removal of microorganisms by product inoculation method

Registered Documentation

Bioburden Test Report

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-ri, Hyangnam-eup, Hwaseong-si,
Gyeonggi-do, KOREA
TEL : 031-353-6999
FAX : 031-353-6979
http://www.soyagreentec.co.kr

Report No	:	SOYA1234
Test Site	:	Laboratory room
Product Name	:	KM-6612L
Lot No	:	HH-20, HH-14, HH-04
Test Period	:	Nov. 05. 2012. ~ Nov. 12. 2012.

Technology for better life!
SOYAGREENTEC

(Attachment 1)

Technology for better life!
SOYAGREENTEC
900-3, Sangsin-ri, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, KOREA,
TEL: (031)353-6999(代) FAX: (031)353-6979

Bioburden Test Report

Report No. : SOYA1234

1. Information

업 체 명 (Customer)	: KM CORPORATION
주 소 (Address)	: 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea
제 품 명 (Products)	: KM-6612L
제품제조번호 (Products batch No.)	: HH-20, HH-14, HH-04

시 험 방 법 (Test method)	: ISO 11737-1 / Membrane filter
총 시 료 수 (Total test sample size)	: 30 ea
실 험 환 경 (Laboratory condition)	: 온도(temperature) 25 ℃/습도(humidity) 50 %
배 지 (Media)	: Tryptic Soy Agar
배 양 온 도 (Incubation temperature)	: 32.5 ℃
배 양 기 간 (Incubation)	: 7 Day 168 Hour
시 험 기 간 (Test period)	: Nov. 05. 2012. ~ Nov. 12. 2012.

2. Result

Test Item	Unit	Result	Test Method
Bioburden Estimation	C.F.U / Unit	**9.72**	ISO 11737-1

*첨 부. (Attach.) : Pre-sterilization count report, Final report
*용 도. (Usage.) : 품질관리용 (Quality control)
*비 고. (Note.) :
1. 이 시험성적서는 용도 이외의 사용을 금함.
(This test report shall be used with in the purpose of its defined usage.)
2. 상기 내용을 의뢰자가 제공한 시료에 대한 결과이며, 시료명은 의뢰자가 제시한 것임.
(The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.)

Nov. 12. 2012.

*시험자 Testing Personnel
Sim Hyunchul

*승인자 Approval Staff
Park Jaejung

(Attachment 1)

Pre-sterilization Count Report

업 체 명 (Customer)	: KM CORPORATION
제 품 명 (Products)	: KM-6612L
제품제조번호 (Products batch No.)	: HH-20, HH-14, HH-04
시 험 방 법 (Test method)	: ISO 11737-1
접 종 방 법 (Transfer to culture medium)	: Membrane filter
전 처 리 (Sample treatment)	: Pre-sterilization (비멸균)
완 충 제 (Eluent)	: Sodium Chloride Peptone Broth [pH 7.0±0.2]
배 지 (Media)	: Tryptic Soy Agar
배 양 온 도 (Incubation temperature)	: 32.5 ℃
배 양 기 간 (Incubation)	: 7 Day 168 Hour
시 험 기 간 (Test period)	: Nov. 05. 2012. ~ Nov. 12. 2012.

호기성 세균 계수 (Nonselective Aerobic Count)

Products Batch No. →	HH-20		HH-14		HH-04	
시 료 번 호 (Sample No.)	결 과 (Recovered CFU/Unit)	비 고 (Remark)	결 과 (Recovered CFU/Unit)	비 고 (Remark)	결 과 (Recovered CFU/Unit)	비 고 (Remark)
1.	3		2		6	
2.	5		5		8	
3.	13		5		6	
4.	4		1		10	
5.	8		11		7	
6.	7		1		5	
7.	2		7		5	
8.	4		7		12	
9.	8		5		8	
10.	3		5		7	
합 계 (Sum)	57		49		74	
평 균 (Average)	5.7		4.9		7.4	

*가능하다면 첨부가능. *(Photo of micro-organisms)*

(Attachment 1)

Final Report

*Bioburden Estimation determination			
*SIP Bioburden Results			SIP : 1
Batch No.	HH-20	HH-14	HH-04
Amount countable colony	57 CFU	49 CFU	74 CFU
Average Of Batch	5.7 CFU	4.9 CFU	7.4 CFU
Average Recovery (% Removal)	61.8 %		
Recovery Multiplication Factor (RMF)	1.62		
Adjusted average by RMF	9.23 CFU	7.94 CFU	11.99 CFU
Overall Average SIP Bioburden	9.72	CFU	
Highest SIP Bioburden Batch	11.99	CFU (Batch : HJ-04)	
SIP Bioburden Estimation	9.72	CFU/SIP	
*Bioburden Estimation			
Batch 1 : HH-20	9.23	CFU/Unit	
Batch 2 : HH-14	7.94	CFU/Unit	
Batch 3 : HH-04	11.99	CFU/Unit	
Overall Batch Average (OBA)	9.72	CFU/Unit	
Highest Bioburden Batch	11.99	CFU (Batch : HJ-04)	
Bioburden Estimation	9.72	CFU/Unit	

*용 도. (Usage.) : 품질관리용 (Quality control)
*비 고. (Note.) :
1. 이 시험성적서는 용도 이외의 사용을 금함.
(This test report shall be used with in the purpose of its defined usage.)
2. 상기 내용을 의뢰자가 제공한 시료에 대한 결과이며, 시료명은 의뢰자가 제시한 것임.
(The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.)

Nov. 12. 2012.

*시험자 Testing Personnel
Sim Hyunchul

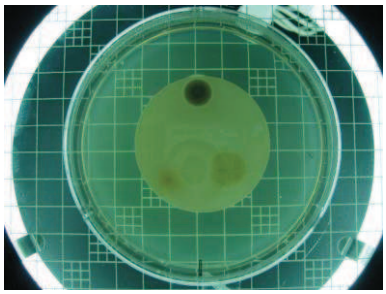
*승인자 Approval Staff
Park Jaejung

(Attachment 1)

Pictures of Bioburden test result

Nonselective Aerobic Bacteria

Lot No. : HH-20



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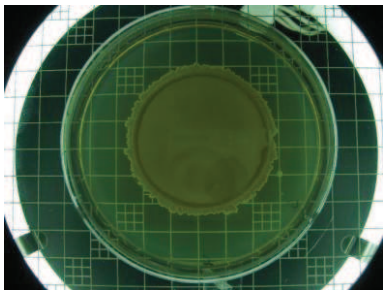

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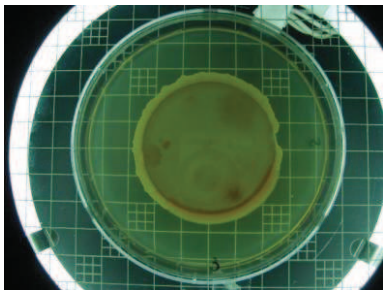

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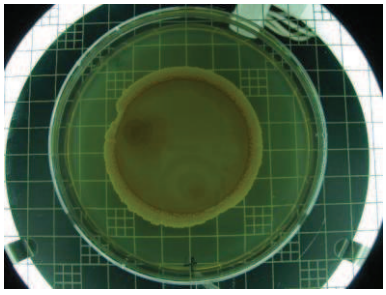

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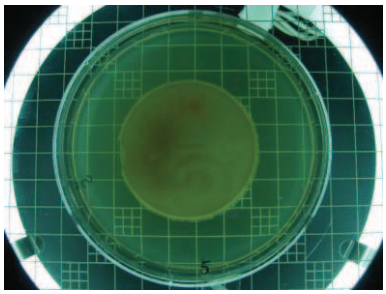

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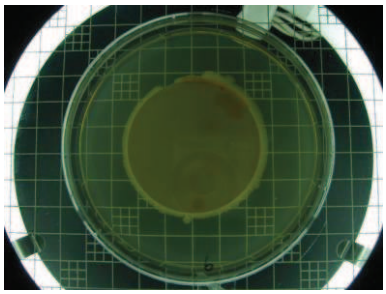

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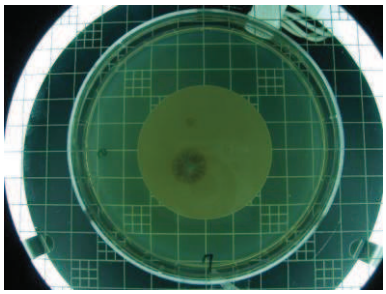

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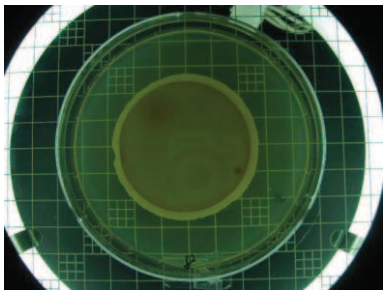

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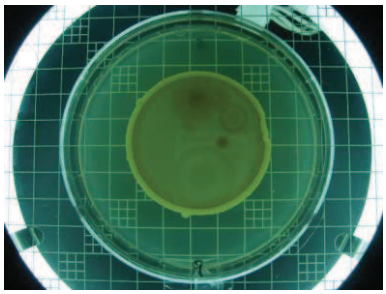

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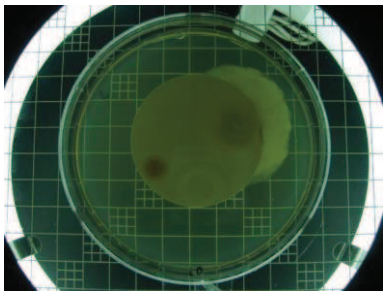


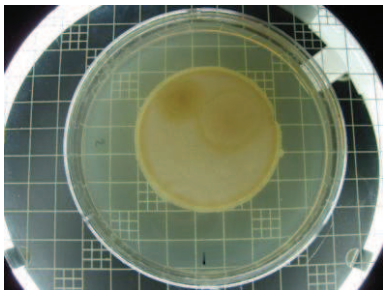
10

(Attachment 1)

Pictures of Bioburden test result

Nonselective Aerobic Bacteria

Lot No. : HH-14



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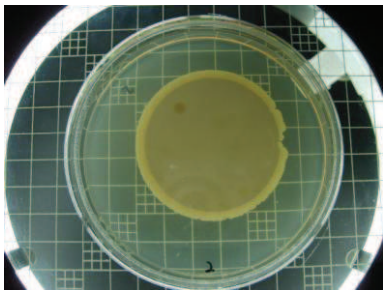

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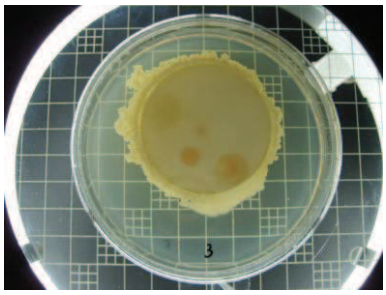

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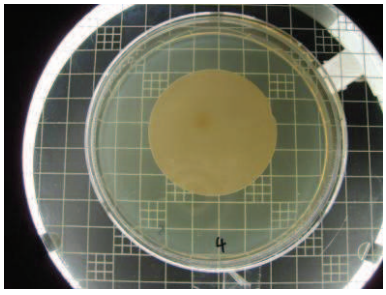

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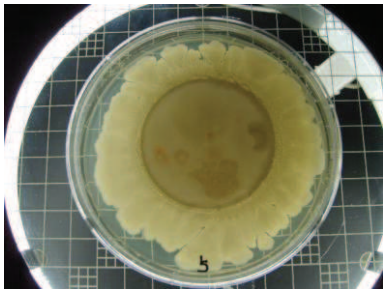

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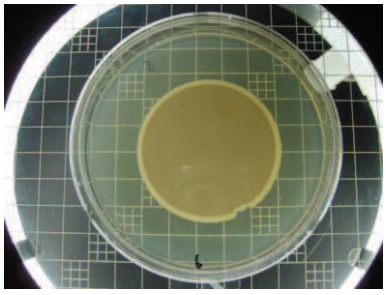

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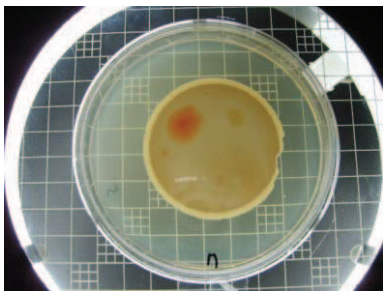

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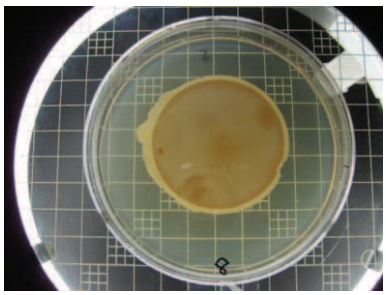

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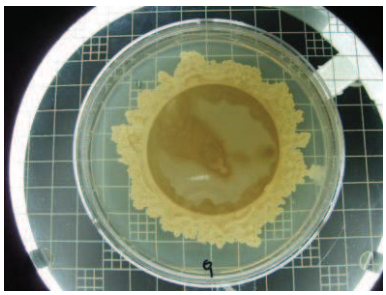

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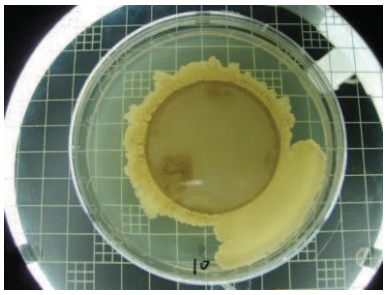


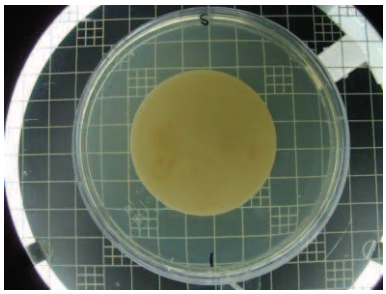
10

(Attachment 1)

Pictures of Bioburden test result

Nonselective Aerobic Bacteria

Lot No. : HH-04



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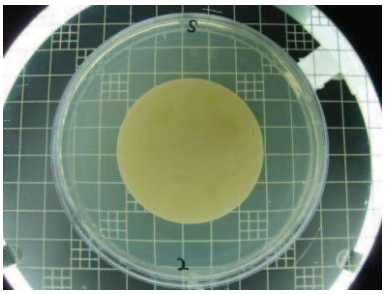

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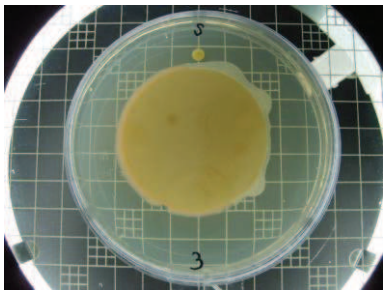

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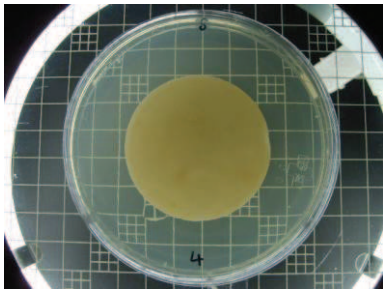

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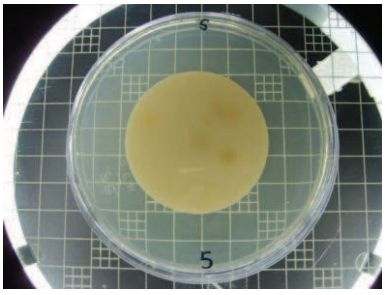

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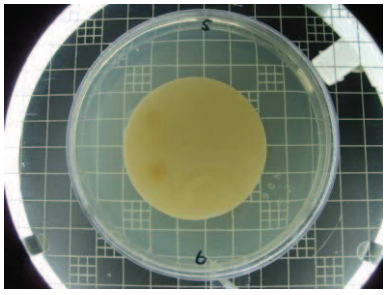

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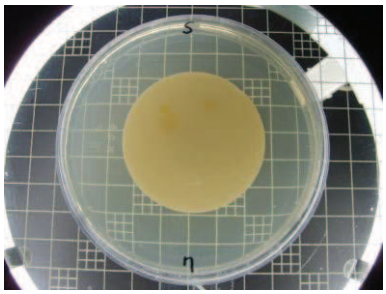

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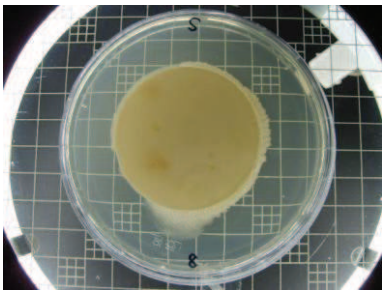

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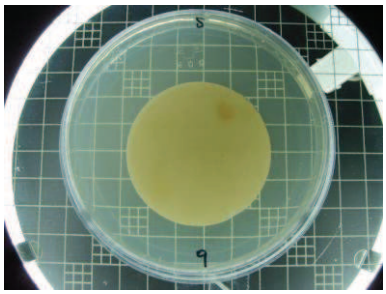

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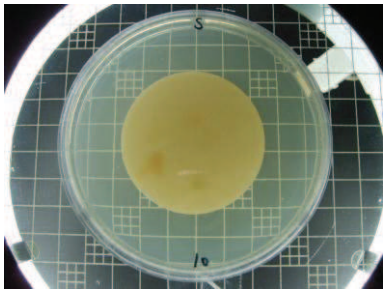


10

(Attachment 3)

미생물 제거법 유효성 확인

Validation of technique for removal of microorganisms by product inoculation method

업 체 명 (Customer)	: KM CORPORATION
제 품 명 (Products)	: KM-6612L
제 품 제 조 번 호 (Products batch No.)	: HH-20
시 험 방 법 (Test method)	: ISO 11737-1
총 시 료 수 (Total test sample size)	: 5 ea
시 험 기 간 (Test period)	: Nov. 05. 2012. ~ Nov. 12. 2012.

처리 횟수 Treatment	반복 계수 Replicate Count										평균 콜로니 계수 Mean colony count
	1	2	3	4	5	6	7	8	9	10	
접종 균수 (Inoculated Microorganism)	100	100	100	100	100	–	–	–	–	–	-
초기 균수 (Initial Microorganism)	59	62	66	57	65	–	–	–	–	–	-
회수율(%) (Recovery rate)	59	62	66	57	65	–	–	–	–	–	–
평균회수율 (Average recovery rate)	61.8 %										회수율범위 (Recovery rate range) (68~ 79 %)
Correction factors	100 (Inoculated Microorganism) ÷ 61.8 (Average recovery rate) = **1.62** (Correction factors)										

- Eluent : Sodium Chloride Peptone Broth(Buffered), [pH 7.0±0.2 at 25℃]
- Transfer to culture medium : Removal of Microorganisms (미생물 제거법)
- Media & Incubation conditions : Difco™ Tryptic Soya Agar pH 7.3±0.2
- Laboratory condition : 25℃ / 50%
- Inoculation spores : Bacillus pumilus

*첨 부. (Attach.) : –
*용 도. (Usage.) : 품질관리용 (Quality control)
*비 고. (Note.) :
1. 이 시험성적서는 용도 이외의 사용을 금함.
(This test report shall be used with in the purpose of its defined usage.)
2. 상기 내용을 의뢰자가 제공한 시료에 대한 결과이며, 시료명은 의뢰자가 제시한 것임.
(The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.)

Nov. 12. 2012.

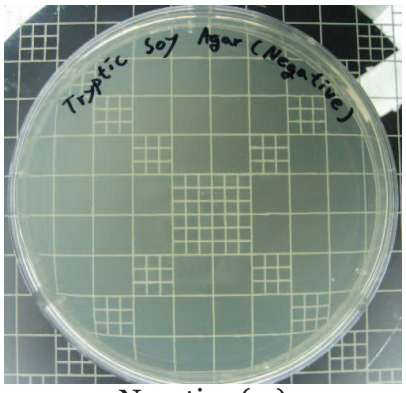
*시험자 Testing Personnel
Sim Hyunchul

*승인자 Approval Staff
Park Jaejung

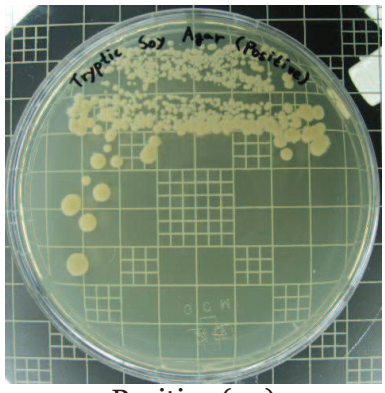
(첨부양식 2)

Test Report for Sterility & Growth Promotion of Culture Media

배 지 명 (Media)	: Tryptic Soy Agar
제 조 사 (Manufacturer)	: BD
제조번호 (Batch No)	: 1227460
시험방법 (Test method)	: ISO 11737-1:2006 / Direct
실험환경 (Laboratory condition)	: temperature 20.4 ℃, humidity 32.7 %
배양조건 (Incubation condition)	: 32.5 ℃, 5 days(120 hour)
배양시간 (Incubation time)	: 2012. 10. 05. ~ 2012. 10. 10.



Negative (-)



Positive (+)

*Test Method

(A) Sterility Test of Media	사용한 배지가 오염되었는지 확인한다. Ensure that contaminated a sterile medium(Negative medium)
(B) Growth Promotion Test of Media	배지에 균주*(Candida albicans)*를 접종한다. Inoculate with colony*(Candida albicans)* in the medium.

*Result

(A) Sterility Test of Media	Negative (음성-)
(B) Growth Promotion Test of Media	Positive (양성+)
→ Tryptic Soy Agar는 미생물이 생장 할 수 있는 배지이며, 고압증기멸균(121℃, 15분)도 성공적으로 수행되었다. Tryptic Soy Agar is the microorganisms can grow and it has been sterilized(121℃, 15 Minute) very well.	

Oct. 10. 2012.

*시험자 Testing Personnel
이 상 수 (서 명)

*승인자 Approval Staff
박 재 정 (서 명)

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE TRYPTIC SOY AGAR 500G
Catalog Number : 236950 **Manufacture Date :** 2011/07/21
Batch Number : 1227460
Expiration Date : 2016/04/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 4.0% solution, soluble in distilled or deionized water on boiling
03. Solution Appearance: Light amber, slightly to moderately opalescent
04. Plate Appearance: Clear to slightly opalescent, without precipitate
05. CAMP Test: Streptococcus agalactiae ATCC® 12386 gave a + reaction and Streptococcus pyogenes ATCC® 19615 gave a - reaction when tested with Staphylococcus aureus ATCC® 33862.
06. USP/EP/JP Growth Promotion test performance specification where applicable.

TEST ORGANISMS	ATCC®	INOC	RECOVERY	TEMP	INCUBATION
Aspergillus niger	16404	<100 CFUs	growth	30-35˚C	Up to 5 days
Bacillus subtilis	6633	<100 CFUs	growth	30-35˚C	Up to 3 days
Candida albicans	10231	<100 CFUs	growth	30-35˚C	Up to 5 days
Escherichia coli	8739	<100 CFUs	growth	30-35˚C	Up to 3 days
Pseudomonas aeruginosa	9027	<100 CFUs	growth	30-35˚C	Up to 3 days
Salmonella typhimurium	14028	<100 CFUs	growth	30-35˚C	Up to 3 days
Staphylococcus aureus	6538	<100 CFUs	growth	30-35˚C	Up to 3 days

07. Cultural Response: Medium was prepared per label instructions. Plates with and without 5% sheep blood (SB) were inoculated with the test organisms and incubated under 5-10% CO2 at 35 ± 2˚C for 18-48 hours.

TEST ORGANISMS	ATCC®	RECOVERY		HEMOLYSIS
		PLAIN	w/SB	
Escherichia coli	25922	good	good	beta
Neisseria meningitidis	13090	good	good	none
Staphylococcus aureus	25923	good	good	beta
Streptococcus pneumoniae	6305	good	good	alpha
Streptococcus pyogenes	19615	good	good	beta

08. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Agar indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	LowLimit	HighLimit
pH at 25˚C :		7.3	7.1	7.5
Bulk Lot Number :	-	1193929		

Creation Date: 2011/09/02 16:27:44

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE TRYPTIC SOY AGAR 500G
Catalog Number : 236950 **Manufacture Date** : 2011/07/21
Batch Number : 1227460
Expiration Date : 2016/04/30

Animal Source	Country of Origin	Tissue Category BIC	SIC	ABC
Porcine	USA	III	III	IB
Bovine	New Zealand	IV	IV	MLK
Porcine	Canada	III	III	IB

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2008 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.

At the time the BDDS Certificate of Analysis is created and sent to the Internet website address at http://www.bd.com/regdocs/, the animal origin information as provided to BDDS by its suppliers is pulled into the certificate as it is created by the BDDS automated certificate system.

At times, suppliers notify BDDS of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BDDS. When this situation occurs, BDDS updates the animal origin information in the automated certificate system, recreates the affected finished product COAs for batches within expiration date, and sends them to the Internet website where they replace the prior certificate and are immediately available to customers.

Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name	: BOTTLE TRYPTIC SOY AGAR 500G		
Catalog Number	: 236950	**Manufacture Date :**	2011/07/21
Batch Number	: 1227460		
Expiration Date	: 2016/04/30		

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at http://www.bd.com/regdocs/.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2011/09/02

Attachment 4.

Gamma Irradiation for verification experiment

(Gamma Irradiation for Verification Experiment)

Validation report for application of verification doses during microbiological dose setting exercises

▷ Summary

SO 11137-2 is described in the Method VDmax^{25} test dose of the product in a very low dose is required to investigate the correct dose. The sample survey of the additional equipment attached to the Research Loop (test container) using a low area to investigate the dose accurately.

Research Loop, and the product of the research path has a separate Timer and a small amount of product for the correct dose can be investigated.

▷ Procedures and methods

Research Loop container products in 10(ea) in the form of a fixed loading dose of maximum and minimum load and are expected to absorb part of the designated locations, including products that are irradiated by attaching Dosimeter.

After a certain time has elapsed spin product Dose uniformity of the product will improve. 1 hour intervals by the crew of the incident direction and then rotated 90 ° each product will rotate every 30 minutes.

After investigating a number of products that are attached to the Dosimeter will assess and record dose.

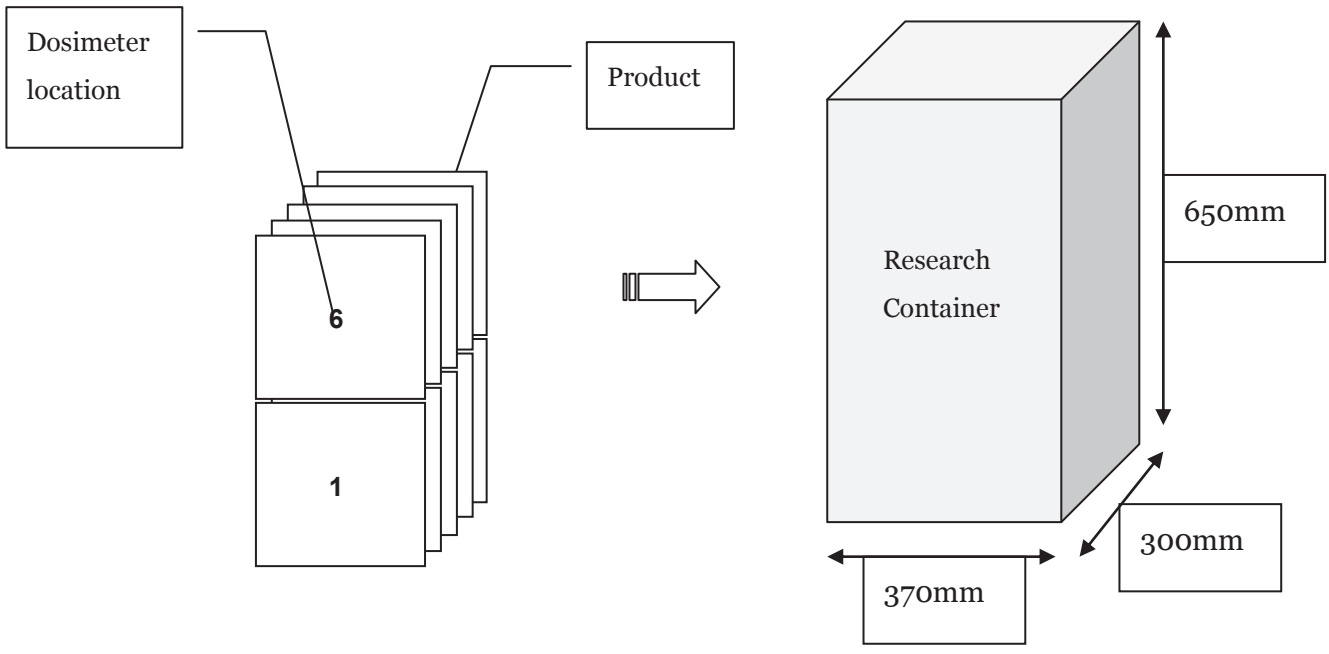
▷ Verification dose acceptance criteria

The highest dose to the measured dose may not exceed VDmax^{25} by more than 10%. If the arithmetic mean of the highest and lowest doses of measured doses is < 90% of VDmax^{25}, the verification dose experiment may be repeated. If this mean dose is < 90% of VDmax^{25} and, on performance of the test of sterility, acceptable results are observed, the verification experiment need not be repeated.

Research Loading Pattern & Dosimeter Readings

Customer	: KM CORPORATION
Device Name	: KM-6612L
Batch No.	: HH-04
Quantity	: Total 10 unit
Total Weight	: 1,752 g
Density	: 0.024 g/cm^3
Verification dose	: 7.1 kGy
Dose Range Specification	: 6.39 kGy ~ 7.81 kGy
Dosimeter	: Amber 3042 R
Exposure Time	: 08 hour 10 min
Exposure Date	: Nov. 26. 2012. ~ Nov. 27. 2012.

1. Loading pattern & Dosimeter locations



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2. Dosimeter Readings

Dosimeter position	ABS (Absorbance)	Thickness (cm)	ABS/cm	Dose(kGy)
1	0.826	0.297	2.78	7.26
2	0.840	0.302	2.78	7.26
3	0.925	0.334	2.77	7.23
4	0.872	0.316	2.76	7.20
5	0.789	0.285	2.77	7.23
6	0.862	0.309	2.79	7.29
7	0.865	0.311	2.78	7.26
8	0.908	0.329	2.76	7.20
9	0.945	0.340	2.78	7.26
10	0.848	0.305	2.78	7.26
-				

3. Dosimetry Results

Minimum Dose reading : **7.20** kGy

Maximum Dose reading : **7.29** kGy

*Signatures

Tested By  Date : Nov. 27. 2012.

Sim Hyunchul / Validation Team

Approved By  Date : Nov. 27. 2012.

Park Jaejung / Validation Team

Attachment 5.

Sterility test report

*Test Report for Sterility & Growth Promotion of Culture Media

* Bacteriostasis & Fungistasis Test Report

Registered Documentation

Sterility Test Report

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-ri, Hyangnam-eup, Hwaseong-si,
Gyeonggi-do, KOREA
TEL : 031-353-6999
FAX : 031-353-6979
http://www.soyagreentec.co.kr

Report No	:	SOYA1234
Test Site	:	Laboratory room
Product Name	:	KM-6612L
Lot No	:	HH-04
Test Period	:	Nov. 28. 2012. ~ Dec. 12. 2012.

Technology for better life!
SOYAGREENTEC

(Attachment 1)

Technology for better life!
SOYAGREENTEC
900-3, Sangsin-ri, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, KOREA,
TEL: (031)353-6999(代) FAX: (031)353-6979

Sterility Test Report

Report No. : SOYA1234

1. Information

업 체 명 (Customer)	: KM CORPORATION
주 소 (Address)	: 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea
제 품 명 (Products)	: KM-6612L
제품제조번호 (Products batch No.)	: HH-04

시 험 방 법 (Test method)	:ISO 11737-2:2007 / Direct method
총 시 료 수 (Total test sample size)	: 10 ea
실 험 환 경 (Laboratory condition)	: 온도(temperature) 25 ℃/습도(humidity) 50 %
배 지 (Media)	: Tryptic Soy Broth [Soybean-Casein Digest Medium]
배 양 온 도 (Incubation temperature)	: 32.5 ℃
배 양 기 간 (Incubation)	: 14 Day 336 Hour
시 험 기 간 (Test period)	: Nov. 28. 2012. ~ Dec. 12. 2012.

2. Result

Test Item	Positive(+)	Negative(-)
무 균 성 (Sterility)	0 unit	10 unit

*첨 부. (Attach.) : Sterilization count report
*용 도. (Usage.) : 품질관리용 (Quality control)
*비 고. (Note.) :
1. 이 시험성적서는 용도 이외의 사용을 금함.
(This test report shall be used with in the purpose of its defined usage.)
2. 상기 내용을 의뢰자가 제공한 시료에 대한 결과이며, 시료명은 의뢰자가 제시한 것임.
(The results have been made for the sample presented by the client, and it is the decision of the client naming the presented sample.)

Dec. 12. 2012

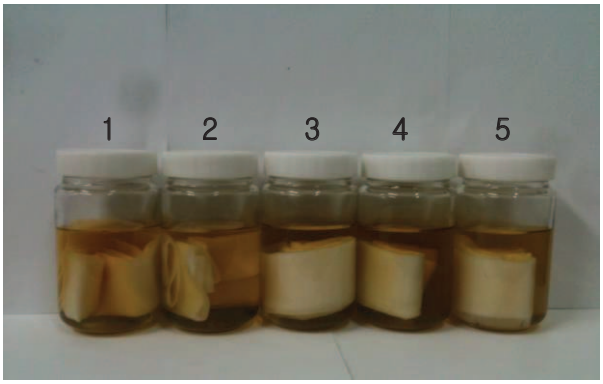
*시험자 Testing Personnel
Sim Hyunchul

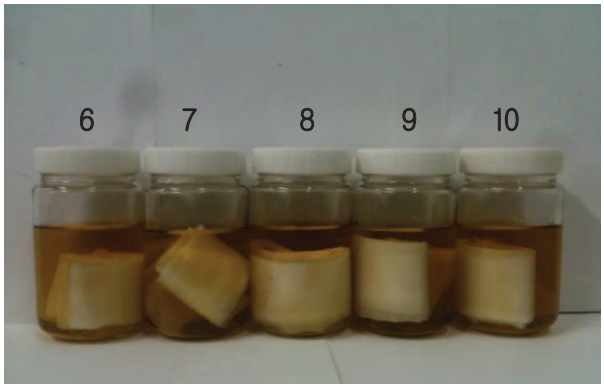
*승인자 Approval Staff
Park Jaejung

(Attachment 1)

Sterilization Count Report

Test Media	No.	Result	No.	Result
Tryptic Soy Broth	1.	Negative (-)	6.	Negative (-)
	2.	Negative (-)	7.	Negative (-)
	3.	Negative (-)	8.	Negative (-)
	4.	Negative (-)	9.	Negative (-)
	5.	Negative (-)	10.	Negative (-)





Positive (+) assessment : 00 ea

Negative (–) assessment : 10 ea

*가능하다면 첨부가능. *(Photo of micro-organisms)*

(Attachment 3)

Bacteriostasis & Fungistasis Test Report

1. Information

시 험 방 법 (Test method)	: ISO 11737-2:2007 / Direct method
제 품 명 (Products)	: KM-6612L
제품제조번호 (Products batch No.)	: HH-04
총 시 료 수 (Total test sample size)	: 3 ea
실 험 환 경 (Laboratory condition)	: 온도(temperature) 25 ℃/습도(humidity) 50 %
배 지 (Media)	: Tryptic Soy Broth [Soybean-Casein Digest Medium]
배 양 온 도 (Incubation temperature)	: 32.5 ℃
배 양 기 간 (Incubation)	: 7 Day 168 Hour
시 험 기 간 (Test period)	: Nov. 28. 2012. ~ Dec. 05. 2012.

2. Result

시 험 균 주 (Test Microorganisms)		Inoculation amount	Culturing	Sample medium	Control group medium	Decision
				A	B	
1	*Bacilus atrophaeus*	10~100cfu	32.5℃	G	G	No inhibiting material
2	*Candida albicans (ATCC10231)*	10~100cfu	32.5℃	G	G	No inhibiting material
3	*Aspergillus niger (ATCC16404)*	10~100cfu	32.5℃	G	G	No inhibiting material

G = Growth, N/G = Not Growth

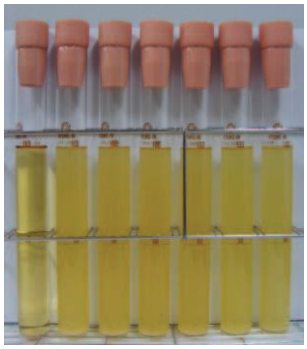
Dec. 05. 2012.

*시험자 Testing Personnel
Sim Hyunchul

*승인자 Approval Staff
Park Jaejung

Media performance test documentation
(배지성능시험 기록서)

Media (배지명)	: Tryptic Soy Broth (대두카제인소화액체배지)		
Test Method (시험방법)	: The Korean Pharmacopoeia : Sterility test / ISO 11737-2:2009 / Direct		
Manufacturer (제조사)	BD	Batch No. (제조번호)	0286473
Manufacture date (제조일자)	2010.09.23.	Effective date (유효일자)	2015.09.30.
Purchase date (구입일자)	2011.08.17.	Open(Test)Date (개봉시험일자)	2012.10.05.
Incubation terms and incubation time (배양조건 및 배양시간)		**22.5℃, 5days** (2012.10.05. ~ 2012.10.10.)	

Microorganism (균주)	Test Standards (시험기준)	Results (결과)	Results photo (결과사진)
Negative control	No Growth	No Growth	
Bacillus subtilis ATCC 6633	Growth	Growth	
Candida albicans ATCC 10231	Growth	Growth	
Aspergillus niger ATCC 16404	Growth	Growth	
Remarks (비고)			

Result **(결과)**	**Result Date** **(결과일자)**	**Experimenter** **(시험자)**	**Checker** **(확인자)**
O.K.	2012.10.10.		

SOYAGREENTEC Co., Ltd

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE BACTO TSB CASEIN MED 500G
Catalog Number : 211825 **Manufacture Date :** 2010/09/23
Batch Number : 0286473
Expiration Date : 2015/09/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 3% solution, soluble in distilled or deionized water
03. Solution Appearance: Light amber, clear
04. Medium was tested per European (EP) and United States Pharmacopeia (USP) Growth Promotion requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for (*) organisms and gave cultural responses as indicated.

TEST ORGANISMS	ATCC®	RECOVERY	TEMPERATURE	INCUBATION
*Asperigillus brasiliensis	16404	growth	20-25˚C	Up to 5 days
Bacillus subtilis	6633	growth	30-35˚C,20-25˚C	Up to 3 days
*Candida albicans	10231	growth	20-25˚C	Up to 5 days
Escherichia coli	8739	growth	30-35˚C	Up to 3 days
Pseudomonas aeruginosa	9027	growth	30-35˚C	Up to 3 days
Salmonella typhimurium	14028	growth	30-35˚C	Up to 3 days
Staphylococcus aureus	6538	growth	30-35˚C	Up to 3 days

05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at the temperatures specified for 18-48 hours, or up to 72 hours if necessary.

TEST ORGANISMS	ATCC®	TEMPERATURE	RECOVERY
Neisseria meningitidis	13090	30-35˚C	fair to good
Staphylococcus epidermidis	12228	30-35˚C	good
Streptococcus pneumoniae	6305	30-35˚C	good
Streptococcus pyogenes	19615	30-35˚C	good

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Broth indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	LowLimit	HighLimit
Loss on Drying :	%	1	0	5
pH at 25˚C :		7.4	7.1	7.5
Bulk Lot Number :	-	0258422		

Creation Date: 2010/11/02 16:02:36

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name : BOTTLE BACTO TSB CASEIN MED 500G
Catalog Number : 211825 **Manufacture Date :** 2010/09/23
Batch Number : 0286473
Expiration Date : 2015/09/30

Animal Source	Country of Origin	Tissue Category BIC	SIC	ABC
Porcine	USA	III	III	B
Bovine	Australia	IV	IV	C
Bovine	New Zealand	IV	IV	C
Porcine	Canada	III	III	B

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostic Systems (BDDS) is an ISO 13485:2003 and ISO 9001:2008 Registered facility. BDDS products are manufactured in facilities registered with the United States Food and Drug Administration (FDA), and are regulated by the FDA's Quality System Regulations (QSRs). This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release.

BD Diagnostic Systems' Certificates of Analysis (COA) typically are set up to contain animal origin information for finished products manufactured using materials of animal origin. The animal origin information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. This information is a compilation of animal origin data from the individual lots of raw materials used to manufacture the batch of BD Diagnostic Systems (BDDS) finished product for which the COA was created.

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Customers enrolled in BD Diagnostic Systems' Automated Change Notification Program will be notified of the changes described above.

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Certificate of Analysis

Product Name	: BOTTLE BACTO TSB CASEIN MED 500G		
Catalog Number	: 211825	**Manufacture Date :**	2010/09/23
Batch Number	: 0286473		
Expiration Date	: 2015/09/30		

For complete details refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", located on the Internet website address at http://www.bd.com/regdocs/.

John Gerlich
Vice President,
Quality Management and
Regulatory Compliance
Signature Date: 2010/11/02

Attachment 6.

Certificate

Item	Specification	Certified by
ISO9001: 2008	Service of Sterilization by irradiation	*TUV service
EN ISO13485:2003	Provision of Irradiation Service of Medical Devices	*TUV service
EN / ISO11137-1 : 2006	Sterilization of healthcare product- Requirement of validation and routine Control – Radiation sterilization	*TUV service
US FDA Registration	Contract Sterilizer	*US FDA Registration
Certificate of GMP	We hereby certify that the above manufacture complies with Korea Good Manufacturing Practices for the product(s) listed above.	*Korea Environment & Merchandise Testing Institute *Korea Food & Drug Administration
Ministry of Health, Labour and Welfare (JAPAN)	It is certified that the above manufacturer is certificated foreign medical device manufacturer pursuant to Article 13-3 of the Pharmaceutical Affairs Act.	* Ministry of Health, Labour and Welfare (JAPAN)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Asia Pacific TÜV SÜD Group

certifies that

Technology for better life!
SOYAGREENTEC

SOYAGREENTEC Co., Ltd.

900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si Gyeonggi-Do, 445-922, Korea

has established and applies
a Quality Management System for

Provision of Irradiation Service of Medical Devices
Design, Development, Production and Distribution of Sterile Blood Collection Tubes

An audit was performed, Report No. **20041555**

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled. The certificate is valid from **2011-03-01** until **2014-02-28**

Certificate Registration No. **TUV100 01 1501**

2011-03-28

Kim, Du IN

Certification Body
of TÜV SÜD Asia Pacific
TÜV SÜD Group

JAS-ANZ

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Accreditation by the Joint Accreditation System of Australia and New Zealand, URL www.jas-anz.org/register

ISO 9001

TÜV SÜD Korea Ltd. ● 12F, "KLI63" Bldg., #60, Yoido-Dong, Youngdeungpo-Gu ● 150-763 Seoul ● Korea

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q4N 11 01 50558 003

Holder of Certificate: **SOYAGREENTEC Co., Ltd.**
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do 445-922
REPUBLIC OF KOREA

Facility(ies):
SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup, Hwaseong-Si, Gyeonggi-Do
445-922, REPUBLIC OF KOREA

Certification Mark:

Scope of Certificate: **Provision of Gamma Sterilization of Medical Devices**

Applied Standard(s): **EN ISO 13485:2003/AC:2009**
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 74926742

Valid from: 2011-03-01
Valid until: 2013-02-28

Date, 2011-02-25

Hans-Heiner Junker

355065

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Supplement to Quality System Certificate Q4N 11 01 50558 003

issued by TÜV SÜD PRODUCT SERVICE GMBH on 2011-03-01

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do
445-922, KOREA

for the facility

SOYAGREENTEC Co., Ltd.
900-3, Sangsin-Ri, Hyangnam-Eup
Hwaseong-Si, Gyeonggi-Do
445-922, KOREA

The quality system certified as stated above additionally fulfills the applicable requirements of **EN / ISO 11137:2006 – Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices** - as documented in the audit report no. 74926742.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

This supplement is valid only together with the certificate stated above.

TÜV SÜD PRODUCT SERVICE GMBH
Certification Committee for Medical Devices

Munich, 2011-03-01

TÜV SÜD KOREA LTD. TÜV SÜD

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is a Notified Body (identification number 0123) according to Council Directive 93/42/ EEC concerning medical devices.

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

US FDA Registered (Contract Sterilizer)

Establishment Registration Database

Establishment Registration Name : *soya*

Establishment Name		Registration Number	Current Registration Yr
SOYA CO., LTD.	KOREA, REPUBLIC OF	3004525100	2012
• Bandage, Elastic			Contract Sterilizer
• Tape And Bandage, Adhesive			Contract Sterilizer
• Bone Grafting Material, Synthetic - OSTEON			Contract Sterilizer

New Search Back To Search Results

Establishment:
SOYA CO., LTD.
900-3 Sangsin-Ri
Hyangnam-Myun, Hwasung-Gun
Kyunggi-Do, KOREA, REPUBLIC OF
Registration Number: 3004525100
Status: Active
Date Of Registration Status: 2012

Owner/Operator:
SOYA CO., LTD.
900-3 Sangsin-Ri
Hyangnam-Myun, Hwasung-Gun
Kyunggi-Do, KOREA, REPUBLIC OF
Owner/Operator Number: 9062715

Official Correspondent:
John H Choi
PISCIUM INTERNATIONAL, INC.
779 Granite Ave.
Langhorne, PA 19047
Phone: 267-2109365

US Agent:
Peter
GQ America
300 Atwood St. Pittsburgh
Oakland, PA 15213
Phone: 412 5128802 Ext
Fax: 412 6873976
Email: Pittcmi@Hotmail.com

KEMTI-AA-100015

1315

의료기기 제조 및 품질관리기준 적합인정서

(Certificate of GMP)

▪ 업 소 명 (Name of Manufacture)

(주)소야그린텍

SOYAGREENTEC Co., Ltd.

▪ 소 재 지 (Address of Manufacture)

경기도 화성시 향남읍 상신리 900-3번지.

900-3 Sangsin-ri, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Korea.

▪ 대 표 자 명 (Representative of Manufacture)

박 윤 석(Yun Seok. Park,), 박 재 돈(Jae Done. Park,)

▪ 품 목 군 : 품 목 명 (붙임 참조)

(Name of Category : Name of Classification) (See attached list)

의료기기제조및품질관리기준에 적합함을 인정합니다.

We hereby certify that the above manufacture complies with Korea Good Manufacturing Practices for the product(s) listed above.

발행일자 (the Date of Issue) : 2010. 01. 14

유효기한 (the Date of Expiration) : 2013. 01. 13

식품의약품안전청장

Korea Food & Drug Administration

한국생활환경시험연구원장

Korea Environment & Merchandise Testing Institute

認定番号 BG10300069
Number of accreditation

医療機器 外国製造業者認定証

Accreditation certificate of foreign medical devicemanufacturer

氏名又は名称 Name(Name of corporation)	Soyagreentec Co.,Ltd.
製造所の名称 Name of the manufacturing establishment	Soyagreentec Co.,Ltd.
製造所の所在地 Location of the manufacturing establishment	900-3,Sangsin-Ri Hyangnam-Eup Hwaseong-Si Gyeonggi -Do,445-746,Korea
認定の区分 Accreditation categories	医療機器 滅菌医療機器(Sterile Medical devices)

薬事法第１３条の３の規定により認定された 医療機器外国製造業者であることを証明する。

It is certified that the above manufacturer is certificated foreign medical device manufacturer pursuant to Article 13-3 of the Pharmaceutical Affairs Act.

平成 24年　10月　12日
2012 Year　Month　Day

厚生労働大臣　三井　辨雄
Minister of Health, Labour and Welfare　Wakio Mitsui

有効期間　平成 24年　9月　6日から
Valid period From 2012 Year　Month　Day
平成 29年　9月　5日まで
until 2017 Year　Month　Day

5122477019030

Attachment 7.

Agreement for contract sterilization

Contract Protocol for Gamma Irradiation

This agreement between **KM CORPORATION**(hereinafter called "A")and **SOYAGREENTEC Co., Ltd.**(hereinafter called "B") on the gamma sterilization commissioned to an agreement about the following:

Article 1. General

"A" shall consign the Gamma Irradiation process for **Sterilized Non-Woven Wiper** of "A" to "B", and "B" shall deliver the irradiated product to "A" after the Gamma irradiation process.

Article 2. Package and Quality of Material

The package of product shall be packed suitable for the Gamma irradiation process, and the quality of the packaging material shall be radiation-resistant. "B" is not responsible for the related change(chemical and physical) of property of matter of the product.

Article 3. Method of Gamma Irradiation Process

Decision for the method of Gamma irradiation process shall follow the below :

1> Gamma irradiation conditions are as follows, "B" is responsibility for next condition.

a> Use to Irradiation source of Co^{-60}.

b> "A" is SAL should be 10^{-6}, "B"' is the correct action should proceed accordingly.

c> "A" always give Request for Gamma Irradiation to "B".

d> Specified Dose use to document(that required dose is written by "A").

2> "A" is responsibility for Product shelf life and product safety test

3> "A" and "B" shall label the mark for Gamma irradiated product on the outer carton by mutual agreement.

4> "A" takes charge of sterilization test to verify the quality of sterilization.

5> "B" may claim the damages to "A" in case that "A" distributes the product that is not processed by Gamma irradiation in the state of putting the mark or words for Gamma irradiation process on.

Article 4. Payment condition

Fee for irradiation service and payment terms follows separate price agreement.

Article 5. Warehousing and Deliver

"A" shall notice "B" of warehousing of goods at least 2 days prior to warehousing. Unless it is inevitable, "B" shall meet the requested deliver of "A", "A" takes charge of all

the transport charges.

Article 6. Force Majeure

Neither party shall hold the other responsible for any delay or failure of performance occasioned or caused by strikes, riots, fire, insurrection, the elements, embargoes, failure of carriers, inability to obtain materials or transportation facilities, act of God or of the public enemy, governmental tariffs or quotas, compliance with any law, regulation or other governmental or court order whether or not valid, or other causes beyond the reasonable control of the parties.

Article 7. Duration of agreement

This agreement shall be in full force and effect on the day of last signing of both parties, and remain to be valid for 12 months. If one of the parties wish to terminate or revise this agreement, give notice to the other party in writing 30 days before the expiry of this agreement. If not, this agreement automatically a continues to be valid another one(1) year.

Article 8. Cancellation of agreement and Claim damages

"A" and "B" may cancel the agreement by written notice if any one condition conforms to the following cases :

1> If the production of goods of "A" stopped for a certain long term of period so that it is judged to be impossible for "A" to resume working.

2> If "A" does not start doing the business or does not continue the business with "B" within 6months without any reasonable cause.

3> If "A" does the business with only a part of quantity of the products mentioned in the contract.

4> If "B" does not irradiate and deliver the products without meeting the request of "A"

5> If the other reasonable cause unable to fulfill the contract occurs.

6> "A" shall compensate "B" for the damage from the cancellation of contract caused by "A" within the term of the contract.

7> "B" shall compensate "A" for the damage for the clause 4.

Article 9. Arbitration

All disputes, controversies, or differences that may arise among the parties, out of or

in relation to this agreement, or for the breach thereof, shall be settled by the competent court for "A" and the arbitration shall be held in the competent court for "A".

Article 10. Miscellaneous

The other particulars which are not mentioned in this contract shall be decided by mutual agreement according to general practice.

In witness whereof, "A" and "B" have caused this Agreement to be signed by their duly authorized.

December 28, 2012

A : For : KM CORPORATION
Address : 348-1, Boche, Miyang, Anseong, Gyeonggi, Korea
President : Byung Soon Shin

B : For : SOYAGREENTEC Co., Ltd.
Address : 900-3, Sangsin-ri, Hyangnam-eup, Hwasung-si, Gyeonggi-do, Korea
President : Jae Don Park

Attachment 7.

JS-10000 Brochure

*Fig. 1: JS 10000 Lay out

*Fig. 2 : Factory Layout

*Fig. 3 : Source pass

*Fig. 4 : load and Unload area

*Fig. 5-1, 5-2 : “Tote” Irradiation container

*Fig. 5-3. Research Loop

*Fig. 6. Source and Source rack

The JS-10000 Hanging Tote Irradiator is the ultimate in flexibility and performance, providing an ideal solution in high-mix, high-volume environments where the focus is on getting the highest value of product out the door at the lowest cost.

JS-10000

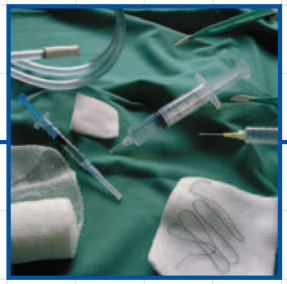
Hanging Tote Irradiator

Superior Performance on a Large Scale

MDS Nordion

JS-10000

Hanging Tote Irradiator



Gamma Processing Solutions from the Leader

MDS Nordion combines world-class capabilities in electro-mechanical design, controls, radiation physics, dosimetry and regulatory affairs with a global reach in sales, installation and service to lead the industry in delivering end-to-end solutions for our customers. The ultimate measure of our success is your success, which begins with an intimate understanding of your business, and ends in total customer satisfaction.

Superior Performance on a Large Scale

Using state-of-the-art controls technology, precision electric drives and a tote designed for maximum durability and minimum absorption, the **JS-10000** is the workhorse of industrial irradiators. Unsurpassed reliability and uptime mean more operating hours and better utilization of capital, a key performance measure whether you are a medical device manufacturer or contract service provider.

For the Way You Do Business

The Multi-Mode Operation (MMO) feature available on the **JS-10000** provides a selection of source pass product flows, allowing the operator to optimize production for different business environments, from high-volume where efficiency is paramount, to high-mix with frequent product changeovers and widely varying dose requirements, including difficult-to-process products with demanding dose uniformity specifications.

Information at Your Fingertips

The **JS-10000** employs Programmable Logic Control (PLC) and Supervisory Control And Data Acquisition (SCADA) technology for reliable and intuitive operation. The user interface provides real-time status of all irradiator components, including the integrated safety systems. Data logging and reporting is accomplished with a robust database, and network connectivity provides the option for remote diagnostics and troubleshooting.

A Passion for Safety

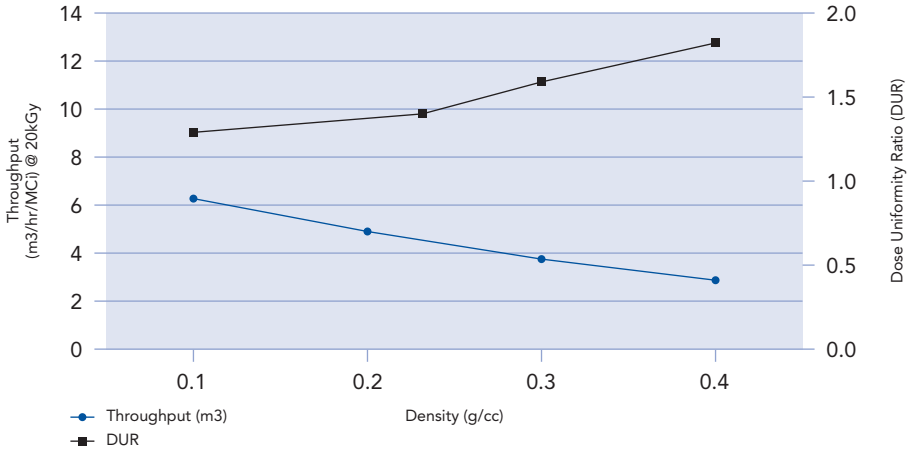
All of MDS Nordion's irradiators meet internationally recognized safety and security standards, such as 10 CFR Part 36, IAEA Safety Series 107 and ANSI 43.10. MDS Nordion's industry involvement and years of experience in regulatory affairs means you can be assured that our products incorporate the latest advancements in safety and security.

The Gamma Advantage

- High penetration for treatment of products with mated surfaces, thin lumens and higher densities, all in final packaging
- Scalable so that your throughput can grow when your business does
- Immediate product release through dosimetry gets product to your customer faster
- Robust and reliable technology that is easy to operate and maintain
- Safety and efficacy track record, sterilizing more than 40% of the world's single-use medical devices

Specifications	
Source Rack Capacity	5 MCi
Maximum Product Stack (L x W x H)	24 in. x 41 in. x 72 in. (610 mm x 1041 mm x 1829 mm)
Maximum Product Weight	1022 lbs. (465 kg)
Maximum Product Density	0.4 g/cc
Floor Area Required (with standard storage)	119 ft. x 46 ft. (36 m x 14 m)
Modes of Operation	Standard: 4 pass automatic continuous
	Optional: 2 pass automatic continuous, 2 pass automatic batch, 2 pass incremental dose

JS-10000 Performance



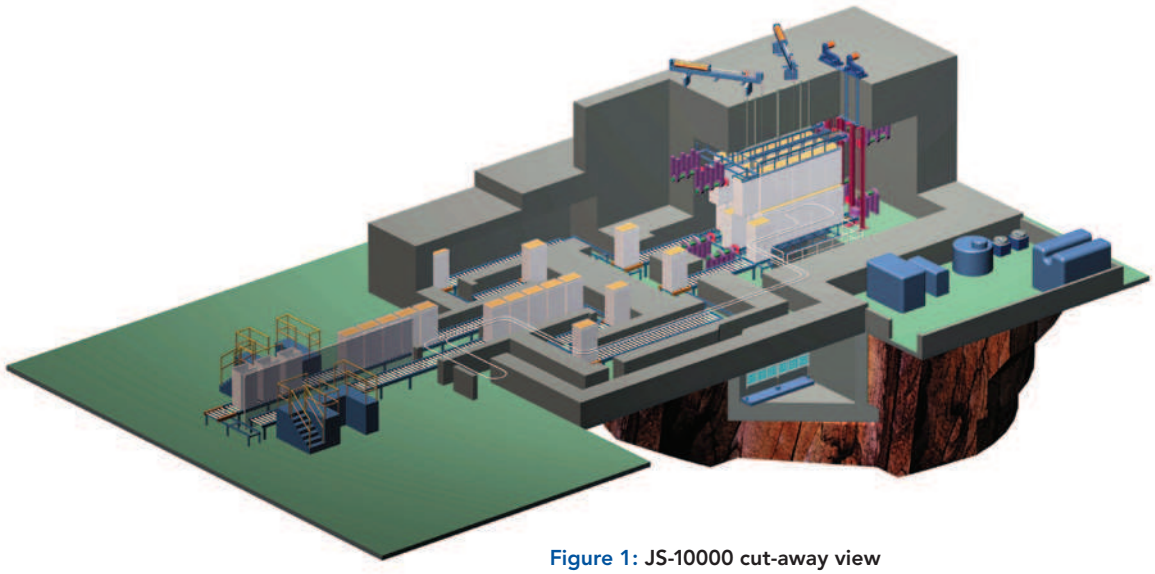


Figure 1: JS-10000 cut-away view

MDS Nordion

MDS Nordion's products and services are used throughout the world to prevent, diagnose and treat disease. Our applied research and innovation play an integral part in improving global healthcare.

www.mdsnordion.com



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Fax: +1 613 592 6937

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Fax: +852 2827 8302

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Tokyo 101-0047, Japan
Tel: +81 3 5283 6872
Fax: +81 3 5283 6873

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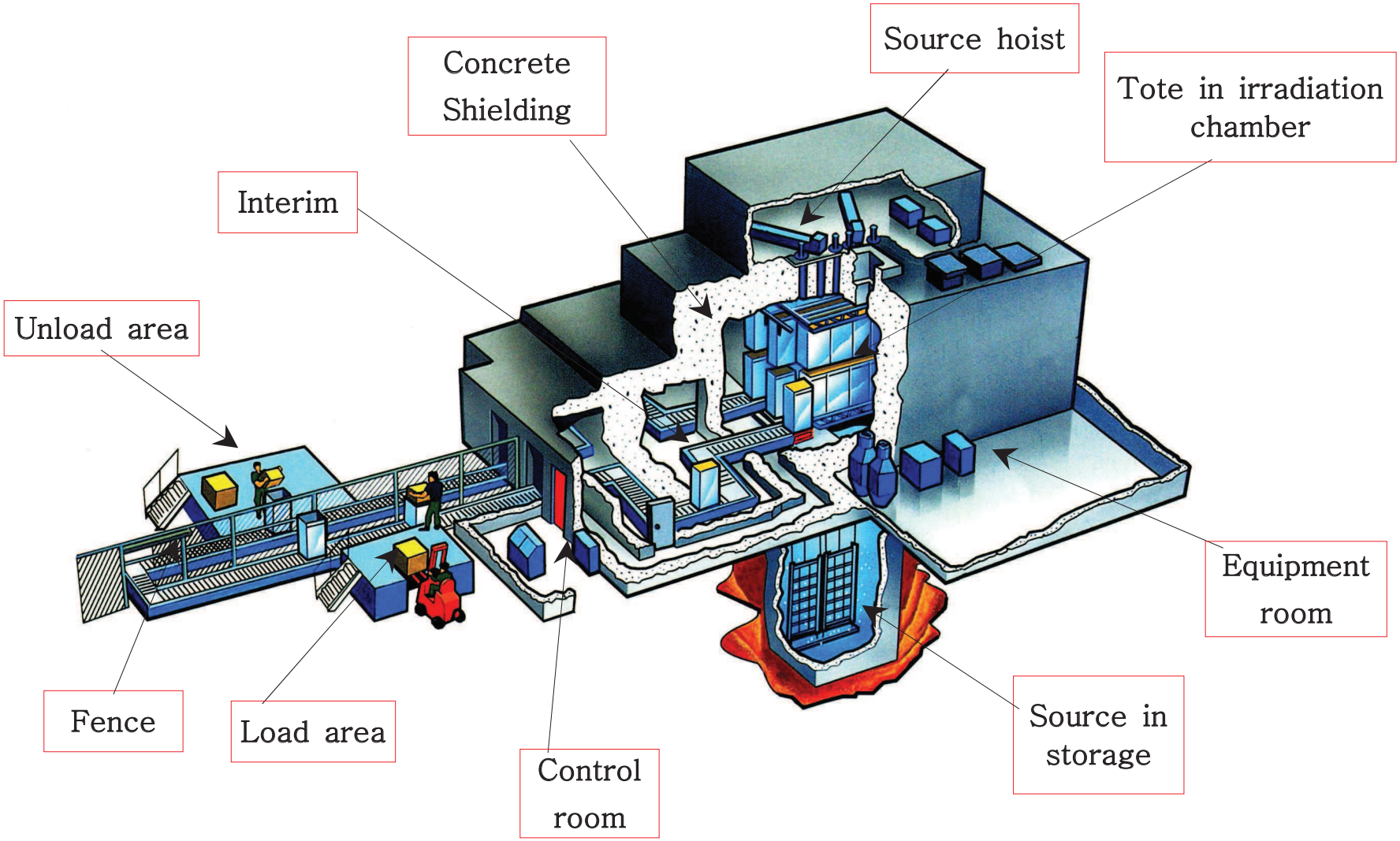
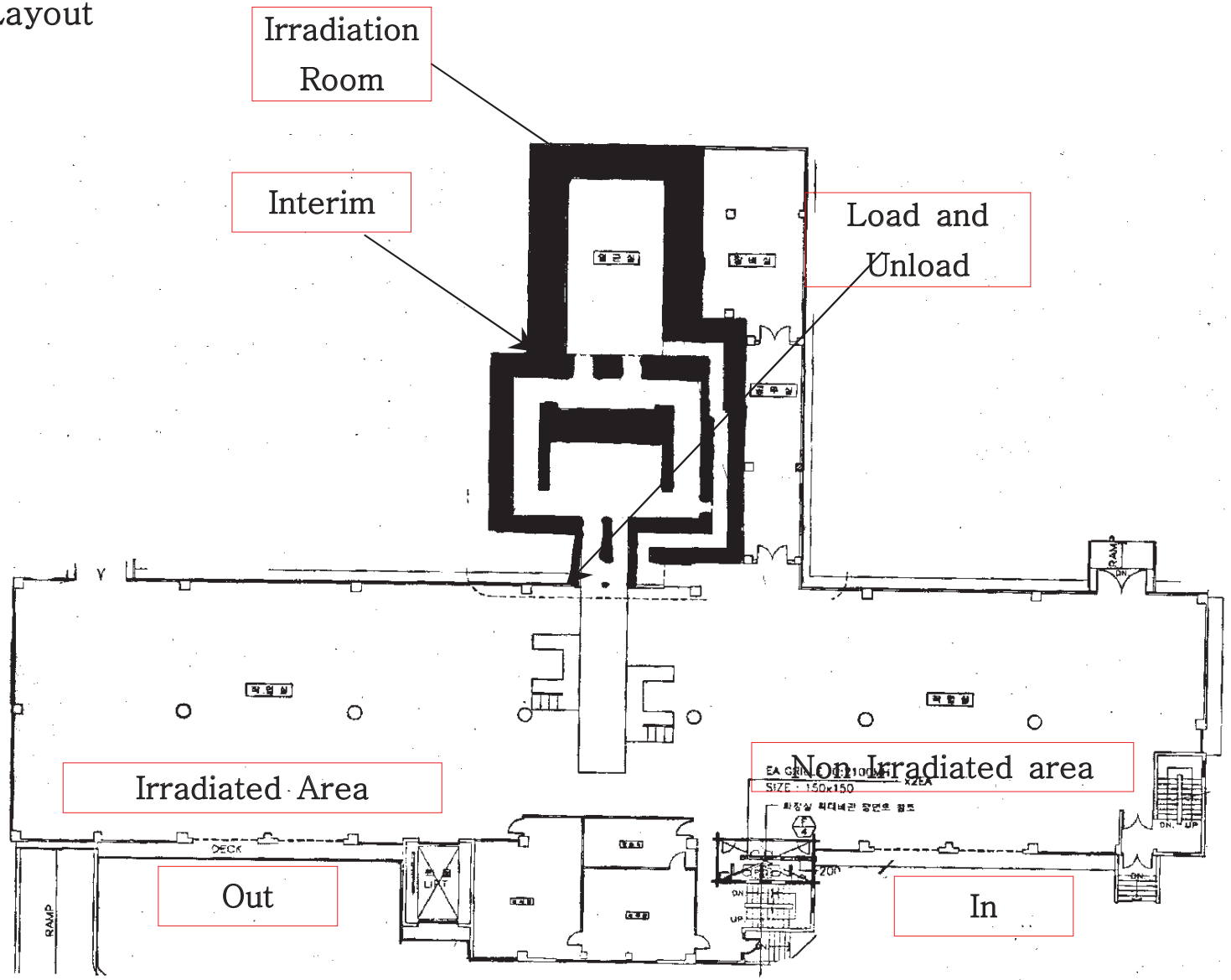
MDS Nordion

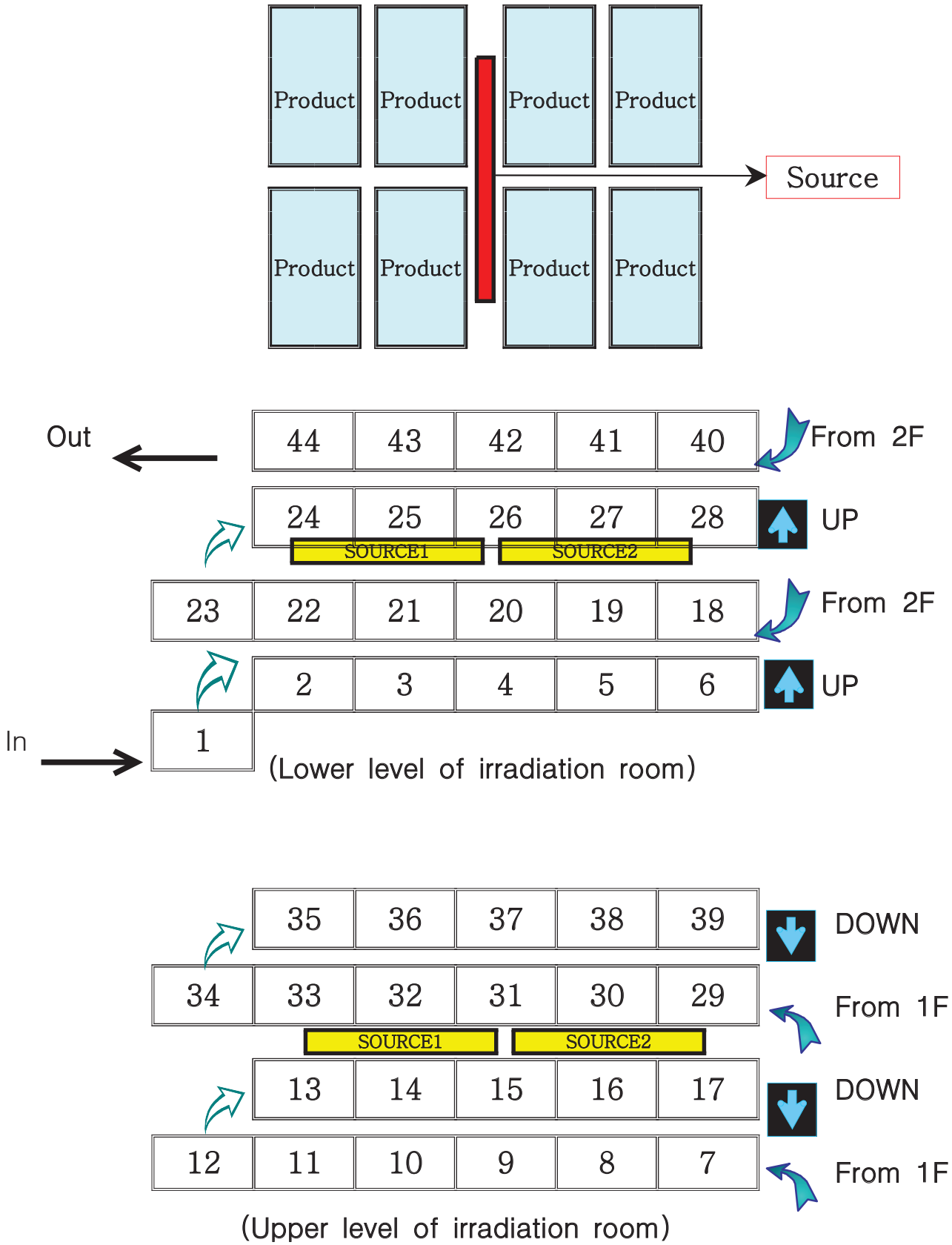
(fig1) JS10000 Layout (Gamma irradiator layout)



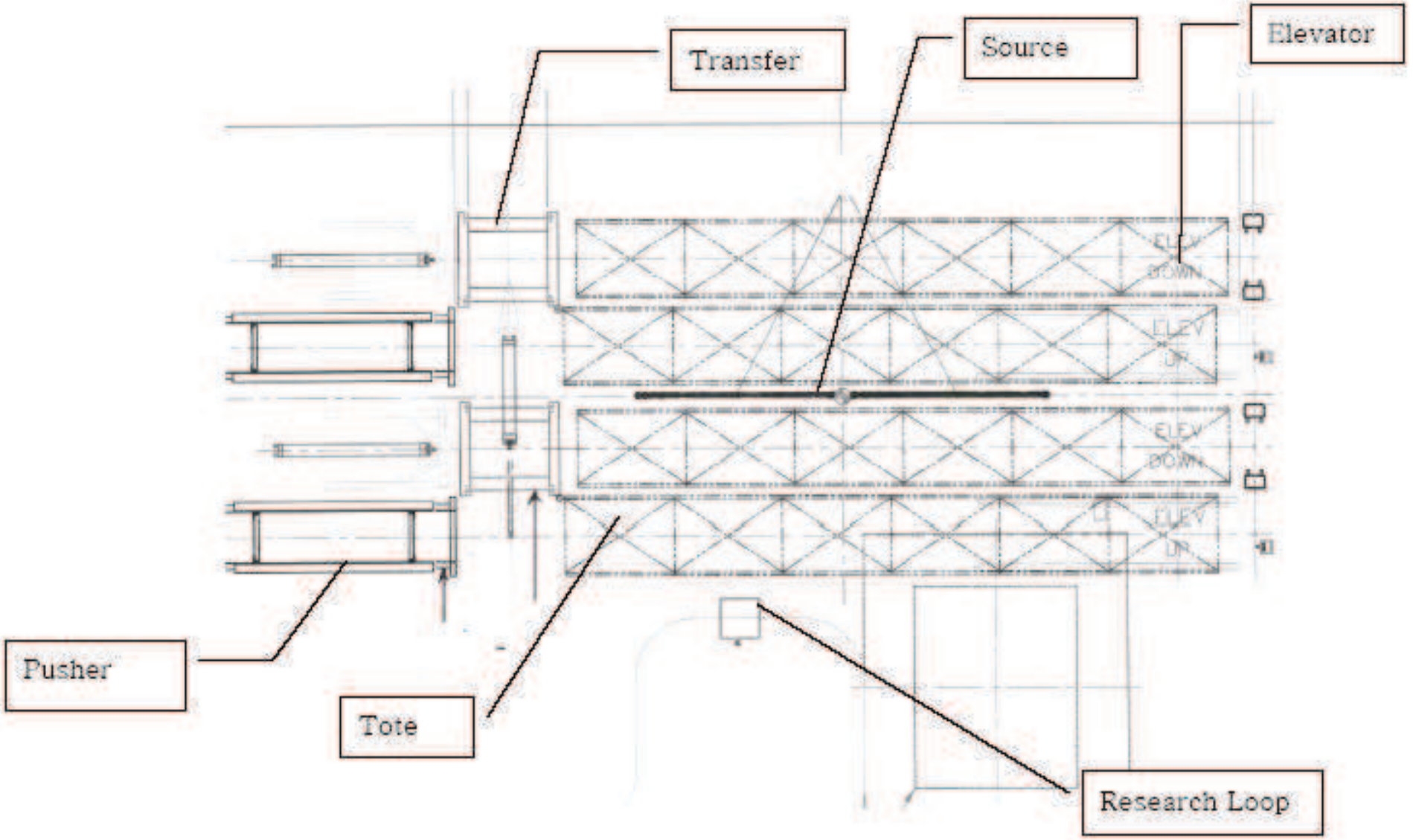
(fig2) factory Layout



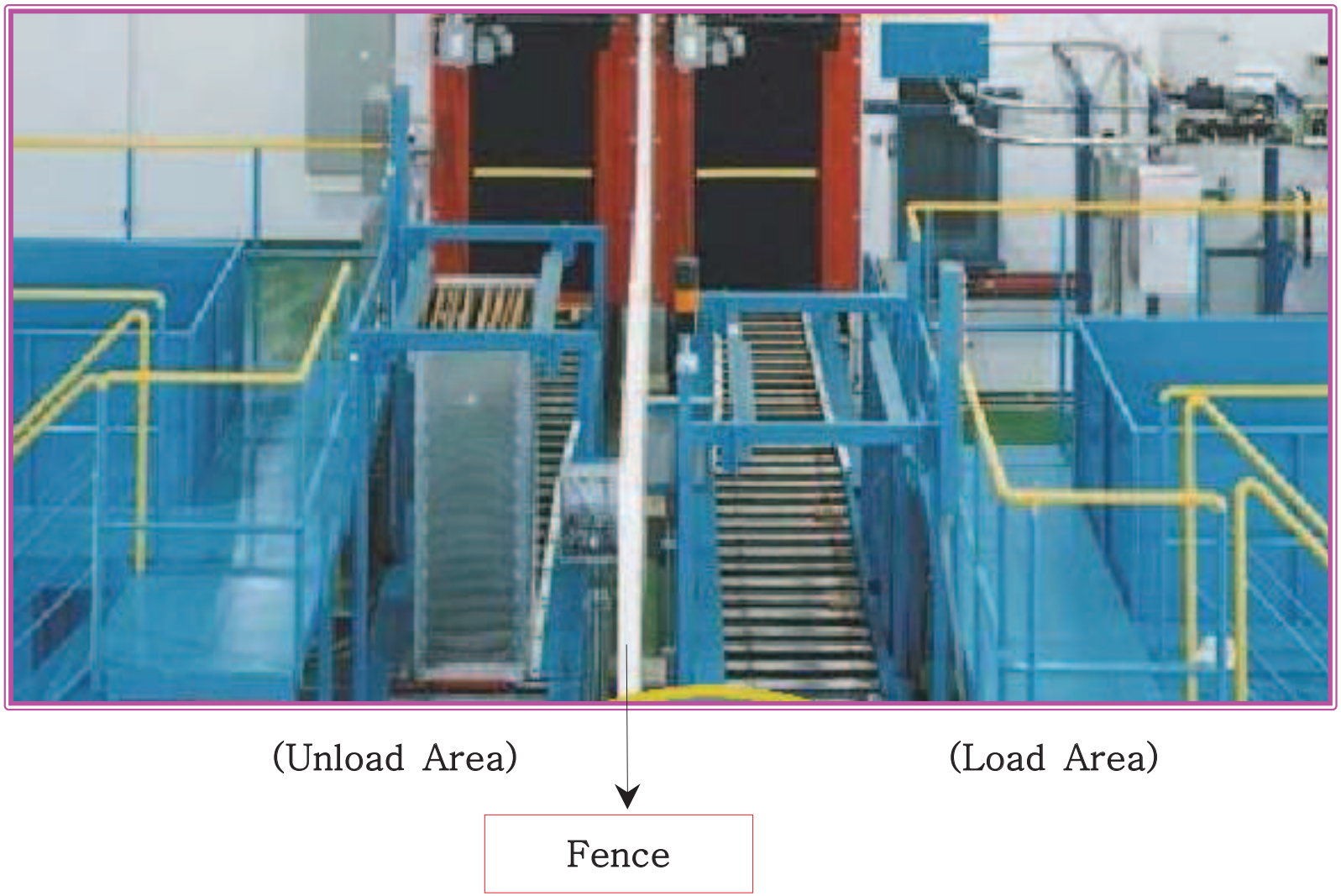
(fig3-1) Source Pass



(fig3-2) Source Pass



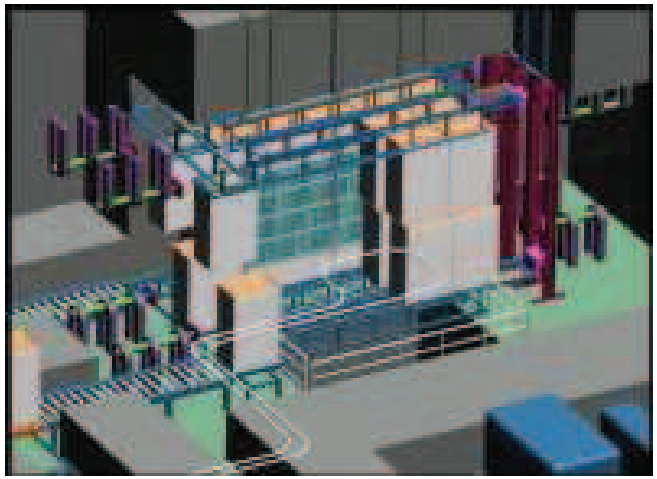
(fig4) Load and Unload Area



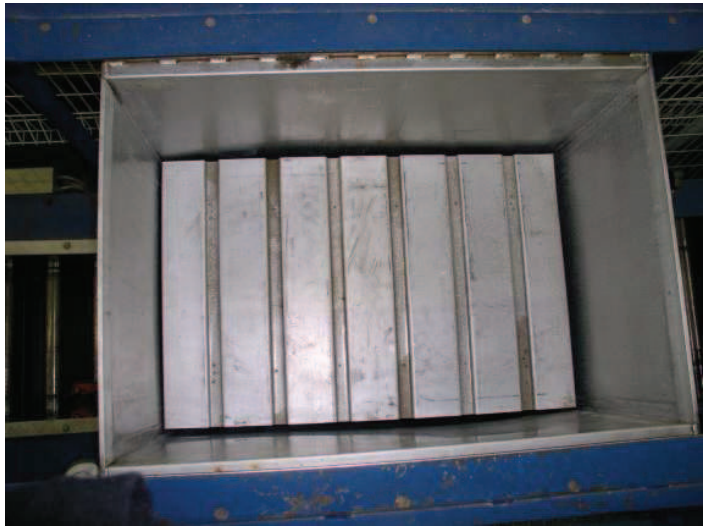
(fig5-1) Tote - Irradiation container (Inner Size : L825mm × W515mm × H1,530mm)

(Tote in Load Area)

(Lift down)

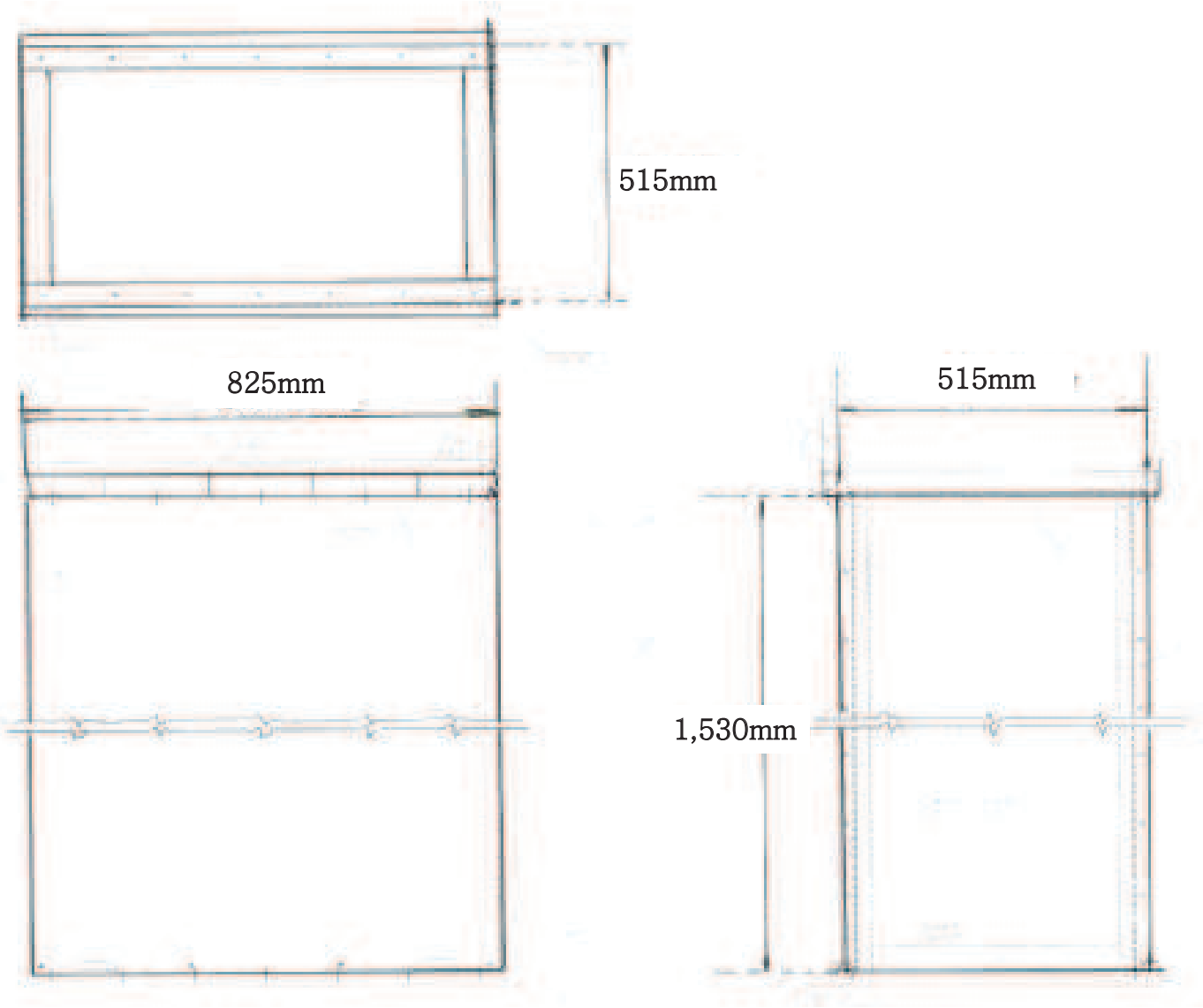


(Tote in Irradiation Area)



(Lift up)

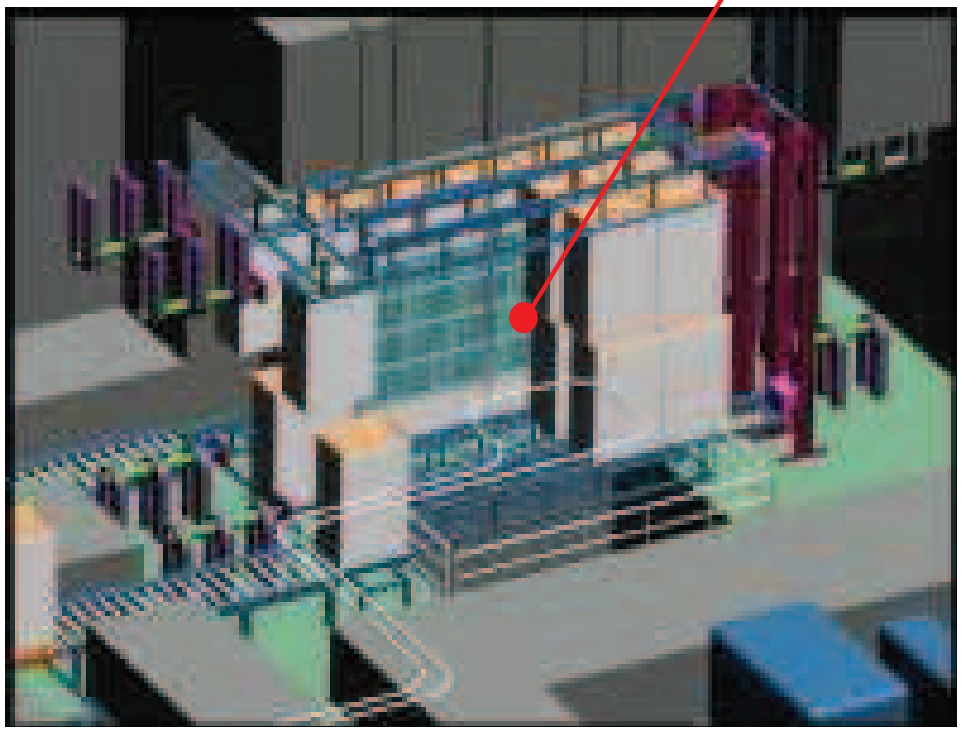
(fig5-2) Dimension of Tote



(fig5-3) Dimension of Research Container

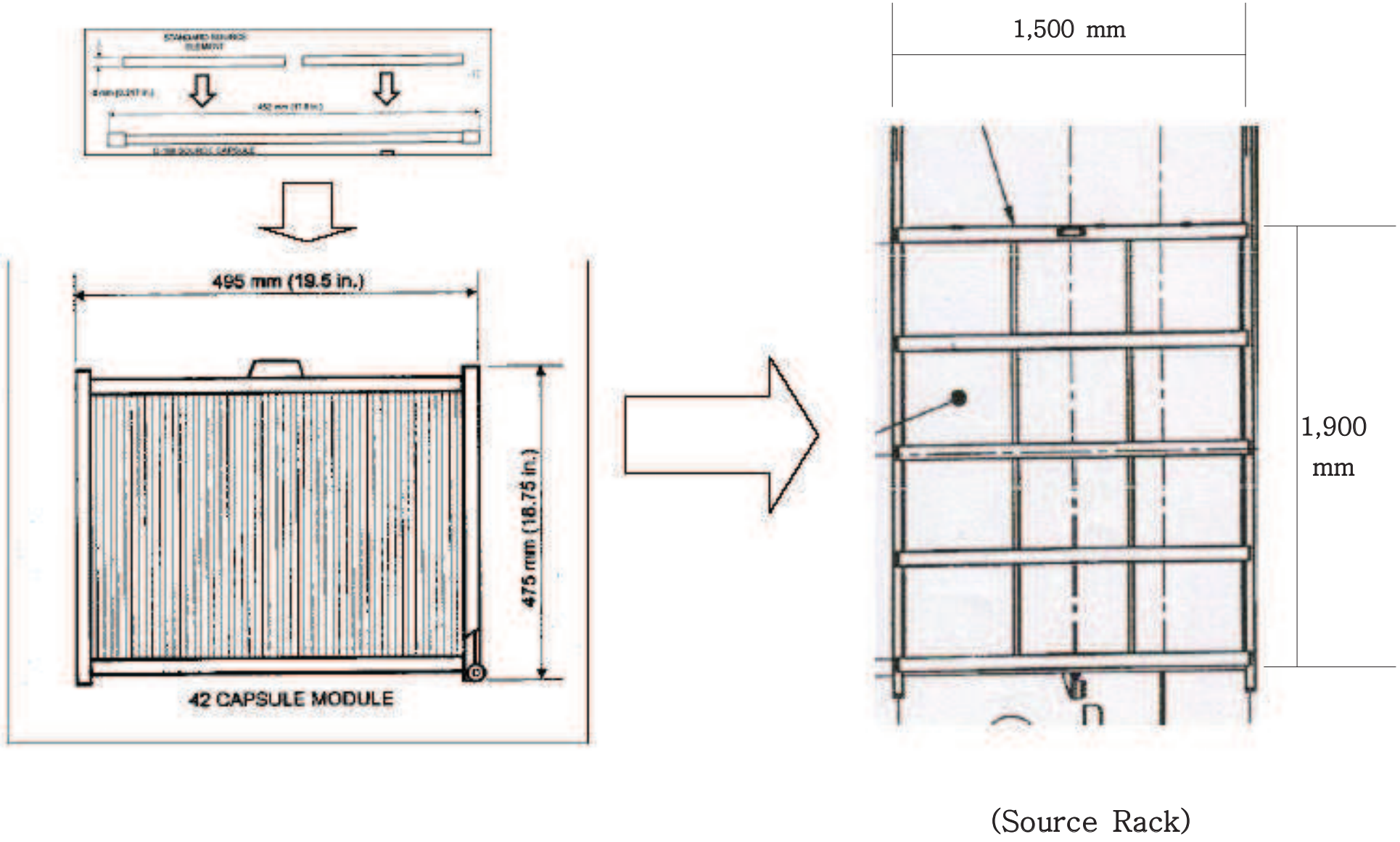
- ▶ Materiel : Aluminum
- ▶ Dimension : 370(L) × 300(W) × 650(H) mm

(Research loop)



(Research loop conveyer)

(fig6) Cobalt Source & Source Rack



(Source Rack)

Attachment 8.

Certificate of self-adhesive Gamma indicator

STERILIZATION INDICATORS

ETIGAM

ETIGAM B.V.
Prinsenweide 30
7317 BB APELDOORN
The Netherlands

Tel. +31 (0) 55 - 5211721
Fax +31 (0) 55 - 5223931

E-mail: info@etigam.nl
Internet: www.etigam.nl

γ

QUALITY CONTROL CERTIFICATE

Product description	:	Selfadhesive Gamma-indicator
ETIGAM code number	:	**2.01**
Dosisrange	:	> 10 kGy
Colour change	:	Yellow - red
Size / description	:	Circular, diameter 12.7 mm
Labels per roll	:	5000
Date of production / lot nr	:	3-120531 (## - YY MM DD)
Expiry date	:	24 months after date of production, when stored properly
Storage	:	Dark and cool

IRRADIATION TEST

Samples of each roll have been irradiated with a dosage of 10 - 15 and 25 kGy
Irradiated and non-irradiated samples are stored in our files

Packed by	PE	**PASSED Q.C.**
Ship date	23-08-2012	ETIGAM B.V. QUALITY CONTROL
Customer	Soya Groentec	Stamp and signature Q.C. Manager
P.O number	SYPO2012-081601	FQ 001 QC GAMMA, version 1.7

* ETIGAM is not responsible for any damage due to improper use of their indicators
* Read instructions on the packaging before use
* For your reference a copy of the lotnumber is placed on the outside of each roll

Attachment 9.

Certificate of calibration

*Spectrophotometer

*Digital Calipers

*Stop watch

*Harwell Brochure

*Routine Dosimeter(Red JT 4034)

*Master Timer

*Over Dose Timer

*Research Timer

*Electronic Balance

Validation에 사용되어지는 계측기

No.	계측기명 (Description)	교정일 (Date of calibration)	차기교정일 (Date of next calibration)	교정주기 (Calibration period)	교정기관 (Calibration organization)	비고 (Note)
1.	Digital Calipers	12. 12. 04.	13. 12. 03.	12 months	한국산업기술시험원 (Korea Testing Laboratory)	
2.	Spectro Photometer	12. 08. 27.	13. 08. 26.	12 months	한국산업기술시험원 (Korea Testing Laboratory)	
3.	Stop Watch	11. 11. 17.	13. 11. 16.	24 months	한국산업기술시험원 (Korea Testing Laboratory)	
4.	Routine Dosimeter	07. 11. 28.	17. 11. 27.	10 years	MDS Nordion	Red 4034
5.	Master Timer	12. 12. 21.	13. 12. 20.	12 months	㈜소야그린텍 (Soyagreentec co.,Ltd.)	
6.	Over Dose Timer	12. 12. 21.	13. 12. 20.	12 months	㈜소야그린텍 (Soyagreentec co.,Ltd.)	
7.	Research Timer	12. 12. 21.	13. 12. 20.	12 months	㈜소야그린텍 (Soyagreentec co.,Ltd.)	
8.	전기식 지시저울 (Digital reading scale)	12. 12. 21.	13. 12. 20.	12 months	㈜소야그린텍 (Soyagreentec co.,Ltd.)	

CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

Certificate No. : 12-065940-02-2

(1) / (2)
Page of Pages

1. Client

Name : SOYAGREENTEC CO.,LTD.

Address : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. Calibration Subject

Description : Calipers, inside/outside

Manufacturer & Model Name : S.TOOLS / (0 ~ 150 / 0.01) mm

Serial Number : F413916

3. Date of Calibration : 04 December 2012

4. Environment

Temperature : (20.0 ± 0.1) ℃ Humidity : (47 ± 1) % R.H.

Location : ▣ KTL Lab. ☐ Mobile Lab. ☐ On Site Calibration

5. Traceability

Calibration method and/or brief description :

The above instrument is calibrated as per standard calibration procedure(CP801-10605-1,KTL) for Calipers, inside/outside and by standards traceabled to National Metrology Institude.

List of used standards/specifications

Description	Manufacturer and Model Name	Serial Number	Calibration valid until	Calibration Laboratory
Gauge Blocks	Mitutoyo / 103 pcs.	77647	2013. 10. 15	KTL
Step gauges	Mitutoyo / 515-585	430127	2014. 07. 09	KTL

6. Calibration Results : Refer to the attached calibration results

7. Measurement Uncertainty : Refer to the attached calibration results

Affirmation	Measurements performed by	Approved by
	Name : Kim Sung-Joong	Title : Technical Supervisor Name : Noh Hyeon-Soo

The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.

04 December 2012

Korea Testing Laboratory
Accredited by KOLAS, Republic of KOREA

(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is likely to affect the validity of the calibration.

FP812-03-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 결 과

CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
Tel : +82-31-500-0217, Fax : +82-31-500-0389
E-mail : standard@ktl.re.kr

성적서 번호 : 12-065940-02-2
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME
KOLAS
CALIBRATION NO. KC01-028

* Description : Calipers, inside/outside
* Manufacturer : S.TOOLS
* Serial No. : F413916

1. Outside measurement hour scaled accuracy

Nominal Size (mm)	Correction Value (mm)	Measurement Uncertainty (mm) (CL about 95 %, k=2)
0	0.00	-
50	0.00	0.01
100	0.00	0.01
150	0.00	0.01

2. The inside measurement hour scaled accuracy

Nominal Size (mm)	Correction Value (mm)	Measurement Uncertainty (mm) (CL about 95 %, k=2)
0	-	-
50	0.07	0.01
100	0.06	0.01
150	0.07	0.01

Note) Calibration Value = Nominal Size + Correction Value

The end.

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

CALIBRATION CERTIFICATE

Korea Testing Laboratory

723, Haean-ro, Sangnok-gu, Ansan-si, Gyeonggi-do, KOREA
TEL : +82-31-500-0217 FAX : +82-31-500-0389

Certificate No. : 12-049550-03-4

1. Client

Name : SOYAGREENTEC CO.,LTD.

Address : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. Calibration Subject

Description : Spectrophotometers

Manufacturer & Model Name : Mecasys / OPTIZEN 1412V

Serial Number : 1V2244-097016-00

3. Date of Calibration : 27 August 2012

4. Environment

Temperature : (23.2 ± 0.1) ℃ Humidity : (51 ± 1) % R.H.

Location : ▣ KTL Lab. ☐ Mobile Lab. ☐ On Site Calibration

5. Traceability

Calibration method and/or brief description :

The above instrument is calibrated as per standard calibration procedure(CP801-70217-1,KTL) for Spectrophotometers and by standards traceabled to National Metrology Institude.

List of used standards/specifications

Description	Manufacturer and Model Name	Serial Number	Calibration valid until	Calibration Laboratory
Didymium Glass Filter	NIST / 204-08-100	C95	2014. 03. 26	KTL
Netural Density Filter	Perkin Elmer / B050-7805	3973/3893/3793	2014. 01. 24	KTL

6. Calibration Results : Refer to the attached calibration results

7. Measurement Uncertainty : Refer to the attached calibration results

Affirmation	Measurements performed by	Approved by
		Title : Technical Supervisor
	Name : Song Myung Jin 송명진	Name : Lee Min-Soo 이민수

The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the LAC-MRA

27 August 2012

Korea Testing Laboratory
Accredited by KOLAS, Republic of KOREA

(NOTE) If any significant instability or other adverse factor(overload, temperature, humidity etc.) manifests itself before, during or after calibration, and is likely to affect the validity of the calibration

FP812-03-00

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

CALIBRATION RESULTS

723, Haean-ro, Sangnok-gu, Ansan-si,
Gyeonggi-do, KOREA
TEL : +82-31-5000-217 FAX : +82-31-5000-389
E-mail :standard@ktl.re.kr

Certificate No. : 12-049550-03-4

KOREA LABORATORY ACCREDITATION SCHEME
KOLAS
CALIBRATION NO.028

◇ Description : Spectrophotometer

◇ Manufacturer & Model Name : Mecasys / OPTIZEN 1412V

◇ Serial Number : 1V2244-097016-00

1. ABSORPTION-PEAK

Std.Value(nm)	Ind.value(nm)	Uncertainty(nm)
440.66	440.6	0.5
480.87	480.7	0.5
529.33	529.3	0.5
573.32	573.2	0.5
684.69	684.6	0.5

◇ Spectral Slitwidth : 2.0 nm

◇ Expanded Uncertainty (C.L. about 95 %, k = 2)

2. ABSORBANCE

Unit : Abs

Wavelength / CRM	440 nm	465 nm	546.1 nm	590 nm	635 nm
Std.Value	0.299 9	0.270 7	0.286 6	0.329 5	0.331 2
Ind.value	0.302	0.272	0.285	0.326	0.329
Uncertainty	0.003	0.003	0.003	0.003	0.003
Std.Value	1.009 0	0.941 1	0.966 3	1.021 0	0.980 3
Ind.value	1.041	0.961	0.976	1.026	0.985
Uncertainty	0.003	0.003	0.003	0.003	0.003
Std.Value	0.495 8	0.455 7	0.469 3	0.523 9	0.518 7
Ind.value	0.502	0.460	0.470	0.523	0.519
Uncertainty	0.003	0.003	0.003	0.003	0.003

◇ Spectral Slitwidth : 2.0 nm

◇ Expanded Uncertainty (C.L. about 95 %, k = 2)

The end.

※ Accreditation system of national calibration laboratories, clause 41 : 12 th months

※위 마크는 추후 전자확인증 대조 프로그램에서 원본대조시 사용되는 2D코드입니다.

교 정 성 적 서

CALIBRATION CERTIFICATE

Korea Testing Laboratory

1271-12 Sa-dong Sangnok-gu Ansansi Gyeonggi-do Korea

TEL : +82-31-500-0251 FAX : +82-31-500-0268

성적서 번호 : 11-2552-1280-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)
   기 관 명 (Name) : SOYAGREENTEC CO.,LTD.
   주 소 (Address) : 900-3,Sangshin-Ri,Hyangnam-Eup,Hwaseong-Si,Kyeonggi-Do,Korea.

2. 측 정 기 (Calibration Subject)
   기 기 명 (Description) : Time interval meters/Stop watches (Stop Watch)
   제작회사 및 형식 (Manufacturer and Model Name) : KENKO (KK-5853)
   기 기 번 호 (Serial Number) : NONE

3. 교정일자 (Date of Calibration) : 17 Nov 2011

4. 교 정 환 경 (Environment)
   온 도 (Temperature) : (23.1 ± 0.3) ℃ 상대습도 (Relative Humidity) : (48 ± 2) % R.H.
   교정장소 (Location) : ■고정표준실 (KTL Lab.) □이동교정(Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)
   교정방법 및 소급성 서술 (Calibration method and/or brief description) :
   The above instrument is calibration as per standard calibration procedure(CP801-30106-1,KTL) for Stop watch & Timer and by standards traceabled to National Metrology Institude.
   교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Stop Watch Calibrator	Witschi / Q test 6000	3582	2012. 03. 08.	KTL

6. 교 정 결 과 (Calibration Results) : Reference to Calibration Results

7. 측정불확도 (Measurement Uncertainty) : Reference to Calibration Results

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : KR KIM	직 위 (Title) : Technical Supervisor 성 명 (Name) : JL JANG

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

17 Nov 2011

한국인정기구 인정
Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

This Certification is invalid under sudden change of voltage, temperature, humidity that affect subjected instrument precision.

교 정 결 과
CALIBRATION RESULTS

1271-12 Sa-dong Sangnok-gu Ansansi Gyeonggi-do Korea
TEL : +82-31-500-0251 FAX : +82-31-500-0268
E-mail : kimkr@wm.ktl.re.kr

성 적 서 번 호 : 11-2552-1280-1
Certificate No.

◇ Description : Time interval meters/Stop watches (Stop Watch)

◇ Manufacturer & Model : KENKO (KK-5853)

◇ Serial Number : NONE

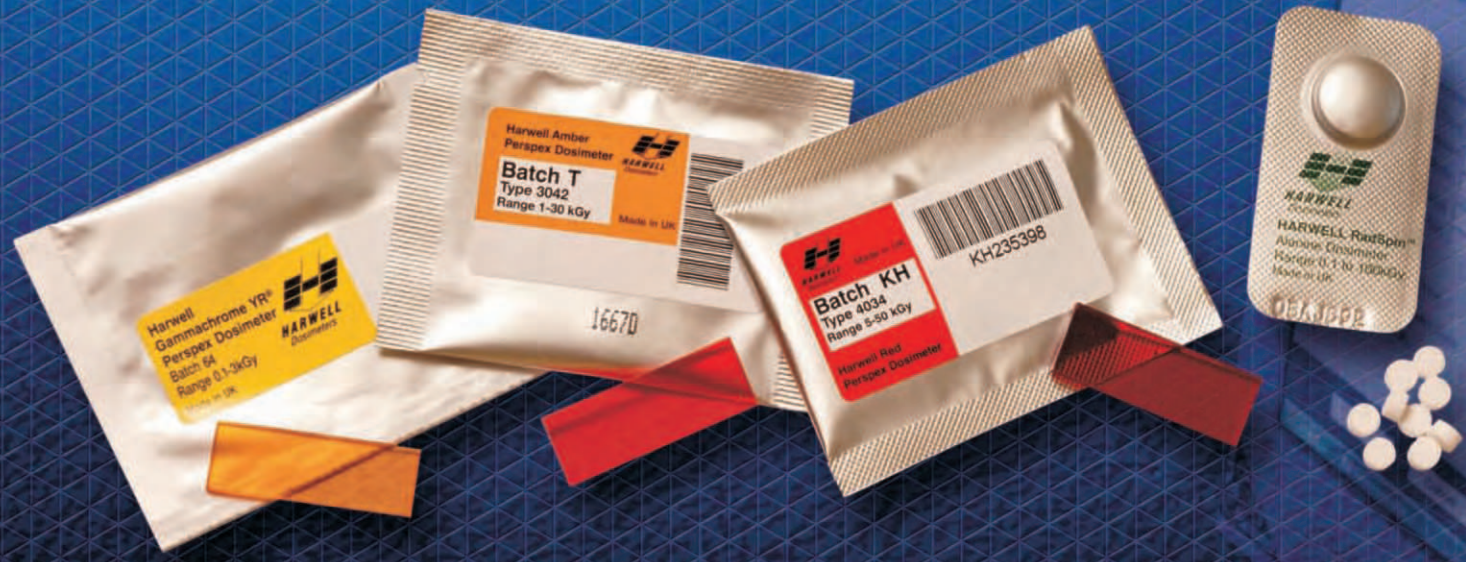
* Error (3.08 ± 0.009) s / d (Confidence Level 95 %, k=2)

* Here, first part means the error and the next means the uncertainty.
ex) (0.23 ± 0.011) s/d
So, one day(86 400 s) error is 0.23 s and uncertainty is 0.011 s.

The End.

Harwell Dosimeters

Dosimeter systems for radiation processing



Supporting radiation processing – worldwide

Harwell: rooted in history...
but with a vision for the future

Harwell Dosimeters are located in a region which has at least 5000 years of human endeavour behind it! Our Science and Innovation Campus is situated on the most ancient road in England, hard by a burial place of Saxon royalty, a Bronze Age monument, an Iron Age settlement, and a Neolithic burial chamber!

We share this campus with the first nuclear reactor to be built in Europe, and with the newest, most powerful synchrotron in the world, opened by Her Majesty the Queen last year.

Even the names of the roads around us evoke some of the greatest contributors to the development of the nuclear industry, ranging from Rutherford and the Curies, to Maxwell and Thomson, not forgetting Röntgen and Fermi. Our address is Becquerel Avenue, after the Frenchman Henri Becquerel, whose fogged photographic film revealed radioactivity and launched the industry.

Our own development is continuous from the earliest days of radiation processing, to the present day.

We continue to advance in technology, and invest in our processes.

To our long established range of optical dosimeters, in 2002 we added the new technology of Alanine/esr dosimetry. We now supply increasing quantities to advanced international companies, as well as to standards laboratories.

The optical dosimeters have not stood still. Following recent investment, Perspex produced to our specification is now processed from raw material to finished dosimeters, all within our own facility.

We have grown with the industry we serve, supply customers on every continent except Antarctica, and look to the future with enthusiasm.

The quality assured manufacturer

Harwell Dosimeter systems for radiation processing

A proven global track record in dosimeters

In the earliest days of radiation processing, Harwell Dosimeters devised disposable, passive dosimeters for validation and control, and has continued to develop with the industry to ensure that its evolving requirements are met.

The dosimeters are foil-packed for reliability in any processing environment. They are:

- ***Rugged***
- ***Reliable***
- ***Precise***
- ***Quality assured***

Dependable dosimeter systems for radiation processing

For precise, accurate dose measurements, Harwell Dosimeters offer:

Optical dosimeters – uniquely labelled and bar-coded aluminium foil laminate sachets containing dyed Perspex,™ which darkens quantitatively when irradiated, and when measured by spectrophotometry yields a precise, accurate, measure of dose;

or **RadSpin™ dosimeters** – uniquely labelled are bar-coded blister-packed pellet which exploit the dose-dependence of the paramagnetic resonance of alanine over a wide dose range.

Your choice

Whether you want the simplicity and confidence inspired by the long-established, worldwide use of our dyed pmma optical systems, or wish to exploit the potential of alanine/esr technology, Harwell Dosimeters aim to meet your dosimeter needs.

Harwell®, RadSpin™, and Gammachrome YR® are registered trade names of Harwell Dosimeters Ltd.

Perspex™ is a registered trade name of Lucite Ltd.

Choosing a purchase plan

Traditional

Plant by plant, as required. Minimum order 1000 dosimeters.

Large requirements

Buy whole batches – customers distribute to their sites.

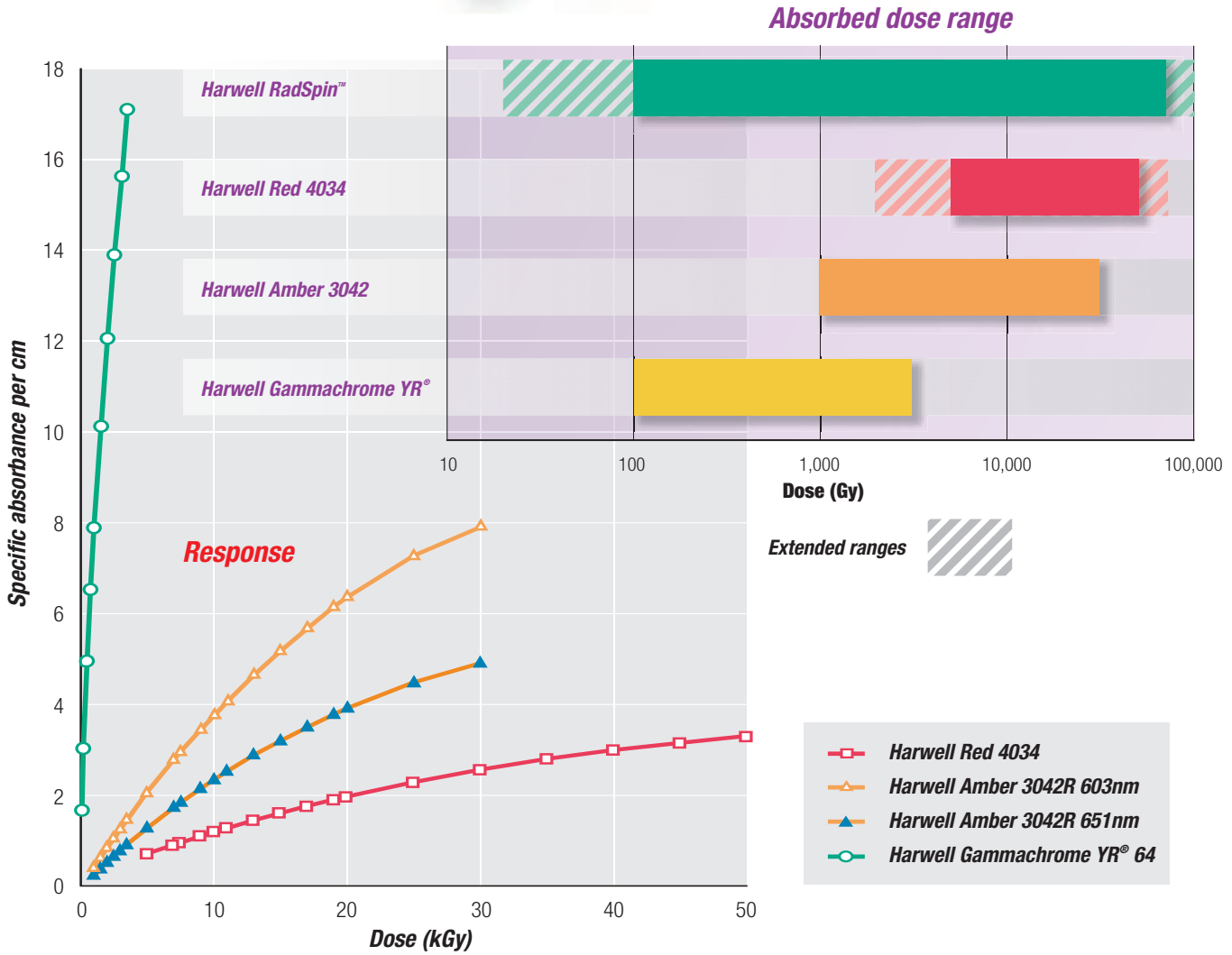
Phased delivery

- customer estimates requirement for a year
- minimum order 50k dosimeters
- price ruling on day of first despatch
- we allocate and store a batch from which to supply
- we despatch to a timetable, or on demand
- invoice on despatch.

or

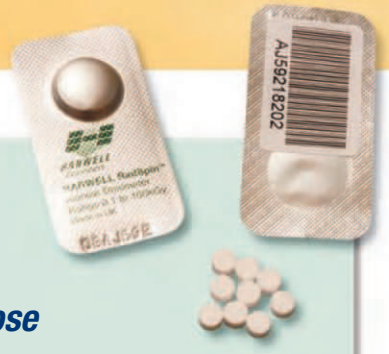
- customer estimates requirements for two years
- minimum order 50k dosimeters
- we allocate and store a batch from which to supply
- we supply to demand, minimum 10k
- price ruling on day of call-off
- invoice on despatch.

Radiation dose ranges



Harwell Dosimeter systems for radiation processing

Specifications, responses and sensitivities



Harwell RadSpin™

Harwell RadSpin™ Dosimeters for the measurement of radiation dose

When pellets containing the amino acid alanine are irradiated, stable free radicals are produced in a concentration which depends on the exposure. The measured response to microwaves of the pellet placed in the magnetic field of a paramagnetic resonance spectrometer, is quantitatively related to the radiation dose which the pellet absorbed.

Form

White cylindrical pellets of alanine in a wax binder.

Material

Active	amino acid L-alpha alanine	90.9%
	Binderparaffin wax	9.1%

Dimensions

Diameter	4.825mm ± 0.01mm (5mm to special order).
Height	2.8mm ± 0.1mm.
Mass	overall 60mg ± 2mg within a lot ± 0.6mg standard deviation 0.3mg.

Measurement reproducibility

mass	CV 0.5%
response	CV 0.5% NPL irradiated, not packed.

Dose range

Standard range 100 Gy to 70 kGy
10 Gy to 100 kGy may be achieved.

Performance

Each batch is verified by NPL comparison.

Packaging

Two formats
- plain pellets, bulk packed
- RadSpin™ Dosimeters consisting of pellets sealed in labelled aluminium foil blisters, packed 1,000 per carton.

Labelling

Each dosimeter is uniquely labelled and barcoded.

Harwell Red 4034 Dosimeters

Harwell Red 4034 Dosimeters for the measurement of radiation dose

Material

A single batch of Red 4034 Perspex cast polymethylmethacrylate sheets.

Dimensions

30mm x 11mm. Thickness 3 ± 0.55mm.

Measurement reproducibility

Coefficient of variation of specific absorbance measurements on sets of dosimeters from the batch, simultaneously irradiated together, in a gamma radiation field uniform within ±1%, is 2% over the entire calibrated range, 5 to 50 kGy.

Calibration quality

Over the calibrated range, all mean specific absorbance data points thus obtained are within 2% of a fourth-order polynomial least-squares fit to the data.

Traceability

Harwell calibration is traceable to the UK standard of absorbed dose at the National Physical Laboratory (NPL).

Shelf-life

Ten years from date of release.

Packaging

Sealed in labelled sachets made of polyester/aluminium foil/polyester/polyethylene laminate, packed 1000 per carton.

Packing to defined AQL's checked to BS6001 (ISO 2859-1), single normal inspection, level II.

Labelling

Each dosimeter is uniquely labelled and barcoded.

Harwell Amber 3042 Dosimeters

Harwell Amber 3042 Dosimeters for the measurement of radiation dose

Material

A single batch of Amber 3042 Perspex cast polymethylmethacrylate sheets.

Dimensions

30mm x 11mm. Thickness 3 ± 0.55mm.

Measurement reproducibility

Coefficient of variation of specific absorbance measurements on sets of dosimeters from the batch, simultaneously irradiated together, in a radiation field uniform within ±1%, is ≤2.5% over the ranges 1 to 10 kGy at 603 nm wavelength and 10 to 30 kGy at 651 nm.

Calibration quality

Over the calibrated range, all mean specific absorbance data points thus obtained are within 3% of a fourth-order polynomial least-squares fit to the data.

Traceability

Harwell calibration is traceable to the UK standard of absorbed dose at the National Physical Laboratory (NPL).

Calibration performance of each batch is verified by NPL intercomparison.

Shelf-life

Ten years from date of release.

Packaging

Sealed in labelled sachets made of polyester/aluminium foil/polyester/polyethylene laminate, packed 1000 per carton.

Packing to defined AQL's checked to BS6001 (ISO 2859-1), single normal inspection, level II.

Labelling

Each dosimeter is uniquely labelled and barcoded.

Harwell Gammachrome YR® Dosimeters

Harwell Gammachrome YR® Dosimeters for the measurement of radiation dose

Material

A single batch of Gammachrome YR® Perspex cast polymethylmethacrylate sheets.

Dimensions

30mm x 11mm. Thickness 1.7mm nominal.

Measurement reproducibility

Coefficient of variation of specific absorbance measurements on sets of dosimeters from the batch, simultaneously irradiated together, in a radiation field uniform within ±1%, is ≤3% over the ranges 100 to 300 Gy at 530 nm wavelength.

Calibration quality

Over the calibrated range, all mean specific absorbance data points are within 3% of a polynomial least-squares fit to the data.

Traceability

Harwell calibration is traceable to the UK standard of absorbed dose at the National Physical Laboratory (NPL).

Calibration performance of each batch is verified by NPL intercomparison.

Shelf-life

Ten years from date of release.

Packaging

Sealed in labelled sachets made of polyester/aluminium foil/polyester/polyethylene laminate, packed 1000 per carton.

Packing to defined AQL's checked to BS6001 (ISO 2859-1), single normal inspection, level II.

Labelling

Each dosimeter is labelled with the batch code.

For further information, please contact:

Harwell Dosimeters Ltd

Supporting radiation processing – worldwide

540 Becquerel Avenue
Harwell Science and Innovation Campus
Didcot, Oxfordshire OX11 0TA
United Kingdom

Phone *+44 (0)1235 435704*
Fax *+44 (0)1235 436313*
E-mail *info@harwell-dosimeters.co.uk*

www.harwell-dosimeters.co.uk

HARWELL
Dosimeters

Harwell Dosimeters Limited

HARWELL PERSPEX (PMMA) DOSIMETERS

The following dyed-polymethylmethacrylate **(PMMA)** dosimeters have been developed at Harwell for the measurement of high doses of gamma radiation in industrial radiation processing.

Type	Recommended Dose Range	Recommended Read-out Wavelength
Red 4034	5 to 50 Kilograys (kGy)	640 nanometers
Amber 3042	1 to 30 kGy	603 nm or 651 nm
GAMMACHROME YR®	100 Gy to 3 kGy	530 nm

The dosimeters are 30 x 11 mm optically clear rectangular pieces of material, conditioned and individually sealed in labelled polyester/aluminium foil/polyethylene laminate sachets. On irradiation the dosimeters visibly darken and the degree of darkening, accurately measurable by spectrophotometry, is related to absorbed (water-equivalent) dose.

The dosimeters are produced in batches. The batch reference numbers or letters are displayed on the dosimeter labels. (For example 4034 AX is Red 4034 batch AX). Each batch of dosimeters is subjected to rigorous quality-control, checked for conformance with specification, and finally calibrated using a standardised cobalt-60 irradiator and spectrophotometer before release for sale. The standardisation of the irradiator, and the final dosimeter calibrations, are directly traceable to UK National Standards.

INSTRUMENTATION REQUIRED

A good quality spectrophotometer, and a micrometer or dial gauge. It is recommended that these instruments are regularly tested for accuracy by means of standardised glass filters and hardened-steel gauge blocks.

METHOD

1. The dosimeters must remain sealed before, during and after irradiation, until the time of reading. (The packaging material is specially selected to protect the **PMMA** from the effects of extremes of atmospheric humidity).

2. Preferably, the dosimeters should be read within 2 days after irradiation.

3. In the case of **GAMMACHROME YR ®**, allow a minimum of two hours (normal temperature) for full colour development after irradiation.

4. Select the recommended readout wavelength. For Amber 3042 dosimeters, 603 nm provides higher sensitivity which can be useful up to a dose of 10 kGy.

5. After opening the pack it is recommended that the irradiated dosimeter is wiped with paper tissue moistened with a suitable solvent such as ethyl alcohol.

6. Using the spectrophotometer, measure the total optical absorbance (A) of the dosimeter. (Air as reference in the case of double-beam instruments).

(Note: tests have shown that corrections for pre-irradiation absorbance (Ao) are unnecessary, and can in fact result in reduced precision).

7. Measure the thickness (t) of the dosimeter.

8. Calculate the specific absorbance A/t. This is normally expressed in units of cm-1 or mm-1, depending on dosimeter type.

9. Using a specific absorbance versus dose calibration graph, table, or polynomial equation, convert each A/t value to derived dose.

ACCURACY OF INSTRUMENTATION

The following are useful (and achievable) goals.

Selection of readout wavelength	within +/- 1 nm
Measurement of A	within +/- 1%
Measurement of t	within +/- 1%

CALIBRATION

Harwell supplies calibration curves and tables with each batch of dosimeters which are meant to be used as a guide and to demonstrate that calibration can be satisfactorily achieved. Users are advised to calibrate their stocks of dosimeters, using their own instrumentation. For this purpose Harwell, and national laboratories such as NPL the National Physical Laboratory (UK), and NIST (USA), will irradiate sets of users dosimeters to accurately known doses.

If the conditions of use are unusual, for example there are exceptionally high or low irradiation temperatures or there are to be delays of several days before measurement, then equivalent calibration conditions should be used.

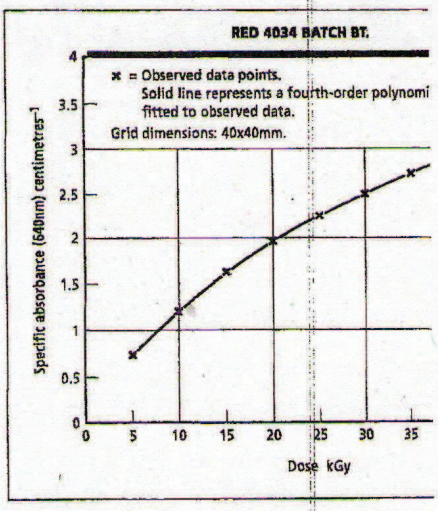
RECOMMENDED PRACTICE

A valuable guide to the use of pmma dosimeters is E1276, published by ASTM, the American Society for Testing and Materials.

CONTACTS

Orders and routine contact:	Mrs M E Plested	Tel: +44 (0) 1235 435704
General Manager:	Dr R Bett	Tel: +44 (0) 1235 435812
		Fax: +44 (0) 1235 436313

Although the wavelength of 640 nm gives the minimum post-irradiation changes in absorbance, the rate of change of absorbance with wavelength in this region is quite steep. For accurate measurements a spectrophotometer with a wavelength calibration accuracy of ±1 nm is required.



Effect of Dose Rate and Radiation Type

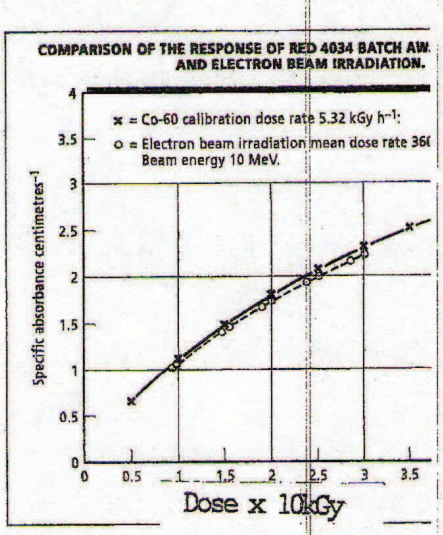
Figure 3 compares the responses of one batch of Red 4034 dosimeters to cobalt-60 and electron-beam (EB) radiation. The cobalt-60 irradiations were carried out in the Harwell calibration facility described above, at a dose rate of 5.33 kGy/h. The EB irradiations were carried out in the NPL electron accelerator at 10 MeV energy and a considerably higher dose rate of 360 kGy/h. Under these very different conditions the response at 25 kGy was only 3.8% lower than for the cobalt-60 irradiation.

Whittaker et al [3] observed that across a range of gamma dose rates from 5.58 kGy/h to 11.7 kGy/h the gamma dose-rate effect within the same batch of Red 4034 dosimeters was insignificant.

Measurement Uncertainty

The precision of the specific absorbance measurements on dosimeters irradiated to the same dose at the same temperature has a coefficient of variation of ±2%.

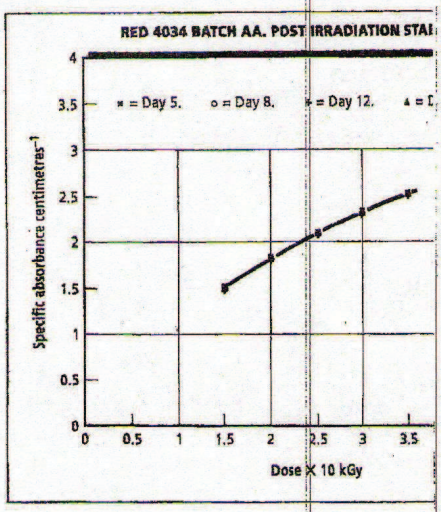
In an intercomparison exercise under controlled conditions, good agreement was obtained between the participating laboratories [4]. Measurement precision (defined as the uncertainty associated with an individual laboratory's measurements on sets of dosimeters irradiated to the same dose) in all cases lay within ±1.5% of the grand mean.



Temperature Effects

The temperature coefficient of Red 4034 dosimeters over the range –78°C to +100°C has been measured as –0.13% per °C, at a dose of 20kGy [5]. Barrett et al observed a 1% increase in radiation response over the temperature range 25-43°C [6]. More recently, Al- Sheikhly et al reported that the temperature dependence of the dose response in the range 20-40°C is small, at a cobalt-60 gamma dose-rate of 31 kGy/h and doses of 30 kGy or less [7]. This last set of experiments employed a post-irradiation storage temperature of 22°C.

The temperature coefficient becomes more significant at higher doses, higher irradiation temperatures and higher temperatures of post-irradiation storage. It is therefore important to establish a protocol for the routine in-plant measurement of absorbed dose.

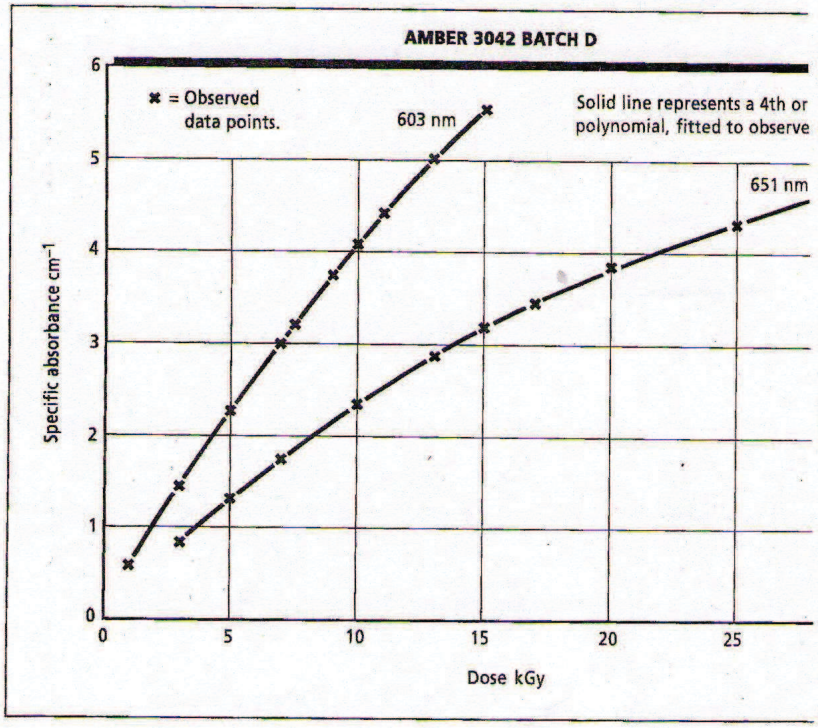


Post-Irradiation Stability

Post-irradiation storage temperature is important, and for the best accuracy exposed dosimeters should be stored - still sealed in their sachets - at 20±5°C.

For a set of dosimeters which were irradiated at 25°C to doses of 25, 30 and 35 kGy and then stored in their sachets at the same temperature, post-irradiation fading of the specific absorbance has been shown to be less than 2% over a 27-day period (Figure 4) [4].

Figure 2 shows typical cobalt-60 gamma irradiation response curves at 603 nm and at 651 nm. The data were obtained by irradiating sets of dosimeters to known doses in the Harwell cobalt-60 calibration facility, in which the dose rate is traceable to the UK National Standard of absorbed dose maintained by the National Physical Laboratory (NPL) [2]. Traceability is established through dichromate reference dosimeters supplied by NPL, irradiated at Harwell and measured by NPL. The accuracy of Harwell's spectrophotometer absorbance measurements is also traceable to NPL through the use of certified neutral density filters. The thickness gauge is checked using standard hardened steel gauge blocks.



Temperature Effects

The temperature coefficient of Amber 3042 dosimeters over the range -78°C to +100°C has been measured as +0.5% per °C, at a dose of 10kGy [3].

The temperature coefficient becomes more significant at higher doses, higher irradiation temperatures and higher temperatures of post-irradiation storage. It is therefore important to establish a protocol for the routine in-plant measurement of absorbed dose.

Measurement Uncertainty

The precision of specific absorbance measurements on dosimeters irradiated to the same dose at the same temperature has a coefficient of variation of ±2%.

Post-Irradiation Stability

After irradiation Amber 3042 continues to darken a little, leading to an initial increase in absorbance. Subsequently the colour intensity decreases, and after 10 days the absorbance is 2% less than the value measured immediately after irradiation. Time after irradiation is therefore an extremely important element of the protocol for dose measurement using Amber 3042 dosimeters.

Batch-to-Batch Variations

Amber 3042 dosimeters are manufactured in batches, and the batch number is printed on the label (eg 3042 B refers to batch B). As already noted, variations within the same batch are minimal. Each batch also undergoes a performance intercomparison which is traceable to NPL (see Manufacturing Quality Control below).

HARWELL
Dosimeters
Harwell Dosimeters Limited

HARWELL RED 4034 DOSIMETERS

SPECIFICATION

Harwell Red 4034 Dosimeters for the measurement of radiation dose.

Material:	A single batch of Red 4034 Perspex cast polymethylmethacrylate sheets.
Dimensions:	30 mm x 11 mm. Thickness 3±0.55 mm.
Measurement Reproducibility:	Coefficient of variation of specific absorbance measurements on sets of dosimeters from the batch, simultaneously irradiated together, in a radiation field uniform within ±1%, is ≤2% over the entire calibrated range, 5 to 50 kGy.
Calibration Quality:	Over the calibrated range, all mean specific absorbance data points are within 2% of a fourth-order polynomial least-squares fit to the data.
Traceability:	Harwell calibration is traceable to the UK standard of absorbed dose at the National Physical Laboratory (NPL). Calibration performance of each batch is verified by NPL inter-comparison.
Shelf life:	10 Years from date of release
Packaging:	Sealed in labelled sachets made of polyester/aluminium foil/polyester/ polythene laminate, packed 1000 per carton. Packing to defined AQL's checked to BS6001 (ISO 2859-1), single normal inspection, level II.

Registration in England and Wales, No.2917906. Registered office, Harwell, Didcot, Oxfordshire OX11 0RA, United Kingdom.

HARWELL
Dosimeters

Harwell Dosimeters Limited

HARWELL AMBER 3042 DOSIMETERS

SPECIFICATION

Harwell Amber 3042 Dosimeters for the measurement of radiation dose.

Material:	A single batch of Amber 3042 Perspex cast polymethylmethacrylate sheets.
Dimensions:	30 mm x 11 mm. Thickness 3 ± 0.55 mm.
Measurement Reproducibility:	Coefficient of variation of specific absorbance measurements on sets of dosimeters from the batch, simultaneously irradiated together, in a radiation field uniform within $\pm 1\%$, is $\leq 2.5\%$ over the ranges 1 to 10 kGy at 603nm wavelength and 10 to 30 kGy at 651nm.
Calibration Quality:	Over the calibrated range, all mean specific absorbance data points are within 3% of a fourth-order polynomial least-squares fit to the data.
Traceability:	Harwell calibration is traceable to the UK standard of absorbed dose at the National Physical Laboratory (NPL). Calibration performance of each batch is verified by NPL inter-comparison.
Packaging:	Sealed in labelled sachets made of polyester/aluminium foil/polyester/ polythene laminate, packed 1000 per carton. Packing to defined AQL's checked to BS6001 (ISO 2859-1), single normal inspection, level II.

447 March Road
Ottawa, Ontario
K2K 1X8 Canada
www.mdsnordion.com
Tel: +1 613 592-2790
Fax: +1 613 592-637

CERTIFICATE OF CALIBRATION

Harwell Red Perspex Type 4034 Batch JT
Spectrophotometer Optizen 1412V (1v2102-069010-0118)
MDS Nordion's High-Range Ceric-Cerous Dosimeters Batch B2006
IR203, Soya, Korea **Order No. 203J111, Report No. 07-0547-1**

REFERENCE STANDARD DOSIMETERS MEASUREMENT RESULTS
MDS Nordion Reference Standard Measurements are contained in Report 07-0547 and summarized in this report.

ROUTINE DOSIMETERS MEASUREMENT RESULTS
Customer-supplied measurement data are found in Physics File F20308 and summarized in Report 05-0547-2.

Traceability Measurements

MDS Nordion's Dosimetry Laboratory is recognized under NIST's National Voluntary Laboratory Accreditation Program (NVLAP) for the calibration of routine dosimeters against Ceric-Cerous or Fricke reference-standard dosimeters.

NVLAP Code 200370-0

Calibration Method
The calibration was carried-out in accordance with ISO/ASTM 51261:2002 – Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing, ISO/ASTM 51707:2002 – Guide for Estimating Uncertainties in Dosimetry for Radiation Processing, and our internal procedure IN/OP 0554 DosLab IR000.

Calibration Results
The calibration report is found in this report.

Comment Section: The application of the results is the responsibility of the user, and care must be taken when interpolating the results.

Certificate Issued By:	Kevin O'Hara	Technical Manager (Title)	2007 Nov. 28 (Date)
Certificate Approved By:	Kevin O'Hara	Technical Manager (Title)	2007 Nov. 28 (Date)

This report shall not be reproduced except in full, without the written approval of MDS Nordion`s Dosimetry Laboratory. This report contains the results of dosimetry services performed by MDS Nordion and recognized by NVLAP. However, the customer cannot claim product endorsement by NVLAP, NIST or any agency of the U.S. federal government.

Comparison of Dosimetry Systems
Soya Company Order# N203J111
Optizen 1412F (1v2102-069010-0 28-Nov-07

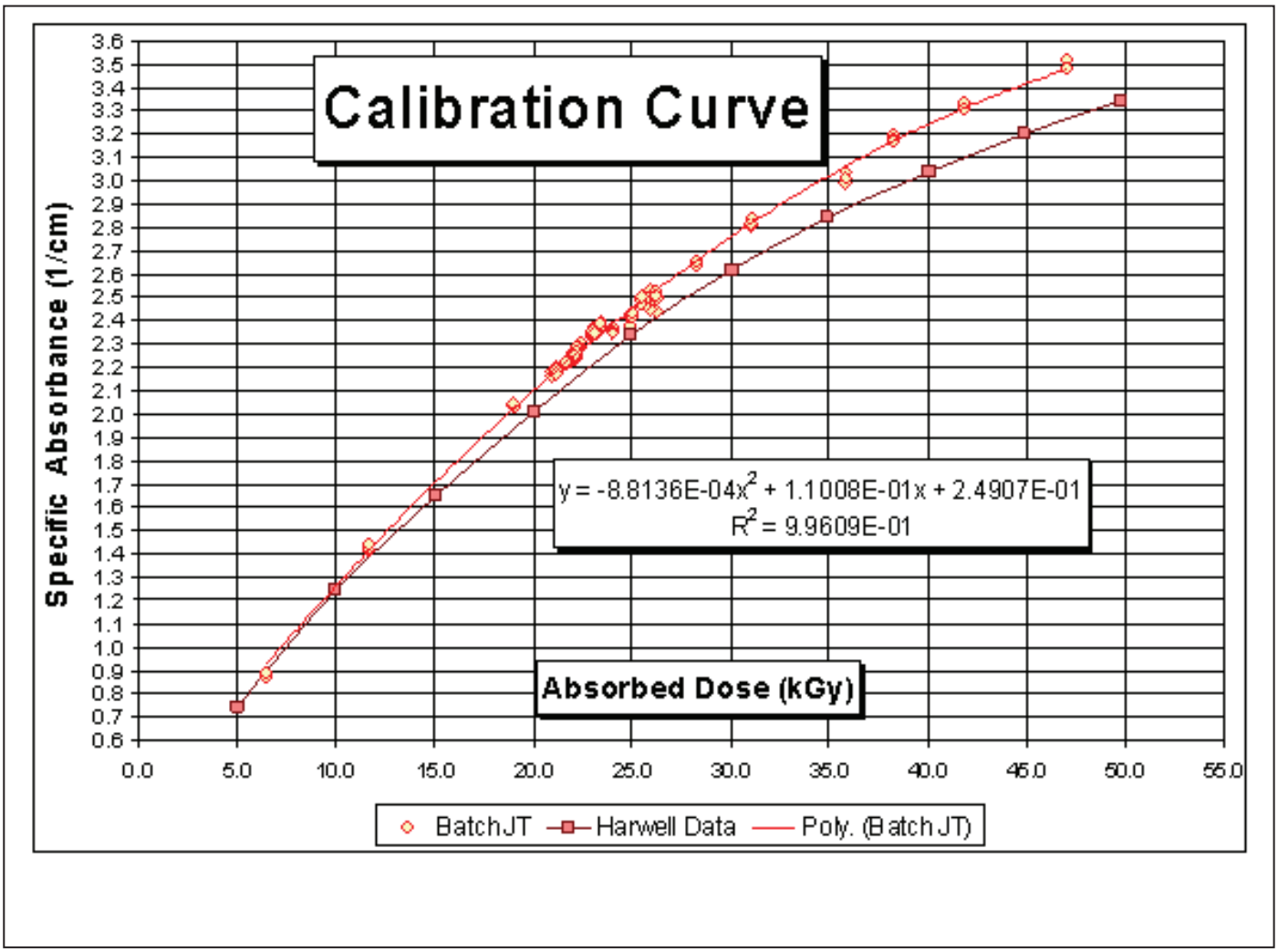
Dosimeter Package No.	Ceric-Cerous Dosimeters Batch B2006 Absorbed-dose Readings #1 (kGy)	#2 (kGy)	Average Reading (kGy)	Average Harwell Red Perspex Batch JT Specific Absorbance Measurement 1/cm	Harwell Red Perspex Batch JT Absorbed Dose (kGy)	Absorbed Dose Ratio Harwell Red Perspex /Ceric-Cerous
1	25.83	26.08	25.96	2.479	25.44	0.980
2	21.90	21.94	21.92	2.251	22.10	1.008
3	22.90	22.97	22.94	2.343	23.41	1.021
4	23.10	23.24	23.17	2.358	23.62	1.019
5	23.04	23.01	23.03	2.344	23.43	1.017
6	26.49	26.03	26.26	2.479	25.43	0.969
7	23.61	23.07	23.34	2.364	23.71	1.016
8	22.27	22.43	22.35	2.292	22.67	1.014
9	25.01	24.87	24.94	2.407	24.35	0.977
10	23.89	24.15	24.02	2.359	23.64	0.984
11	24.87	25.00	24.94	2.421	24.57	0.985
12	21.44	20.86	21.15	2.196	21.33	1.009
13	21.81	21.95	21.88	2.235	21.87	0.999
14	20.89	20.99	20.94	2.177	21.06	1.006
15	23.39	23.38	23.39	2.382	23.99	1.026
16	22.24	22.48	22.36	2.293	22.69	1.015
17	23.19	23.12	23.16	2.347	23.47	1.014
18	22.07	22.25	22.16	2.272	22.39	1.010
19	26.08	25.88	25.98	2.481	25.47	0.980
20	25.65	25.69	25.67	2.472	25.33	0.987
21	25.06	24.97	25.02	2.430	24.70	0.987
22	26.12	26.17	26.15	2.518	26.04	0.996
23	20.92	21.31	21.12	2.182	21.14	1.001
24	21.72	21.59	21.66	2.218	21.63	0.999
25	6.46	6.43	6.45	0.883	6.06	0.940
26	11.63	11.64	11.64	1.425	11.80	1.014
27	18.93	19.11	19.02	2.034	19.15	1.007
28	22.00	22.27	22.14	2.246	22.03	0.995
29	25.31	25.57	25.44	2.488	25.58	1.005
30	31.07	31.02	31.05	2.821	31.11	1.002
31	38.39	38.11	38.25	3.185	38.60	1.009
32	42.00	41.61	41.81	3.321	42.10	1.007
33	46.94	47.12	47.03	3.495	47.73	1.015
34	28.38	28.13	28.26	2.652	28.19	0.998
35	35.86	35.85	35.86	3.013	34.82	0.971
					Average	1.000
					Standard Deviation	0.018
					Coefficient of Variation (%)	1.8%

-8.8136E-04 (kGy)^2 + 1.1008E-01 (kGy) + (2.4907E-01 - Response (1/cm)) = 0

Quadratic equation was best fit based on F-Statistic.

Therefore, Dose (kGy) =

$$\frac{-1.1008E-01 + SQRT[(1.1008E-01^2 - 4 \times (-8.8136E-01 \times (2.4907E-01 - Response(1/cm))]}{2 \times -8.813E-04}$$



Soya Company

IR-203
Order# N203J111
28-Nov-07

Components of Uncertainty for the Calibration and Use of Routine Dosimeters Calibrated against Ceric-Cerous (mid-point of calibration range)		
Component of Uncertainty	Type A (%)	Type B (%)
1. Uncertainty in Ceric-Cerous Absorbed Dose (TR 9410 IR000)		1.80
2. Uncertainty in Curve Fitting (at 20 kGy)	0.56	
System Calibration: Type A and B combined in Quadrature	0.56	1.80
1. Uncertainties in Reading Specific Absorbance of One Routine Dosimeter	1.29	
2 Effects due to Different Irradiation Temperature, and Dose Rate from In-situ Calibration Conditions		1.50
Routine Use: Type A and Type B components combined in quadrature separately	1.29	1.50
Both Components combined in quadrature (One Standard Deviations)	2.73	
Both Components combined in quadrature (Two Standard Deviations)	5.5	

Soya Company

IR-203 28-Nov-07

Harwell Red Perspex Batch JT

Optizen 1412V (1v2102-069010-0118)

Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)
0.90	6.2	1.24	9.8	1.58	13.6	1.92	17.7
0.91	6.3	1.25	9.9	1.59	13.7	1.93	17.8
0.92	6.4	1.26	10.0	1.60	13.8	1.94	17.9
0.93	6.5	1.27	10.1	1.61	13.9	1.95	18.1
0.94	6.6	1.28	10.2	1.62	14.0	1.96	18.2
0.95	6.7	1.29	10.3	1.63	14.1	1.97	18.3
0.96	6.8	1.30	10.4	1.64	14.3	1.98	18.4
0.97	6.9	1.31	10.5	1.65	14.4	1.99	18.6
0.98	7.0	1.32	10.6	1.66	14.5	2.00	18.7
0.99	7.1	1.33	10.7	1.67	14.6	2.01	18.8
1.00	7.2	1.34	10.9	1.68	14.7	2.02	19.0
1.01	7.3	1.35	11.0	1.69	14.9	2.03	19.1
1.02	7.4	1.36	11.1	1.70	15.0	2.04	19.2
1.03	7.6	1.37	11.2	1.71	15.1	2.05	19.4
1.04	7.7	1.38	11.3	1.72	15.2	2.06	19.5
1.05	7.8	1.39	11.4	1.73	15.3	2.07	19.6
1.06	7.9	1.40	11.5	1.74	15.5	2.08	19.8
1.07	8.0	1.41	11.6	1.75	15.6	2.09	19.9
1.08	8.1	1.42	11.7	1.76	15.7	2.10	20.0
1.09	8.2	1.43	11.9	1.77	15.8	2.11	20.2
1.10	8.3	1.44	12.0	1.78	15.9	2.12	20.3
1.11	8.4	1.45	12.1	1.79	16.1	2.13	20.4
1.12	8.5	1.46	12.2	1.80	16.2	2.14	20.6
1.13	8.6	1.47	12.3	1.81	16.3	2.15	20.7
1.14	8.7	1.48	12.4	1.82	16.4	2.16	20.8
1.15	8.8	1.49	12.5	1.83	16.6	2.17	21.0
1.16	8.9	1.50	12.6	1.84	16.7	2.18	21.1
1.17	9.0	1.51	12.8	1.85	16.8	2.19	21.2
1.18	9.1	1.52	12.9	1.86	16.9	2.20	21.4
1.19	9.2	1.53	13.0	1.87	17.1	2.21	21.5
1.20	9.3	1.54	13.1	1.88	17.2	2.22	21.7
1.21	9.4	1.55	13.2	1.89	17.3	2.23	21.8
1.22	9.6	1.56	13.3	1.90	17.4	2.24	21.9
1.23	9.7	1.57	13.4	1.91	17.6	2.25	22.1

Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)	Specific Abs. 1/cm	Absorbed Dose (kGy)
2.26	22.2	2.60	27.3	2.94	33.4	3.28	41.0
2.27	22.4	2.61	27.5	2.95	33.5	3.29	41.2
2.28	22.5	2.62	27.7	2.96	33.7	3.30	41.5
2.29	22.6	2.63	27.8	2.97	33.9	3.31	41.8
2.30	22.8	2.64	28.0	2.98	34.1	3.32	42.1
2.31	22.9	2.65	28.2	2.99	34.3	3.33	42.3
2.32	23.1	2.66	28.3	3.00	34.5	3.34	42.6
2.33	23.2	2.67	28.5	3.01	34.7	3.35	42.9
2.34	23.4	2.68	28.7	3.02	35.0	3.36	43.2
2.35	23.5	2.69	28.8	3.03	35.2	3.37	43.5
2.36	23.7	2.70	29.0	3.04	35.4	3.38	43.8
2.37	23.8	2.71	29.2	3.05	35.6	3.39	44.1
2.38	24.0	2.72	29.3	3.06	35.8	3.40	44.4
2.39	24.1	2.73	29.5	3.07	36.0	3.41	44.7
2.40	24.2	2.74	29.7	3.08	36.2	3.42	45.1
2.41	24.4	2.75	29.9	3.09	36.4	3.43	45.4
2.42	24.5	2.76	30.0	3.10	36.7	3.44	45.7
2.43	24.7	2.77	30.2	3.11	36.9	3.45	46.1
2.44	24.8	2.78	30.4	3.12	37.1	3.46	46.4
2.45	25.0	2.79	30.6	3.13	37.3	3.47	46.8
2.46	25.1	2.80	30.7	3.14	37.6	3.48	47.2
2.47	25.3	2.81	30.9	3.15	37.8		
2.48	25.5	2.82	31.1	3.16	38.0		
2.49	25.6	2.83	31.3	3.17	38.2		
2.50	25.8	2.84	31.5	3.18	38.5		
2.51	25.9	2.85	31.6	3.19	38.7		
2.52	26.1	2.86	31.8	3.20	39.0		
2.53	26.2	2.87	32.0	3.21	39.2		
2.54	26.4	2.88	32.2	3.22	39.4		
2.55	26.5	2.89	32.4	3.23	39.7		
2.56	26.7	2.90	32.6	3.24	39.9		
2.57	26.9	2.91	32.8	3.25	40.2		
2.58	27.0	2.92	33.0	3.26	40.5		
2.59	27.2	2.93	33.2	3.27	40.7		

교 정(자체) 성 적 서
CERTIFICATE OF CALIBRATION

관 리 번 호(No.)	SYM-18		Page of pages	1 ~ 2
① 교 정 일 자 Date of Cal.	2012. 12. 21.		② 차 기 교 정 일 Recal. Date	2013. 12. 20.
③ 측 정 기 Cal. Subject	품 명 Description		공 칭 능 력 (Authorized Capacity)	제 작 회 사
	Master Timer		시간/분/초(hour/min/sec)	MDS Nordion
④ 교 정 환 경 Environment	온 도 Temperature	20±1℃	습 도 Humidity	30 % RH

⑤ 교정에 사용한 기준기의 소급성
(Calibration Traceability)

본 교정에 사용한 교정용 STOP WATCH의
제원과 교정성적서는 성적서번호 "11-2552-1280-1의 교정성적서" 참조.
(Please refer certificate number 11-2552-1280-1 that stop watch used to calibration.)

⑥ 교 정 결 과 Calibration Resul	"교정결과표" 참조 : (page 2) (Reference to Calibration results : page 2)

확 인 Affirmation	작성자(Measurements performed by) 성 명 : 심 현 철 (인)	승인자(Approved by) 성 명 : 이 규 영 (인)

위 교정결과는 성적서번호 "11-2552-1280-1의 교정성적서"가 확립된 STOP WATCH로 교정한 성적서임을 증명합니다.
(The calibration results that is calibrate by certificate number 11-2552-1280-1 stop watch proves certificate.)
이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(물리적 손상, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.
(This Certificatioin is invalid under sudden change of voltage, temperature, humidity that affect subjected instrument precision.)

Technology for better life!
SOYAGREENTEC

교 정 결 과
Calibration Resul

Master Time set		시간(h)	분(m)	초(s)′
		00	04	40
Master Timer 비교 측정 (STOP WATCH)	1회	00	04	40'13
	2회	00	04	40'07
	3회	00	04	40'19
	Average	00	04	40'13

Overdose Time set		시간(h)	분(m)	초(s)′
		00	04	50
Overdose Time 비교 측정 (STOP WATCH)	1회	00	04	50'03
	2회	00	04	50'16
	3회	00	04	50'10
	Average	00	04	50'09

Research Time set	시간(h)	분(m)	초(s)′
	01	00	00
Research Time 비교 측정 (STOP WATCH)	01	00	01′25

확인 Affirmation	작성자 (Measurements performed b	승인 (Approved by)
	성명 : 심 현 철 (인)	성명 : 이 규 영 (인)

교 정 성 적 서

CALIBRATION CERTIFICATE

한국산업기술시험원

경기도 안산시 상록구 사동 1271-12

TEL : 031) 500-0251 FAX : 031) 500-0268

성적서 번호 : 11-2552-1280-1
Certificate No.

KOREA LABORATORY ACCREDITATION SCHEME KOLAS CALIBRATION NO.028

1. 의 뢰 자 (Client)

기 관 명 (Name) : (주)소아그린텍

주 소 (Address) : 경기도 화성시 향남면 상신리 900-3

2. 측 정 기 (Calibration Subject)

기 기 명 (Description) : Time interval meters/Stop watches (Stop Watch)

제작회사 및 형식 (Manufacturer and Model Name) : KENKO (KK-5853)

기 기 번 호 (Serial Number) : NONE

3. 교정일자 (Date of Calibration) : 2011년 11월 17일

4. 교 정 환 경 (Environment)

온 도 (Temperature) : (23.1 ± 0.3) ℃ 상대습도 (Relative Humidity) : (48 ± 2) % R.H.

교정장소 (Location) : ▣고정표준실 (KTL Lab.) □이동교정(Mobile Lab.) □현장교정 (On Site Calibration)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and/or brief description) :

위의 기기는 시간 간격 측정기 및 초시계의 표준교정절차(CP801-30106-1, KTL)에 따라 국가측정표준대표기관으로부터 소급성이 유지된 표준기를 사용하여 교정 되었음.

교정에 사용한 표준장비 명세 (List of used standards/specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and model	기기번호 Serial Number	교정유효일자 Calibration valid until	교정기관 Calibration Laboratory
Stop Watch Calibrator	Witschi / Q test 6000	3582	2012. 03. 08.	한국산업기술시험원

6. 교 정 결 과 (Calibration Results) : 교정결과 참조

7. 측정불확도 (Measurement Uncertainty) : 교정결과참조

확 인 (Affirmation)	작성자 (Measurements performed by)	승인자 (Approved by)
	성 명 (Name) : 김 경 룡	직 위 (Title) : 기술책임자 성 명 (Name) : 장 재 림

위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정 (Mutual Recognition Arrangement) 에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

(The above calibration certificate is the accredited calibration items by Korea Laboratory Accreditation Scheme, which signed the ILAC-MRA.)

2011 년 11 월 17 일

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

한국산업기술시험원장

Korea Testing Laboratory

(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과
CALIBRATION RESULTS

경기도 안산시 상록구 사동 1271-12
TEL : 031) 500-0251 FAX : 031) 500-0268
E-mail : kimkr@wm.ktl.re.kr

성 적 서 번 호 : 11-2552-1280-1
Certificate No.

◇ 기 기 명 : Time interval meters/Stop watches (Stop Watch)

◇ 제작회사 및 형식 : KENKO (KK-5853)

◇ 기 기 번 호 : NONE

* 오차 (3.08 ± 0.009) s / d (신뢰수준 약 95 %, k=2)

* 여기서, 앞의 숫자는 오차, 뒤의 숫자는 불확도를 나타낸 것이다.
예) (0.23 ± 0.011) s/d
즉, 1일(86 400초)동안의 오차는 0.23 초이고, 불확도는 0.011 초 이다. 끝.

◇ 국가교정기관지정제도 운영요령 제 41조 관련주기 : 24개월

CERITIFICATE OF CALIBRATION

교정 성적서 – 자체

관리번호(No.)	SYM – 27	Page of pages	1 – 3
교정일자 (Date of Calibration)	2012. 12. 21.	차기교정일자 (Date of next calibration)	2013. 12. 20.
측정기기 (Calibration subject)	기기명(Description)	공칭능력 (Authorized Capacity)	5kg ~ 150 kg
	전기식 지시저울 (Electronic reading scale)	제작회사 (Manufacturer)	대림이시다
교정환경 (Environment)	온도(Temperature) : 20±1 ℃ 습도(Humidity) : 30%		

교정에 사용한 기준기의 소급성(Calibration Traceability)

*본 교정에 사용한 교정용 표준분동은 ㈜한국파마와 시험시설 및 기구공용 승인서 내용에 따라 사용한 것임.

*교정에 사용한 표준분동은 교정된 전기식 지시저울을 이용한 것이며, 전기식 지시저울의 제원과 교정결과는 교정번호 'SCT11-0034-25의 교정석적서' 참조.

(Please refer certificate number 'SCT11-0034-25' that Standard weights used to calibrate to Electronic reading scale.)

교정결과 (Calibration results)	Page2의 '교정결과표' 참조 (Reference to Calibration Results)	
확인(Affirmation)	작성자(Measurements performed by) 심 현 철(Sim Hyunchul) (인)	승인자(Approved by) 문 현 수(Moon Hyunsoo) (인)

*위 교정결과는 교정번호 'SCT11-0034-25'의 교정성적서'가 확립된 전기식 지시 저울로 교정한 분동을 이용한 성적서임을 증명한다.

(The calibration results that is calibrate by both certificate number 'SCT11-0034-25' Standard Weights proves certificate.)

*이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(물리적인 손상, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 된다.

(This certification is invalid under sudden change of voltage, temperature, humidity that affect subjected instrument precision.)

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교정결과 Calibration Result

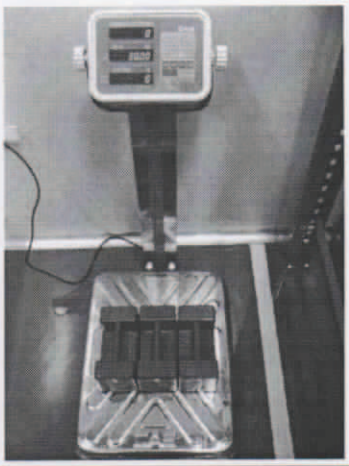
관리번호 : SYM – 27

표준분동(kg)	측정값(kg)	오차값(kg)
10	10.0	0
20	20.0	0
30	20.0	0

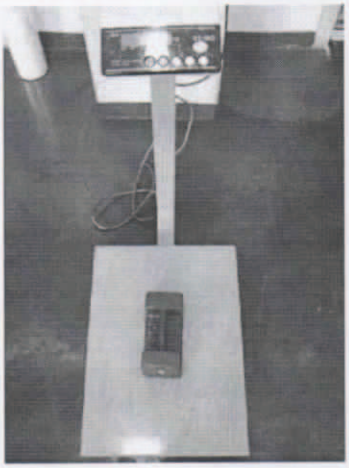
END

교정결과 Calibration Result

교정 받은 저울을 이용한 표준분동 측정.

분동 무게	10 kg	20 kg	30kg
사진			
측정 무게	10.00 kg	20.00 kg	30.00 kg

표준분동을 이용한 SYM-027 전기식 지시저울 측정.

분동 무게	10 kg	20 kg	30 kg
사진			
측정 무게	10.00 kg	20.00 kg	30.00 kg

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교 정 성 적 서

스 케 일 테 크 (주) 인천광역시 부평구 청천동 425-1 Tel : 032-527-2101 , Fax : 032-527-7649	성적서번호 : SCT11-0034-25 페이지 (1) / (총 2)	KOLAS CALIBRATION NO. 320

1. 의 뢰 자
   기 관 명 : ㈜한국과라
   주 소 : 경기도 화성시 향남면 상신리 907-9

2. 측 정 기
   기 기 명 : 분동 [illegible]
   제작회사 및 형식 : 교정결과 참조
   기 기 번 호 : 교정결과 참조

3. 교정일자 : 2011년 2월 10일

4. 교정환경
   온 도 : (20.0 ± 0.9) ℃ 상 대 습 도 : (42 ± 2) % R.H.
   교 정 장 소 : ▣ 고정표준실 □ 이동교정 □ 현장교정

5. 측정표준의 소급성
   교정방법 및 소급성 서술
   위 기기는 분동의 교정절차(SCT-CI-M08)에 따라 국가측정표준대표기관(KRISS)으로부터 소급성이 유지된 아래의 표준장비를 이용하여 교정되었음.

   교정에 사용한 표준장비 명세

사용장비명	제작사 및 형식	기기번호	교정유효일자	교정기관
표준분동	HAFNER E_2 급	1380903	2011.06.19.	한국기기유화시험연구원
전기식저시저울	Sartorius BP210D	51010572	2011.05.17.	인천산업계기(주)
전기식저시저울	Sartorius LC1201S	51007400	2011.05.17.	인천산업계기(주)
전기식저시저울	Sartorius LC6201S	51012519	2011.05.17.	스케일테크㈜
전기식저시저울	Sartorius C30000	37040002	2011.05.17.	인천산업계기(주)

6. 교정결과 : 교정결과 참조

7. 측정불확도 : 교정결과 참조

확 인	작 성 자 성 명 : 심 평 강 (서명)	승 인 자 직 위 : 기술책임자 (정, 부) 성 명 : 명 노 천 (서명)

위 성적서는 국제시험기관인정협력체 (International Laboratory Accreditation Cooperation)상호인정협정 (Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 항목의 교정결과입니다.

2011년 2월 15일

한국인정기구 인정

스 케 일 테 크 (주) 대 표 이 사

(주) 이 성적서는 측정기의 정밀 정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다.

교 정 결 과

스 케 일 테 크 (주)
인천광역시 부평구 청천동 425-1
Tel : 032-527-2101 , Fax : 032-527-7640

성적서번호 : SCT11-0034-25

■ 형식 : 10 kg ~ 200 g

■ 교정값

기기번호	이름값	상용질량값 g	보정값 g	확장불확도 mg
9407	10 kg	10 000.03	0.03	15
9407	5 kg	4 999.99	−0.01	14
9407	2 kg	2 000.00	0.00	15
9407-1	1 kg	999.998	−0.002	2.5
9407-2		1 000.000	0.000	2.6
9407	500 g	499.999	−0.001	2.5
9407-1	200 g	199.999 7	−0.000 3	0.20
9407-2		199.999 7	−0.000 3	0.23

* 신뢰수준 약 95 %, $k=2$

* 상용질량값: 기준온도 20 ℃에서 공기밀도가 1.2 kg/m³ 이고 분동의 밀도를 8 000 kg/m³로 가정한 분동의 질량값. −끝−

※ 자체 설정주기를 따름.

Attachment 10.

Irradiator dose mapping report

관 리 본(Archive)	V
비관리본(Non-archive)	

작성일자(Writed date) : 2003-08-04

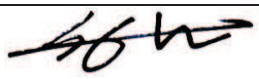
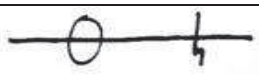
원안부서(Original department) : 품질허가팀(Quality licensed team)

관리부서(Administration department) : 품질허가팀(Quality licensed team)

조사기 도즈 맵핑 보고서

Irradiator Dose Mapping Report

(2012 Year)

구분 Class	작성 Researcher	검토 Review	승인 Approval
부서 Department	품질허가팀 Quality licensed Team	품질허가팀 Quality licensed Team	품질관리경영대리인 Q.M.R
인원 Person	Sim Hyun-chul	Park Jae-jeong	Kim Ki-hwan
서명 Signature			
일자 Date	Nov. 12. 2012.	Nov. 12. 2012.	Nov. 12. 2012.

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1. 적용범위(Scope)

본 보고서는 EN/ISO 11137 제1부 및 제2부, 3부의 조사기 도즈맵핑 관련 요구사항에 대한 지침의 요건을 제공한다.

적법하게 훈련된 판정 및 검증된 인원으로 본 보고서를 정확하게 실행 해야 한다.

(This report of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to irradiation dose mapping. The party accepting responsibilities for defined elements is required to assign these elements to competent personnel, with competence demonstrated through appropriate training and qualification.)

2. 목적(Purpose)

㈜소야그린텍의 감마선 조사설비에 대해 선원의 감쇠로 인한 흡수선량의 변화를 확인하며, 시공사(MDS-Nordion)에서 제공한 “Timer Setting Table”과 흡수선량 및 밀도와의 관계에 따른 적합성을 확인하여, 조사기(Model:JS-10000)의 설치 품질을 유지함을 목적으로 한다.

(Change of absorbed dose due to source attenuation after Gamma irradiator of Soyagreentec Co.,Ltd. shall be confirmed. Suitability in conformity to the "Timer Setting Table" provided by Contractor(MDS-Nordion) and the relationship between absorbed dose and density determine. So Installation qualification of irradiator is aim at maintaining.)

3. 용어와 정의(Terms and definitions)

3.1 흡수 선량(absorbed dose), 선량(dose)

물질의 단위 질량에 전달된 방사능 에너지의 양

(Quantity of ionizing radiation energy imparted per unit mass of a specified material).

3.2 선량 표 작성(dose mapping)

정해 놓은 조건에서 조사한 선량의 피 조사 체는 내 분포와 변화의 측정

(Measurement of dose distribution and variability in material irradiated under defined conditions).

3.3 선량 계(dosimeter)

방사선에 대하여 재현성이 있고 측정 가능한 반응을 하는 특정 물질에 대한 흡수선량 측정에 사용하는 기기

(Device having a reproducible, measurable response to radiation, which can be used to measure the absorbed dose in a given system).

3.4 선량계측(dosimetry)

선량 계를 사용한 흡수선량의 측정

(Measurement of absorbed dose by the use of dosimeters)

3.5 가동품질인정(Operation qualification:OQ0029)

4. 일반사항(General)

OQ의 목적은 설치된 방사선 조사기가 정해진 허용 범위 내에서 가동하고 알맞은 선량을 전달하는지 확인하기 위한 것이다. 이것은 선량표 작성 과정을 통한 선량 분포의 측정과 그 분포를 가공 변수에 적용하여 달성한다.

(The purpose of OQ is to demonstrate that the irradiator, as installed, is capable of operating and delivering appropriate doses within defined acceptance criteria. This is achieved by determining dose distributions through dose mapping exercises and relating these distributions to process parameters.)

5. 시험계획(Test plan)

5.1 설비 및 계측기(Equipments and measuring instruments)

5.1.1 조사기 시설(Irradiation equipment) : JS-10000

5.1.2 버니어켈리퍼스(Vernier calipers) : Mitutoyo : Model / 08608853 : Serial Number)

5.1.3 분광광도계(Spectro photometer) : Optizen1412V : Model / 1V2244-097016-00 : Serial Number)

5.2 준비 재료(Preparation materials)

5.2.1 골판지(Corrugated Cardboard)

크기(Size) : 가로(Width):830mm, 세로(Length):0.7mm, 높이(Height):1,500mm

수량(Quantity):210개, 단위중량(Weight):1kg

5.2.2 전분(Starch)

수량(Quantity):30개, 단위중량(Weight):20kg

5.2.3 조사용기(Tote)

1~55번

5.3 시험기간(Test period)

재 료 명(Materials)	시 험 기 간(Test period)	비 고(note)
골 판 지 (Corrugated Cardboard)	2012. 11. 02. ~ 2012. 11. 03.	최저밀도 (minimum density)
	2012. 11. 03. ~ 2012. 11. 04.	공정중지 적용 (process interruption applied)

전 분 (Starch)	2012. 11. 09. ~ 2012. 11. 10.	최고밀도 (maximum density)
	2012. 11. 10. ~ 2012. 11. 11.	공정중지 적용 (process interruption applied)

5.4 시험기준(Test standard)

5.4.1 OQ에서의 선량표 작성은 방사선 조사기의 선량 분포와 재현성에 대한 특성화 및 공정중지가 선량에 미치는 영향을 설정하기 위한 것이다. 선량표 작성은 균질한 밀도를 가진 재료를 설계한도까지 적재한 조사 용기 내에 선량계를 놓고 실시하여야 한다. 이때 밀도는 조사기를 사용할 밀도범위 내에 속하여야 한다. 최소한 두 차례 선량표 작성을 하여야 하고, 한번은 조사기를 사용할 예정인 밀도 범위의 최저 한계, 또 한번은 최고 한계에 근접해서 실시한다.

(Dose mapping for OQ is carried out to characterize the irradiator with respect to the distribution and reproducibility of dose and to establish the effect of process interruption on dose. Dose mapping should be performed by placing dosimeters in an irradiation container filled to its design limits with material of homogeneous density. This density should be within the density range for which the irradiator is to be used. At least two dose mapping exercises should be carried out, one with material close to the lower limit of the density range for which the irradiator is intended to be used and another with material close to the upper limit of this range.)

5.4.2 조사 용기 사이에서의 선량의 다양성의 선량 분포를 측정할 수 있도록, 각각 선택한 밀도에서 충분한 개수의 조사 용기 (적어도 3개)에 대해 선량표 작성을 하여야 한다.

(A sufficient number of irradiation containers (at least three) should be dose mapped at each chosen density to allow determination of variability of dose and dose distribution between containers.)

5.4.3 개별 선량계, 선량계는 조사 용기 전체 부피에 걸쳐 선량 분포를 측정하고 결정할 수 있도록 3차원적으로 배치하여야 한다.

(Individual dosimeters, dosimeter strips or dosimeter sheets should be placed in a three-dimensional array sufficient to determine and resolve the dose distribution throughout the entire volume of the irradiation container.)

5.4.4 공정 중지의 영향을 확인하기 위해 별도의 선량표 작성 또는 운반 선량(transit – dose) 계산을 실시하여야 한다. 운반 선량 계산이 적당하였는지는 선량계측으로

확인하여야 한다. 이는 조사 용기에 선량계 또는 선량계 박막을 위의 방법으로 설치하고, 선원 이동에 의해 선량이 가장 크게 영향을 받을 것으로 예상되는 곳에 있는 선원에 조사 용기가 근접했을 때 공정을 방해하는 방법을 통해 이루어 질 수 있다. 공정 중지의 영향은 정상 공정 조건에서 작성한 선량표의 결과를 비교하여 평가한다. 그 영향을 정확하게 평가하기 위하여 공정 중지를 수 차례 실시할 필요가 있다.

(A separate dose mapping exercise should be carried out or a calculation of transit dose performed in order to assess the effect of process interruption. The appropriateness of calculations of transit dose should be verified by dosimetry. This exercise can be done through irradiating a container having dosimeters or dosimeter strips located as described above, and interrupting the process when the container is close to the source where dose is expected to be most influenced by source transit. The effect of process interruption is evaluated by comparing the results with those of dose mapping exercises carried out under normal process conditions. It might be necessary to interrupt the process multiple times in order to evaluate accurately the effect.)

6. 시험방법(Test method)

6.1 최저밀도 시험(minimum density test) : 골판지(Corrugated Cardboard)

6.1.1 마스터 타이머를 4분 37초로 설정한다. (Master timer setting : 04 m 37 sec)

6.1.2 2번, 15번, 45번 토트에는 골판지 70개씩 적재한다. 그 외 토트는 빈상태로 둔다. (70 per Tote No.2, No.15 and No.45 for each Corrugated cardboard. The others are empty.)

6.1.3 2, 15, 45번 토트에는 상, 중, 하 부위에 3차원으로 총 27개의 도시메터를 부착한다. (Dosimeters should be placed in a three dimensional array, including the surface, of the test material to be irradiated. The dosimeters should be sufficient in number to measure the dose distribution throughout the entire volume of the irradiation container.)

6.1.4 총 6바퀴의 공정을 거친 후 도시메터를 수거하여 흡수선량을 판독한다. (Process is progressed 6 cycle, and dosimeters(absorbed dose) readout.)

6.2 최고밀도 시험(maximum density test) : 전분(Starch)

6.2.1 마스터 타이머를 4분 37초로 설정한다.(Master timer setting : 04 m 37 sec)

6.2.2 1번, 15번, 45번 토트에는 골판지 70개씩 적재한다. 그 외 토트는 빈상태로 둔다. (70 per Tote No.1, No.15 and No.45 for each Starch. The others are empty.)

6.2.3 1, 15, 45번 토트에는 상,중,하 부위에 3차원으로 총 27개의 도시메터를 부착한다.
(Dosimeters should be placed in a three dimensional array, including the surface, of the test material to be irradiated. The dosimeters should be sufficient in number to measure the dose distribution throughout the entire volume of the irradiation container.)

6.2.4 총 6바퀴의 공정을 거친 후 도시메터를 수거하여 흡수선량을 판독한다.
(Process is progressed 6 cycle, and dosimeters(absorbed dose) readout.)

6.3 공정 중지의 영향을 확인하는 시험(Test for confirm to influence of process interruption)

6.3.1 6.1항 및 6.2항 방법과 같이 준비하여 시험을 한다(1토트만 평가).
(See 6.1, 6.2. and evaluate 1 tote)

6.3.2 6바퀴 공정 중 각 바퀴마다 1시간의 공정 정지를 실시한다.
(Process interruption of 1 hour per 1cycle during 6 cycle.)

6.3.3 총 6바퀴의 공정을 거친 후 도시메터를 수거하여 흡수선량을 판독한다.
(Process is progressed 6 cycle, and dosimeters(absorbed dose) readout.)

7. 시험결과(Test results)

7.1 최저밀도 시험(골판지) 결과(minimum density test results)

Tote No	최소선량 (Minimum dose:kGy)	위치 (Location)	최대선량 (Maximum dose:kGy)	위치 (Location)
2	28.5	M5	33.0	M8
15	28.5	M5	33.2	M8
45	28.5	M5	32.8	M8

참조(Reference) : 첨부 1(Attachment 1)

7.2 공정 중지의 영향을 확인하는 시험(골판지) 결과

(Test results for confirm to influence of process interruption : Corrugated Cardboard)

Tote No	최소선량 (Minimum dose:kGy)	위치 (Location)	최대선량 (Maximum dose:kGy)	위치 (Location)
2	28.2	M5	32.8	M8
-	-	-	-	-

참조(Reference) : 첨부 2(Attachment 2)

7.3 최고밀도 시험(전분) 결과(maximum density test results)

Tote No	최소선량 (Minimum dose:kGy)	위치 (Location)	최대선량 (Maximum dose:kGy)	위치 (Location)
1	20.4	M5	30.9	M8
15	20.6	M5	30.9	M8
45	20.6	M5	31.1	M8

참조(Reference) : 첨부 3(Attachment 3)

7.4 공정 중지의 영향을 확인하는 시험(전분) 결과

(Test results for confirm to influence of process interruption : Starch)

Tote No	최소선량 (Minimum dose:kGy)	위치 (Location)	최대선량 (Maximum dose:kGy)	위치 (Location)
1	20.6	M5	30.9	M8
-	-	-	-	-

참조(Reference) : 첨부 4(Attachment 4)

8. 판정(Decisions)

2가지 기준으로 최소밀도, 최대밀도로 시험을 실시하였고, 공정중지의 변수를 두고 시험을 실시하였다. 즉, EN/ISO 11137-3:2006 규격의 지침을 적용한 시험결과는 적합으로 판단되며, 얻어진 선량표 데이터는 실제 제품 적재 시 최대 및 최소 선량을 제공 가능한 위치에 대해 유용한 정보로 사용할 수 있다.

(Test for minimum density, maximum density, variable of process interruption. EN / ISO 11137-3:2006 standard guidelines applied test result is suitable, data from dose mapping exercises will often provide useful indication of the probable locations of maximum and minimum doses in actual product loads.)

9. 교정주기(Test period)

교정 주기는 1년 이하이며, 차기 교정 일자는 2012년 11월 12일 이전이다.

(Less than 1 year calibration period, the next calibration period before the November 12, 2012.)

단, 차기 교정일 내에 Co-60이 추가 충전이 되었을 경우 재 실시 한다.

(However irradiation dose mapping is re-calibration when Cobalt 60 is re-charging before next calibration period.)

10. 참고문헌(References)

10.1 EN ISO 11137-1, 보건·의료 멸균-방사선-제1부: 의료기기 멸균방법의 작업명세서 작성, 검정 및 일상관리 요구사항
(Sterilization of health care products –Radiation– Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices)

10.2 EN ISO 11137-2, 보건·의료 멸균-방사선-제2부: 멸균선량의 설정
(Sterilization of health care products –Radiation– Part 2 : Establishing the sterilization dose)

10.3 EN ISO 11137-3, 보건·의료 멸균-방사선-제3부: 선량 계측 지침서
(Sterilization of health care products –Radiation– Part 3 : Guidance on dosimetric aspects)

첨부 1(Attachment 1)

최저밀도 시험(골판지) 결과
(Minimum density test results : Corrugated Cardboard)

(Attachment 3-1)

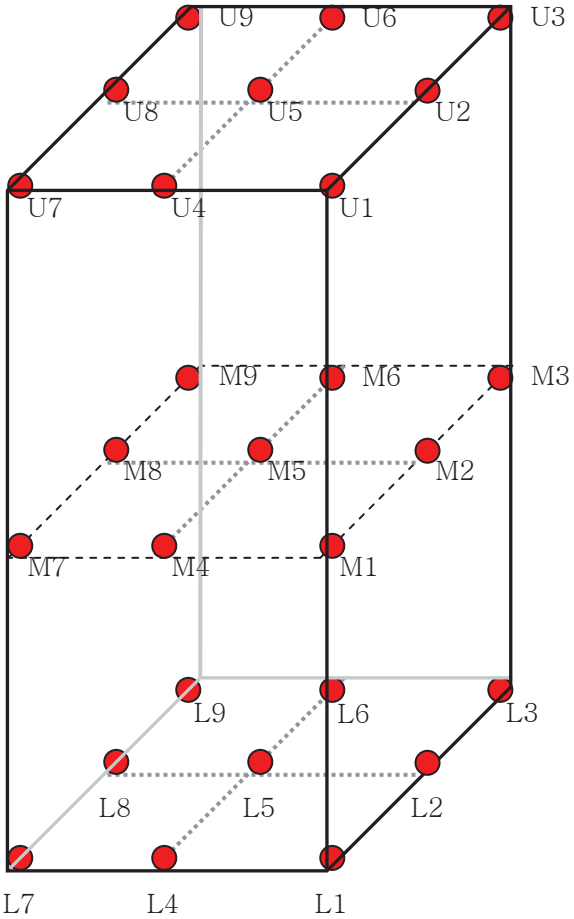
조사기 선량 계획표
Irradiator Dose Mapping

Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 05. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Corrugated Cardboard(골판지)	조사실 온도 (Temperature)	: 15.0 ℃
단위중량(Weight)	: 1 kg	조사실 습도(Humidity)	: 25.0 %
적재수량 (Loading Quantity)	: 70 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 70 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.1 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 2



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.806	0.278	2.90	32.6
	U-2	0.801	0.277	2.89	32.4
	U-3	0.858	0.297	2.89	32.4
	U-4	0.791	0.295	2.68	28.7
	U-5	0.815	0.304	2.68	28.7
	U-6	0.888	0.330	2.69	28.8
	U-7	0.919	0.317	2.90	32.6
	U-8	0.824	0.285	2.89	32.4
	U-9	0.899	0.311	2.89	32.4
Middle	M-1	0.960	0.330	2.91	32.8
	M-2	0.911	0.313	2.91	32.6
	M-3	0.821	0.283	2.90	32.6
	M-4	0.772	0.288	2.68	28.7
	M-5	0.748	0.280	2.67	28.5
	M-6	0.742	0.277	2.68	28.7
	M-7	0.966	0.332	2.91	32.8
	M-8	0.788	0.270	2.92	33.0
	M-9	0.879	0.302	2.91	32.8
Lower	L-1	0.795	0.275	2.89	32.4
	L-2	0.861	0.297	2.90	32.6
	L-3	0.835	0.289	2.89	32.4
	L-4	0.842	0.314	2.68	28.7
	L-5	0.726	0.270	2.69	28.8
	L-6	0.777	0.289	2.69	28.8
	L-7	0.829	0.286	2.90	32.6
	L-8	0.934	0.322	2.90	32.6
	L-9	0.844	0.292	2.89	32.4
Max. Dose		0.788	0.270	2.92	33.0
Min. Dose		0.748	0.280	2.67	28.5

Difference	Average Dose	Tote No
4.5	31.3	2

(Attachment 3-1)

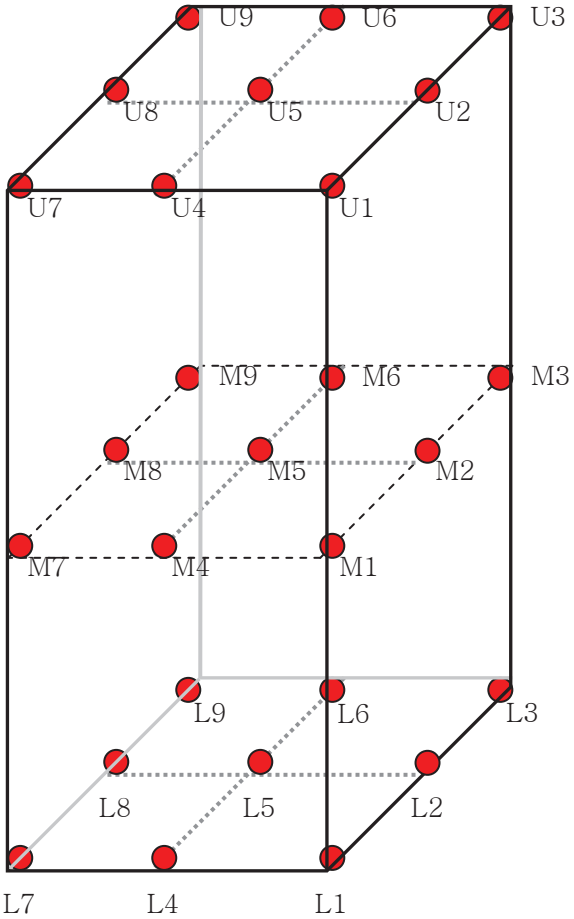
조사기 선량 계획표
Irradiator Dose Mapping

Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 05. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Corrugated Cardboard(골판지)	조사실 온도 (Temperature)	: 15.0 ℃
단위중량(Weight)	: 1 kg	조사실 습도(Humidity)	: 25.0 %
적재수량 (Loading Quantity)	: 70 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 70 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.1 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 15



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.806	0.279	2.89	32.4
	U-2	0.922	0.320	2.88	32.2
	U-3	0.953	0.331	2.88	32.2
	U-4	0.853	0.317	2.69	28.8
	U-5	0.820	0.305	2.69	28.8
	U-6	0.729	0.270	2.70	29.0
	U-7	0.925	0.320	2.89	32.4
	U-8	0.853	0.295	2.89	32.4
	U-9	0.896	0.311	2.88	32.2
Middle	M-1	0.815	0.282	2.89	32.4
	M-2	0.876	0.301	2.91	32.8
	M-3	0.957	0.330	2.90	32.6
	M-4	0.793	0.296	2.68	28.7
	M-5	0.822	0.308	2.67	28.5
	M-6	0.753	0.282	2.67	28.5
	M-7	0.861	0.296	2.91	32.8
	M-8	0.820	0.280	2.93	33.2
	M-9	0.969	0.332	2.92	33.0
Lower	L-1	0.858	0.296	2.90	32.6
	L-2	0.786	0.270	2.91	32.8
	L-3	0.928	0.320	2.90	32.6
	L-4	0.882	0.329	2.68	28.7
	L-5	0.775	0.289	2.68	28.7
	L-6	0.753	0.280	2.69	28.8
	L-7	0.972	0.335	2.90	32.6
	L-8	0.911	0.314	2.90	32.6
	L-9	0.818	0.282	2.90	32.6
Max. Dose		0.820	0.280	2.93	33.2
Min. Dose		0.822	0.308	2.67	28.5

Difference	Average Dose	Tote No
4.7	31.3	15

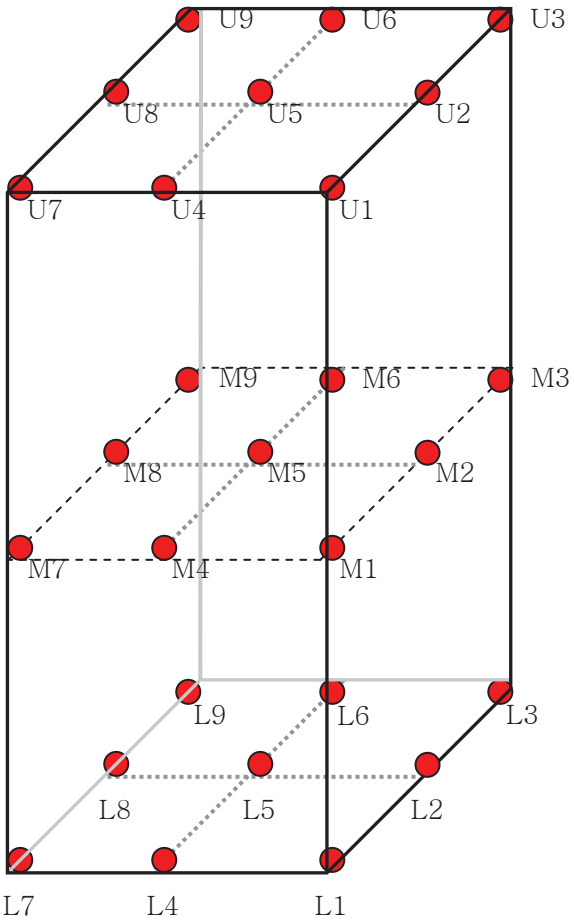
(Attachment 3-1)

조사기 선량 계획표 Irradiator Dose Mapping		Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 05. 2012.	측 정 자(Tester)	: Sim Hyun -chul
견본물질(Product)	: Corrugated Cardboard(골판지)	조사실 온도 (Temperature)	: 15.0 ℃
단위중량(Weight)	: 1 kg	조사실 습도(Humidity)	: 25.0 %
적재수량 (Loading Quantity)	: 70 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 70 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.1 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 45



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.942	0.326	2.89	32.4
	U-2	0.887	0.307	2.89	32.4
	U-3	0.959	0.333	2.88	32.2
	U-4	0.847	0.315	2.69	28.8
	U-5	0.882	0.328	2.69	28.8
	U-6	0.864	0.320	2.70	29.0
	U-7	0.850	0.294	2.89	32.4
	U-8	0.798	0.277	2.88	32.2
	U-9	0.792	0.276	2.87	32.0
Middle	M-1	0.786	0.271	2.90	32.6
	M-2	0.890	0.308	2.89	32.4
	M-3	0.855	0.296	2.89	32.4
	M-4	0.849	0.318	2.67	28.5
	M-5	0.782	0.293	2.67	28.5
	M-6	0.874	0.326	2.68	28.7
	M-7	0.963	0.332	2.90	32.6
	M-8	0.899	0.309	2.91	32.8
	M-9	0.844	0.293	2.88	32.2
Lower	L-1	0.965	0.334	2.89	32.4
	L-2	0.936	0.324	2.89	32.4
	L-3	0.881	0.305	2.89	32.4
	L-4	0.826	0.307	2.69	28.8
	L-5	0.783	0.291	2.69	28.8
	L-6	0.815	0.303	2.69	28.8
	L-7	0.803	0.278	2.89	32.4
	L-8	0.821	0.284	2.89	32.4
	L-9	0.870	0.300	2.90	32.6
Max. Dose		0.899	0.309	2.91	32.8
Min. Dose		0.782	0.293	2.67	28.5

Difference	Average Dose	Tote No
4.3	31.2	45

첨부 2(Attachment 2)

공정 중지의 영향을 확인하는 시험(골판지) 결과
(Test results for confirm to influence of process interruption : Corrugated Cardboard)

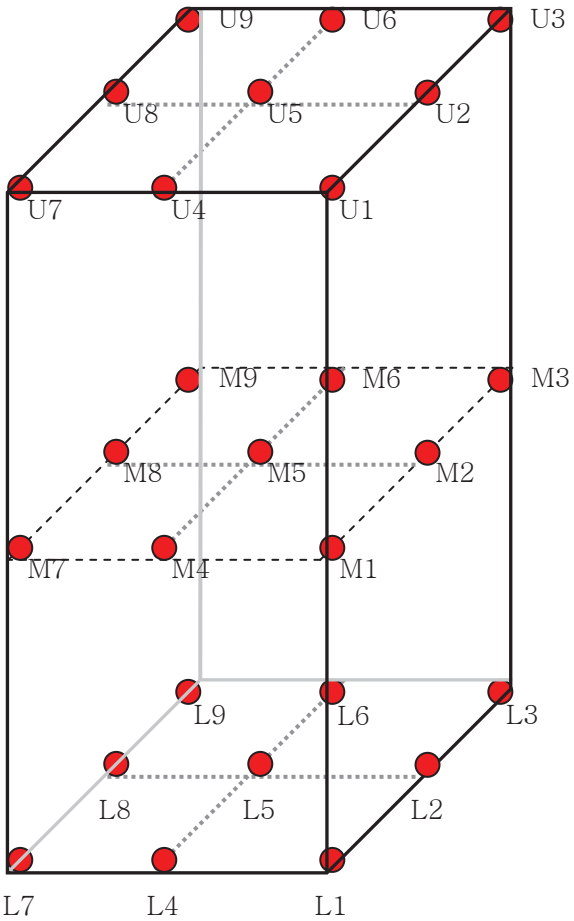
(Attachment 3-1)

조사기 선량 계획표 Irradiator Dose Mapping		Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 05. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Corrugated Cardboard(골판지)	조사실 온도 (Temperature)	: 15.0 ℃
단위중량(Weight)	: 1 kg	조사실 습도(Humidity)	: 25.0 %
적재수량 (Loading Quantity)	: 70 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 70 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.1 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 2



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.873	0.302	2.89	32.4
	U-2	0.864	0.298	2.90	32.6
	U-3	0.887	0.307	2.89	32.4
	U-4	0.866	0.323	2.68	28.7
	U-5	0.847	0.315	2.69	28.8
	U-6	0.823	0.306	2.69	28.8
	U-7	0.812	0.281	2.89	32.4
	U-8	0.914	0.315	2.90	32.6
	U-9	0.919	0.317	2.90	32.6
Middle	M-1	0.951	0.328	2.90	32.6
	M-2	0.841	0.290	2.90	32.6
	M-3	0.882	0.304	2.90	32.6
	M-4	0.771	0.290	2.66	28.3
	M-5	0.856	0.323	2.65	28.2
	M-6	0.756	0.283	2.67	28.5
	M-7	0.870	0.301	2.89	32.4
	M-8	0.928	0.319	2.91	32.8
	M-9	0.899	0.309	2.91	32.8
Lower	L-1	0.812	0.281	2.89	32.4
	L-2	0.916	0.317	2.89	32.4
	L-3	0.893	0.310	2.88	32.2
	L-4	0.817	0.305	2.68	28.7
	L-5	0.785	0.293	2.68	28.7
	L-6	0.868	0.325	2.67	28.5
	L-7	0.870	0.301	2.89	32.4
	L-8	0.827	0.285	2.90	32.6
	L-9	0.873	0.302	2.89	32.4
Max. Dose		0.928	0.319	2.91	32.8
Min. Dose		0.856	0.323	2.65	28.2

Difference	Average Dose	Tote No
4.6	31.2	2

첨부 3(Attachment 3)

최고밀도 시험(전분) 결과
(Maximum density test results : Starch)

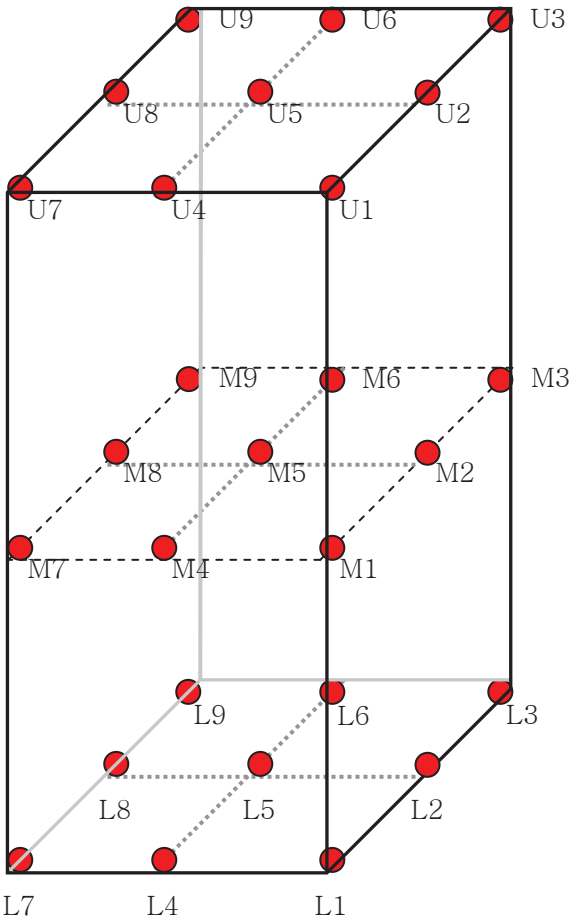
(Attachment 3-1)

조사기 선량 계획표 Irradiator Dose Mapping		Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 12. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Starch(전분)	조사실 온도 (Temperature)	: 12.0 ℃
단위중량(Weight)	: 20 kg	조사실 습도(Humidity)	: 23.5 %
적재수량 (Loading Quantity)	: 10 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 200 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.3 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 1



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.815	0.292	2.79	30.6
	U-2	0.865	0.310	2.79	30.6
	U-3	0.879	0.315	2.79	30.6
	U-4	0.845	0.325	2.60	27.3
	U-5	0.757	0.291	2.60	27.3
	U-6	0.820	0.314	2.61	27.5
	U-7	0.878	0.316	2.78	30.4
	U-8	0.856	0.308	2.78	30.4
	U-9	0.873	0.313	2.79	30.6
Middle	M-1	0.781	0.280	2.79	30.6
	M-2	0.913	0.326	2.80	30.7
	M-3	0.854	0.305	2.80	30.7
	M-4	0.716	0.333	2.15	20.7
	M-5	0.703	0.330	2.13	20.4
	M-6	0.693	0.324	2.14	20.6
	M-7	0.790	0.282	2.80	30.7
	M-8	0.849	0.302	2.81	30.9
	M-9	0.902	0.321	2.81	30.9
Lower	L-1	0.770	0.277	2.78	30.4
	L-2	0.867	0.312	2.78	30.4
	L-3	0.778	0.278	2.80	30.7
	L-4	0.780	0.299	2.61	27.5
	L-5	0.723	0.278	2.60	27.3
	L-6	0.726	0.278	2.61	27.5
	L-7	0.776	0.278	2.79	30.6
	L-8	0.862	0.309	2.79	30.6
	L-9	0.781	0.281	2.78	30.4
Max. Dose		0.849	0.302	2.81	30.9
Min. Dose		0.703	0.330	2.13	20.4

Difference	Average Dose	Tote No
10.5	28.8	1

(Attachment 3-1)

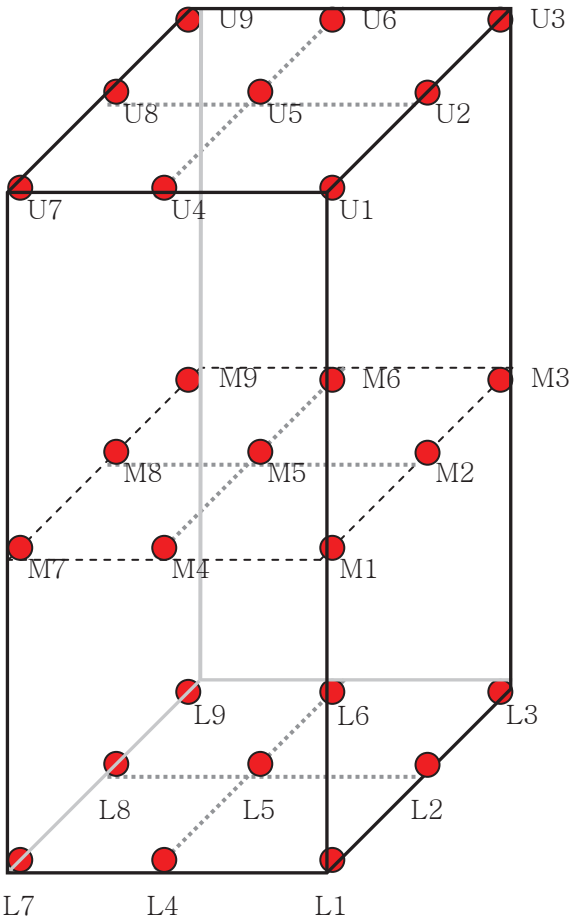
조사기 선량 계획표
Irradiator Dose Mapping

Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 12. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Starch(전분)	조사실 온도 (Temperature)	: 12.0 ℃
단위중량(Weight)	: 20 kg	조사실 습도(Humidity)	: 23.5 %
적재수량 (Loading Quantity)	: 10 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 200 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.3 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 15



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.906	0.326	2.78	30.4
	U-2	0.935	0.335	2.79	30.6
	U-3	0.809	0.290	2.79	30.6
	U-4	0.762	0.292	2.61	27.5
	U-5	0.705	0.271	2.60	27.3
	U-6	0.864	0.331	2.61	27.5
	U-7	0.935	0.335	2.79	30.6
	U-8	0.867	0.312	2.78	30.4
	U-9	0.845	0.305	2.77	30.2
Middle	M-1	0.888	0.317	2.80	30.7
	M-2	0.776	0.277	2.80	30.7
	M-3	0.790	0.283	2.79	30.6
	M-4	0.672	0.314	2.14	20.6
	M-5	0.700	0.327	2.14	20.6
	M-6	0.694	0.323	2.15	20.7
	M-7	0.932	0.333	2.80	30.7
	M-8	0.832	0.296	2.81	30.9
	M-9	0.840	0.300	2.80	30.7
Lower	L-1	0.851	0.306	2.78	30.4
	L-2	0.778	0.279	2.79	30.6
	L-3	0.770	0.277	2.78	30.4
	L-4	0.850	0.327	2.60	27.3
	L-5	0.798	0.308	2.59	27.2
	L-6	0.772	0.298	2.59	27.2
	L-7	0.787	0.282	2.79	30.6
	L-8	0.823	0.295	2.79	30.6
	L-9	0.820	0.293	2.80	30.7
Max. Dose		0.832	0.296	2.81	30.9
Min. Dose		0.700	0.327	2.14	20.6

Difference	Average Dose	Tote No
10.3	28.8	15

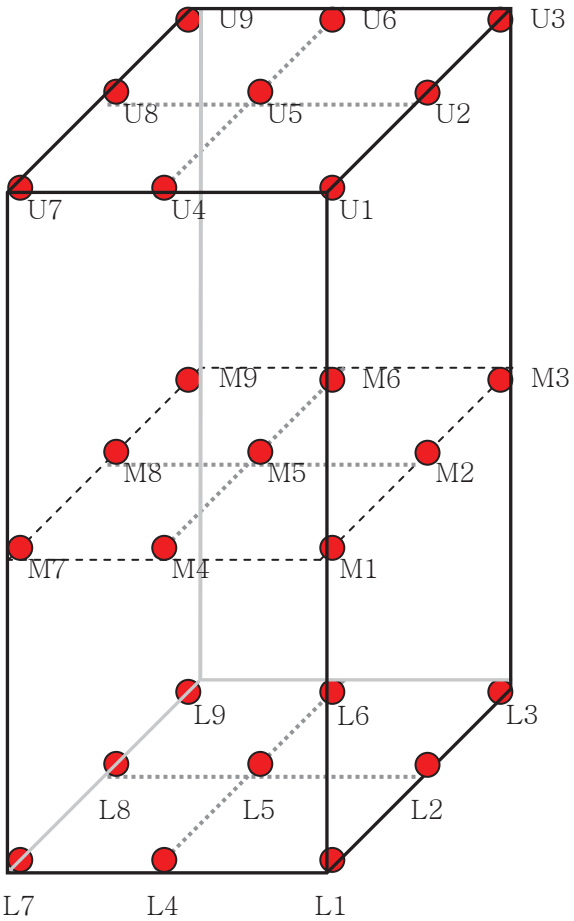
(Attachment 3-1)

조사기 선량 계획표 Irradiator Dose Mapping		Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 12. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Starch(전분)	조사실 온도 (Temperature)	: 12.0 ℃
단위중량(Weight)	: 20 kg	조사실 습도(Humidity)	: 23.5 %
적재수량 (Loading Quantity)	: 10 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 200 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.3 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 45



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.776	0.278	2.79	30.6
	U-2	0.859	0.309	2.78	30.4
	U-3	0.925	0.334	2.77	30.2
	U-4	0.825	0.315	2.62	27.7
	U-5	0.833	0.319	2.61	27.5
	U-6	0.746	0.287	2.60	27.3
	U-7	0.806	0.291	2.77	30.2
	U-8	0.884	0.318	2.78	30.4
	U-9	0.817	0.294	2.78	30.4
Middle	M-1	0.826	0.295	2.80	30.7
	M-2	0.882	0.315	2.80	30.7
	M-3	0.756	0.270	2.80	30.7
	M-4	0.710	0.330	2.15	20.7
	M-5	0.670	0.313	2.14	20.6
	M-6	0.688	0.320	2.15	20.7
	M-7	0.941	0.335	2.81	30.9
	M-8	0.911	0.323	2.82	31.1
	M-9	0.832	0.297	2.80	30.7
Lower	L-1	0.759	0.272	2.79	30.6
	L-2	0.840	0.300	2.80	30.7
	L-3	0.812	0.292	2.78	30.4
	L-4	0.842	0.324	2.60	27.3
	L-5	0.770	0.296	2.60	27.3
	L-6	0.741	0.283	2.62	27.7
	L-7	0.918	0.329	2.79	30.6
	L-8	0.809	0.289	2.80	30.7
	L-9	0.753	0.270	2.79	30.6
Max. Dose		0.911	0.323	2.82	31.1
Min. Dose		0.670	0.313	2.14	20.6

Difference	Average Dose	Tote No
10.5	28.8	45

첨부 4(Attachment 4)

공정 중지의 영향을 확인하는 시험(전분) 결과
(Test results for confirm to influence of process interruption: Starch)

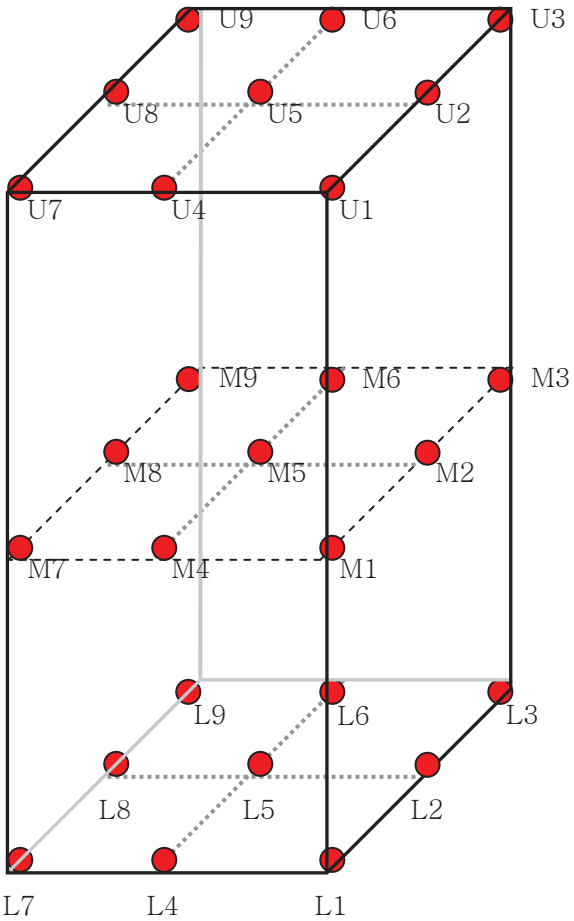
(Attachment 3-1)

조사기 선량 계획표 Irradiator Dose Mapping		Personnel & Responsibilities	Created	Reviewed	Approved

측정일자 (Date of Tested)	: Nov. 12. 2012.	측 정 자(Tester)	: Sim Hyun-chul
견본물질(Product)	: Starch(전분)	조사실 온도 (Temperature)	: 12.0 ℃
단위중량(Weight)	: 20 kg	조사실 습도(Humidity)	: 23.5 %
적재수량 (Loading Quantity)	: 10 ea	Master Time(min)	: 4 min 37 sec
적재중량 (Loading Weight)	: 200 kg	회전수(Cycle)	: 6
적재밀도 (Loading Density)	: 0.3 g/cm^3	Source Activity(Ci)	: 371,063
Dosimeter Type	: Harwell Red	Dosimeter Lot No.	: 4034 JT

Dosimeter Placement

Tote No : 1



※ 측정범위(Measurement range): 5 ~ 50 kGy

※ Dosimeter Results : Dose Mapping Results 참조(Refer to Attachment 3-2.).

(Attachment 3-2)

Dose Mapping Results

Dosimeter Position		ABS(흡광도)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.792	0.285	2.78	30.4
	U-2	0.831	0.299	2.78	30.4
	U-3	0.770	0.276	2.79	30.6
	U-4	0.796	0.305	2.61	27.5
	U-5	0.736	0.283	2.60	27.3
	U-6	0.778	0.298	2.61	27.5
	U-7	0.784	0.281	2.79	30.6
	U-8	0.818	0.292	2.80	30.7
	U-9	0.815	0.293	2.78	30.4
Middle	M-1	0.888	0.317	2.80	30.7
	M-2	0.885	0.316	2.80	30.7
	M-3	0.912	0.327	2.79	30.6
	M-4	0.710	0.330	2.15	20.7
	M-5	0.663	0.310	2.14	20.6
	M-6	0.644	0.301	2.14	20.6
	M-7	0.812	0.291	2.79	30.6
	M-8	0.798	0.284	2.81	30.9
	M-9	0.876	0.313	2.80	30.7
Lower	L-1	0.881	0.318	2.77	30.2
	L-2	0.920	0.332	2.77	30.2
	L-3	0.787	0.283	2.78	30.4
	L-4	0.731	0.281	2.60	27.5
	L-5	0.822	0.316	2.60	27.3
	L-6	0.705	0.271	2.60	27.3
	L-7	0.784	0.282	2.78	30.4
	L-8	0.884	0.317	2.79	30.6
	L-9	0.907	0.325	2.79	30.6
Max. Dose		0.798	0.284	2.81	30.9
Min. Dose		0.663	0.310	2.14	20.6

Difference	Average Dose	Tote No
10.3	28.7	1

Attachment 11.

Master process specification

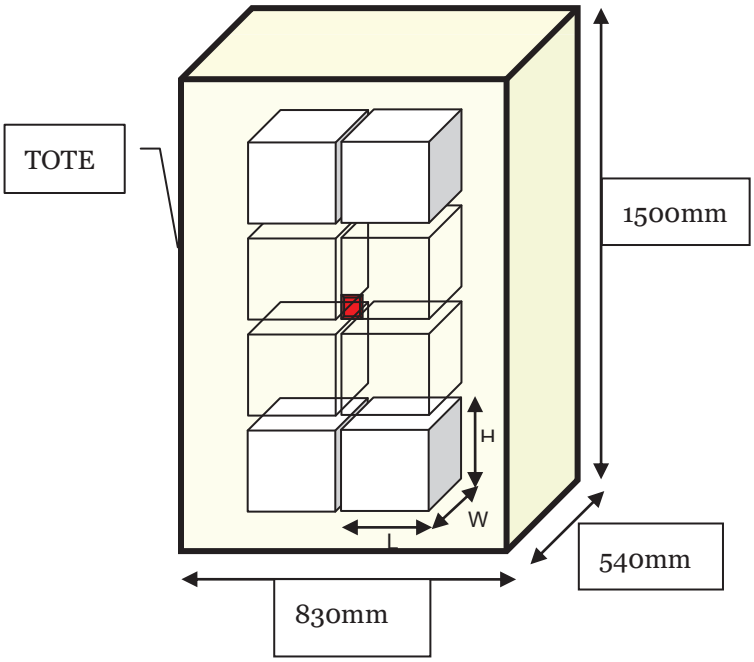
(Attachment 4)

	Create	Review	Approval
Personnel & Responsibilities		n/a	
	Nov. 22. 2012.	-	Nov. 22. 2012.

Master Process Specification

Control Number **SYL – 1102**

Customer	**KM CORPORATION**		Specific Dose	
Product	**Sterilized Non-Woven Wiper**		**Min : 25 kGy**	**Max : 40 kGy**
Box Information	Weight	Width	Length	Height
	5,300 g	**340** mm	**315** mm	**320** mm
Loading quantity	**8** Carton		Total Weight	**42,400** g
Product Density	**0.155** g/cm³		Loading Density	**0.064** g/cm³



Photo

Routine Monitoring Position & Correction factor

Routine monitoring location (D_{Min}) : **M-5**

Correction factor (D_{Min}) : **D_{min} × 0.99** kGy

Correction factor (D_{Max}) : **D_{max} × 1.28** kGy

***How to Attach Dosimeter**

– The first and last Tote at least part of the middle and one on each of 3(ea) each should be attached.

– Part of loading up on parts of 1(ea) should be attached.

Customer Endorsement

KM CORPORATION

Name :_____

Department

:_____

Signature :_____

Attachment 12.

Product dose mapping report

Mixed density within the irradiator,

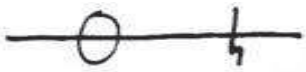
Partially filled irradiation containers AND

Product Dose Mapping for a dose assessment

***Signatures**

Tested By  Date : Nov. 22. 2012.

Sim Hyunchul / Validation Team

Approved By  Date : Nov. 22. 2012.

Park Jaejung / Q.A Manager

Technology for better life!

SOYAGREENTEC

900-3, Sangsin-ri, Hyangnam-eup, Hwasung-si, Gyeonggi-do, Korea, TEL: (031)353-6999(代) FAX: (031)353-6979

1) Purpose

Products can affect the dose of a product (relatively high density of product) of a product loaded with **KM CORPORATION.** Tote (loaded up to full density products 3TOTE, at least part of the density product 1TOTE load) close to its effectiveness after (including temperature) is measured.

2) Definitions

2.1. Master Process Specification : Tote (carried equipment) loaded in the batch of product

2.2. Tote(Irradiation container) : Products that carry the load and to move containers.

2.3. Product Dose mapping : DOSE MAPPING between the dose variability in quantities sufficient to determine the shipping container must be running on. Maximum and minimum doses and routine surveillance to determine the location should be suitable. This test, regardless of the dose to the maximum density and minimum density should be run.

2.4. Mixed density within the irradiator : Difference in the density of each product according to the distribution of the absorbed dose and dose must be evaluated on.

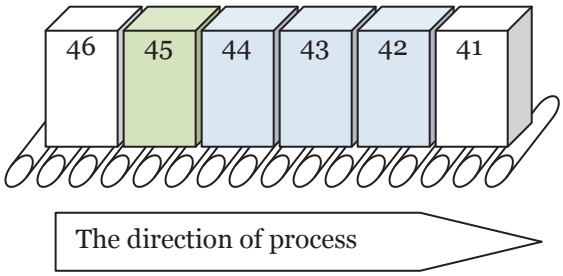
2.5. Partially filled irradiation containers : TOTE loaded part of the maximum and minimum dose to completely fill the position of the product loaded is different from TOTE. This difference is on the process leading to a similar product or substance, or TOTE Shielding materials used to fill in the variance can be reduced

3) Test the products information

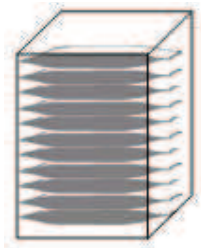
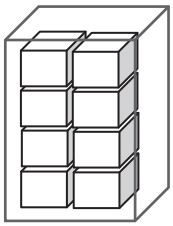
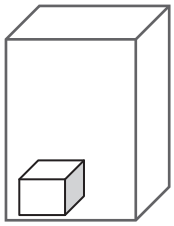
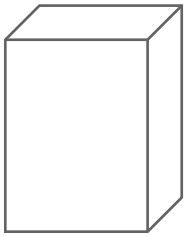
Product name	Unit weight (kg)	Explanation
Starch	20	The high density material.
Empty (No products)	0	The lesser density.
KM-6612L	5.3	This product has the same mass and density as a product replacing dummy.

4) Test method

TOTE loaded with products of the starch in front of the high density (0.41 g/cm3) to fill the TOTE, part of the product is loaded, the last blank in the form of TOTE located behind the operation is carried out.



Picture 1

Tote No.	Product	Density(g/cm³)	Remarks	Load shape
41	Starch	0.41	Filled filled with starch	
42	Sterilized Non-Woven Wiper	0.064	Each per TOTE Full Fill(8 boxs)	
43				
44				
45	Blank Box	0	Part of a box loaded	
46	Blank Tote	0	Do not load anything	

5) Process conditions

Topics		Contents
Master Time		4 min 37 sec (November 2012 by)
Temperature	Irradiation room	5.0 ℃
	Product	Using the results of the temperature tape 29 (℃) is less than that.
Dosimeter		Red 4034 Perspex Dosimeter(Batch : JT)

6) Result and evaluation

6.1. Result

Tote No.	Dose site	ABS	Thickness(cm)	ABS/cm	Dose(kGy)
42	M5(min)	0.836	0.333	2.51	25.9
	M8(max)	0.792	0.273	2.90	32.6
43	M5(min)	0.738	0.294	2.51	25.9
	M8(max)	0.899	0.309	2.91	32.8
44	M5(min)	0.794	0.315	2.52	26.1
	M8(max)	0.894	0.306	2.92	33.0
45	M8(max)	0.941	0.318	2.96	33.7
	-	-	-	-	-

Reference

Tote No. **42, 43, 44 (**Full load**)**

Tote No. **45** (Loaded parts Tote)
M5 : minimum dose position
M8 : maximum dose position

6.2. Evaluation

Set dose 25 kGy (minimum dose = sterilization dose) ~ 40 kGy (maximum dose) is. Tote No.42 is the measured minimum dose of 25.9 kGy and 25 kGy dose, the value is set higher than the minimum requirements included in the dose range is suitable. The No.43, 44, 45 the dose range set also includes Tote is so fit.

PRODUCT DOSE MAPPING

▶ CUSTOMER : KM CORPORATION

▶ PRODUCTS : Sterilized Non-Woven Wiper

Dimension (mm) : 340 mm(W) × 315 mm(L) × 320 mm(H)
Loading Quantity : 8 carton

▶ Process parameter

Set Master Timer : 4 Min 37 Sec

▶ DOSIMETER. : HARWELL Red Perspex Dosimeter 4034

▶ DOSIMETER BATCH : JT

▶ RESULTS

1. Dose Measurement

Position	Dose Map 1 Tote No. **42**	Dose Map 2 Tote No. **43**	Dose Map 3 Tote No. **44**	Average	Location
D_{Min}	25.9	25.9	26.1	26.0	M5
D_{Max}	32.6	32.8	33.0	32.8	M8
D_{Refer}	–	–	–	–	–

2. Variance calculation

$Var(D_{Min}) = [(25.9 - 26.0)^2 + (25.9 - 26.0)^2 + (26.1 - 26.0)^2]/(3 - 1) = 0.015\ (kGy)^2$

$Var(D_{Max}) = [(32.6 - 32.8)^2 + (32.8 - 32.8)^2 + (33.0 - 32.8)^2]/(3 - 1) = 0.04\ (kGy)^2$

3. Standard deviation calculation

$S(D_{Min}) = \sqrt{Var(D_{Min})} = 0.122\ (kGy)^2$

$S(D_{Max}) = \sqrt{Var(D_{Max})} = 0.2\ (kGy)^2$

4. Uncertainty at 95% confidence level

For D_{Min} : 2S $(D_{Min})/(D_{min})$ avg = (2 × 0.122 kGy/26.0 kGy) × 100 = 0.94 %

For D_{Max} : 2S $(D_{Min})/(D_{Max})$ avg = (2 × 0.2 kGy/32.8 kGy) × 100 = 1.22 %

5. Dose Uniformity Ratio

D_{Max} / D_{Min} : 32.8 kGy / 26.0 kGy = 1.26 kGy

6. Routine monitoring position & Correction factor

Routine monitoring location : D_{Min} (M-5)

Correction factor (D_{Min}) : $D_{Min} - (D_{Min} \times 0.0094)$ = $D_{Min} \times 0.99$

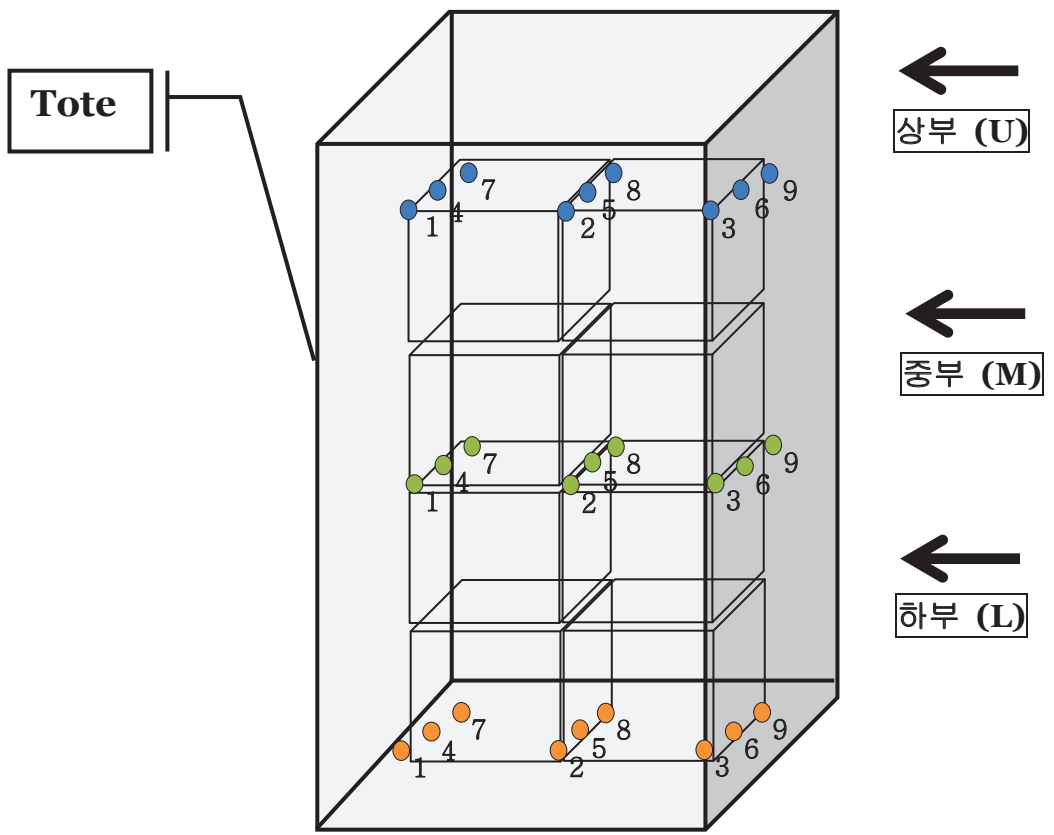
Correction factor (D_{Max}) : $(D_{Min} \times 1.26) \times 1.0122$ = $D_{Min} \times 1.28$

7. Dose Distribution

Dose Distribution Records

Dosimeter Position		ABS (Absorbance)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.869	0.308	2.82	31.1
	U-2	0.894	0.317	2.82	31.1
	U-3	0.860	0.304	2.83	31.3
	U-4	0.749	0.287	2.61	27.5
	U-5	0.833	0.319	2.61	27.5
	U-6	0.710	0.271	2.62	27.7
	U-7	0.934	0.329	2.84	31.5
	U-8	0.855	0.301	2.84	31.5
	U-9	0.948	0.335	2.83	31.3
Middle	M-1	0.895	0.312	2.87	32.0
	M-2	0.884	0.307	2.88	32.2
	M-3	0.827	0.287	2.88	32.2
	M-4	0.753	0.299	2.52	26.1
	M-5	0.836	0.333	2.51	25.9
	M-6	0.693	0.274	2.53	26.2
	M-7	0.968	0.335	2.89	32.4
	M-8	0.792	0.273	2.90	32.6
	M-9	0.934	0.322	2.90	32.6
Lower	L-1	0.778	0.272	2.86	31.8
	L-2	0.775	0.270	2.87	32.0
	L-3	0.935	0.327	2.86	31.8
	L-4	0.747	0.285	2.62	27.7
	L-5	0.731	0.279	2.62	27.7
	L-6	0.768	0.293	2.62	27.7
	L-7	0.884	0.310	2.85	31.6
	L-8	0.869	0.305	2.85	31.6
	L-9	0.912	0.319	2.86	31.8
Min. Dose		0.836	0.333	2.51	25.9
Max. Dose		0.792	0.273	2.90	32.6
Tote Number		**42 ~ 44**		**42**	

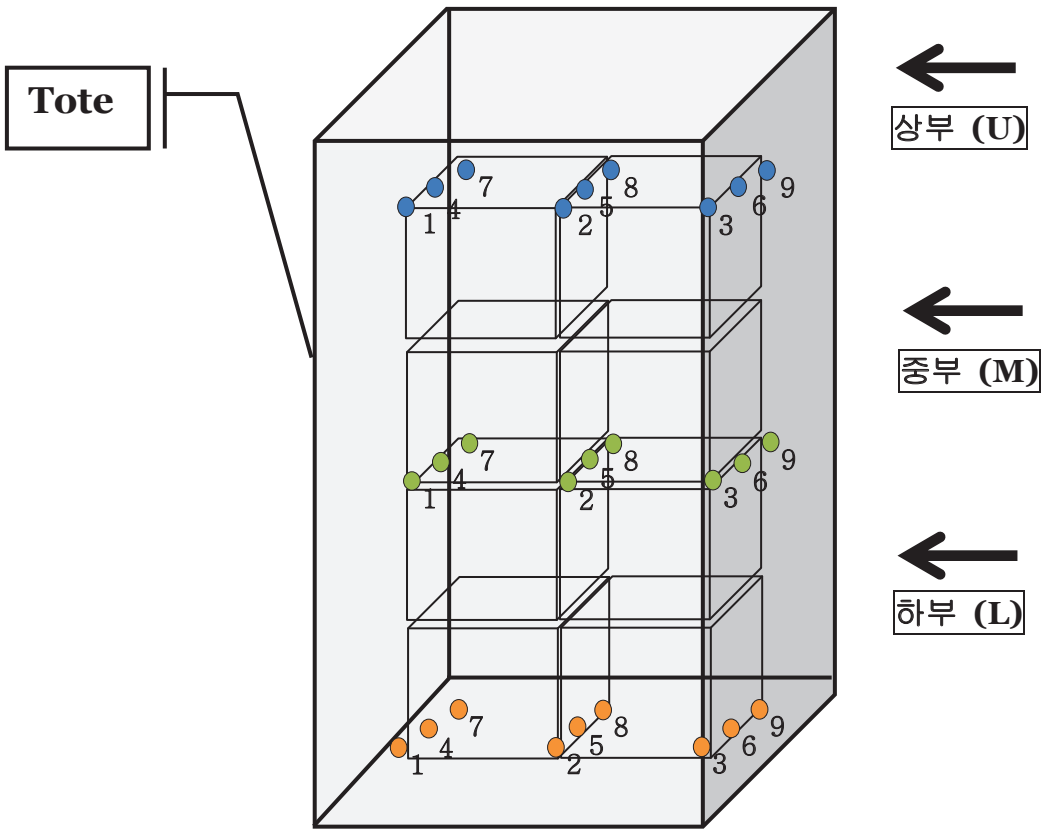
Dosimeter Locations



Dose Distribution Records

Dosimeter Position		ABS (Absorbance)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.792	0.278	2.85	31.6
	U-2	0.903	0.317	2.85	31.6
	U-3	0.812	0.286	2.84	31.5
	U-4	0.859	0.328	2.62	27.7
	U-5	0.856	0.328	2.61	27.5
	U-6	0.726	0.278	2.61	27.5
	U-7	0.815	0.285	2.86	31.8
	U-8	0.804	0.281	2.86	31.8
	U-9	0.915	0.320	2.86	31.8
Middle	M-1	0.801	0.277	2.89	32.4
	M-2	0.861	0.298	2.89	32.4
	M-3	0.954	0.329	2.90	32.6
	M-4	0.805	0.318	2.53	26.2
	M-5	0.738	0.294	2.51	25.9
	M-6	0.798	0.318	2.51	25.9
	M-7	0.876	0.302	2.90	32.6
	M-8	0.899	0.309	2.91	32.8
	M-9	0.786	0.270	2.91	32.8
Lower	L-1	0.815	0.285	2.86	31.8
	L-2	0.787	0.275	2.86	31.8
	L-3	0.881	0.307	2.87	32.0
	L-4	0.802	0.305	2.63	27.8
	L-5	0.780	0.299	2.61	27.5
	L-6	0.862	0.329	2.62	27.7
	L-7	0.844	0.294	2.87	32.0
	L-8	0.924	0.323	2.86	31.8
	L-9	0.798	0.280	2.85	31.6
Min. Dose		0.738	0.294	2.51	25.9
Max. Dose		0.899	0.309	2.91	32.8
Tote Number		**42 ~ 44**		**43**	

Dosimeter Locations



Dose Distribution Records

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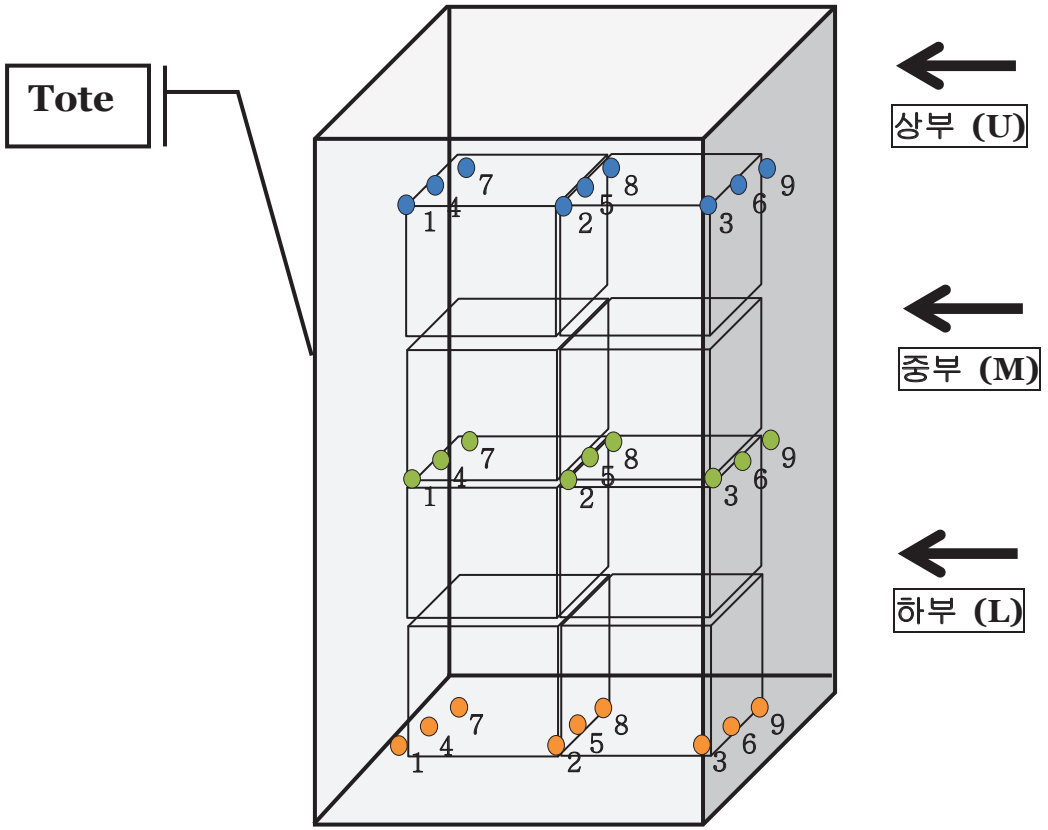
	U-2	0.921	0.321	2.87	32.0
	U-3	0.815	0.286	2.85	31.6
	U-4	0.830	0.318	2.61	27.5
	U-5	0.793	0.304	2.61	27.5
	U-6	0.777	0.299	2.60	27.3
	U-7	0.770	0.271	2.84	31.5
	U-8	0.949	0.333	2.85	31.6
	U-9	0.832	0.292	2.85	31.6
Middle	M-1	0.948	0.328	2.89	32.4
	M-2	0.867	0.300	2.89	32.4
	M-3	0.931	0.321	2.90	32.6
	M-4	0.772	0.305	2.53	26.2
	M-5	0.794	0.315	2.52	26.1
	M-6	0.787	0.310	2.54	26.4
	M-7	0.890	0.307	2.90	32.6
	M-8	0.894	0.306	2.92	33.0
	M-9	0.812	0.279	2.91	32.8
Lower	L-1	0.959	0.334	2.87	32.0
	L-2	0.829	0.288	2.88	32.2
	L-3	0.939	0.325	2.89	32.4
	L-4	0.731	0.281	2.60	27.3
	L-5	0.710	0.275	2.58	27.0
	L-6	0.808	0.312	2.59	27.2
	L-7	0.924	0.321	2.88	32.2
	L-8	0.945	0.328	2.88	32.2
	L-9	0.789	0.275	2.87	32.0
Min. Dose		0.794	0.315	2.52	26.1
Max. Dose		0.894	0.306	2.92	33.0
Tote Number		**42 ~ 44**		**44**	

Dosimeter Locations

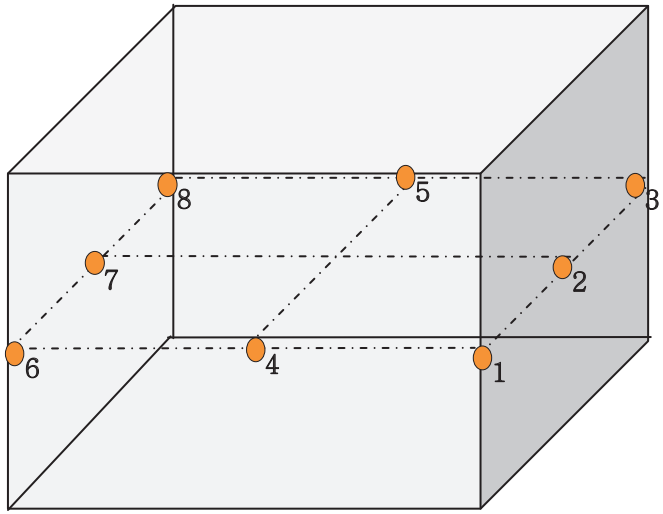


Dose Distribution Records

Dosimeter Position		ABS Absorbance	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Location	M-1	0.929	0.316	2.94	33.4
	M-2	0.988	0.335	2.95	33.5
	M-3	0.885	0.302	2.93	33.2
	M-4	0.882	0.299	2.95	33.5
	M-5	0.929	0.314	2.96	33.7
	M-6	0.800	0.273	2.93	33.2
	M-7	0.950	0.322	2.95	33.5
	M-8	0.941	0.318	2.96	33.7
	-	-	-	-	-
-	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
-	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
Min. Dose		-	-	-	-
Max. Dose		0.941	0.318	2.96	33.7
Tote Number		**45**		-	

Dosimeter Locations

A box Part load



* Central Dosimeter Position (5) located in the middle of the Carton outside.
* Dosimeter Position in order to enhance the understanding and create larger picture of Carton .

Mixed density within the irradiator,

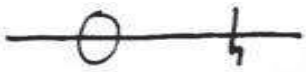
Partially filled irradiation containers AND

Product Dose Mapping for a dose assessment

***Signatures**

Tested By  Date : Nov. 22. 2012.

Sim Hyunchul / Validation Team

Approved By  Date : Nov. 22. 2012.

Park Jaejung / Q.A Manager

Technology for better life!

SOYAGREENTEC

900-3, Sangsin-ri, Hyangnam-eup, Hwasung-si, Gyeonggi-do, Korea, TEL: (031)353-6999(代) FAX: (031)353-6979

1) Purpose

Products can affect the dose of a product (relatively high density of product) of a product loaded with **KM CORPORATION.** Tote (loaded up to full density products 3TOTE, at least part of the density product 1TOTE load) close to its effectiveness after (including temperature) is measured.

2) Definitions

2.1. Master Process Specification : Tote (carried equipment) loaded in the batch of product

2.2. Tote(Irradiation container) : Products that carry the load and to move containers.

2.3. Product Dose mapping : DOSE MAPPING between the dose variability in quantities sufficient to determine the shipping container must be running on. Maximum and minimum doses and routine surveillance to determine the location should be suitable. This test, regardless of the dose to the maximum density and minimum density should be run.

2.4. Mixed density within the irradiator : Difference in the density of each product according to the distribution of the absorbed dose and dose must be evaluated on.

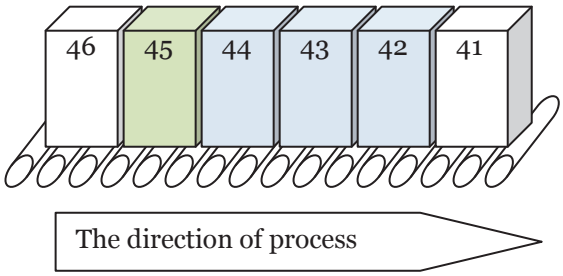
2.5. Partially filled irradiation containers : TOTE loaded part of the maximum and minimum dose to completely fill the position of the product loaded is different from TOTE. This difference is on the process leading to a similar product or substance, or TOTE Shielding materials used to fill in the variance can be reduced

3) Test the products information

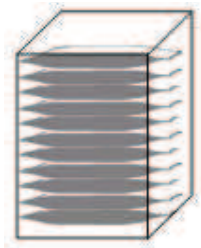
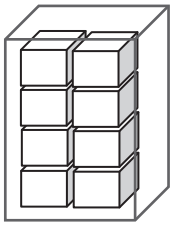
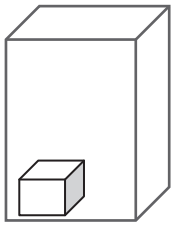
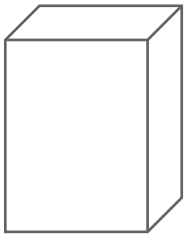
Product name	Unit weight (kg)	Explanation
Starch	20	The high density material.
Empty (No products)	0	The lesser density.
KM-6612L	7.4	This product has the same mass and density as a product replacing dummy.

4) Test method

TOTE loaded with products of the starch in front of the high density (0.41 g/cm3) to fill the TOTE, part of the product is loaded, the last blank in the form of TOTE located behind the operation is carried out.



Picture 1

Tote No.	Product	Density(g/cm3)	Remarks	Load shape
41	Starch	0.41	Filled filled with starch	
42	Sterilized Non-Woven Wiper	0.09	Each per TOTE Full Fill(8 boxs)	
43				
44				
45	Blank Box	0	Part of a box loaded	
46	Blank Tote	0	Do not load anything	

5) Process conditions

Topics		Contents
Master Time		4 min 37 sec (November 2012 by)
Temperature	Irradiation room	5.0 ℃
	Product	Using the results of the temperature tape 29 (℃) is less than that.
Dosimeter		Red 4034 Perspex Dosimeter(Batch : JT)

6) Result and evaluation

6.1. Result

Tote No.	Dose site	ABS	Thickness(cm)	ABS/cm	Dose(kGy)
42	M5(min)	0.836	0.333	2.51	25.9
	M8(max)	0.792	0.273	2.90	32.6
43	M5(min)	0.738	0.294	2.51	25.9
	M8(max)	0.899	0.309	2.91	32.8
44	M5(min)	0.794	0.315	2.52	26.1
	M8(max)	0.894	0.306	2.92	33.0
45	M8(max)	0.941	0.318	2.96	33.7
	-	-	-	-	-

Reference

Tote No. **42, 43, 44 (**Full load**)**

Tote No. **45** (Loaded parts Tote)
M5 : minimum dose position
M8 : maximum dose position

6.2. Evaluation

Set dose 25 kGy (minimum dose = sterilization dose) ~ 40 kGy (maximum dose) is. Tote No.42 is the measured minimum dose of 25.9 kGy and 25 kGy dose, the value is set higher than the minimum requirements included in the dose range is suitable. The No.43, 44, 45 the dose range set also includes Tote is so fit.

PRODUCT DOSE MAPPING

▶ CUSTOMER : KM CORPORATION

▶ PRODUCTS : Sterilized Non-Woven Wiper

Dimension (mm) : 465 mm(W) × 330 mm(L) × 360 mm(H)
Loading Quantity : 8 carton

▶ Process parameter

Set Master Timer : 4 Min 37 Sec

▶ DOSIMETER. : HARWELL Red Perspex Dosimeter 4034

▶ DOSIMETER BATCH : JT

▶ RESULTS

1. Dose Measurement

Position	Dose Map 1 Tote No. **42**	Dose Map 2 Tote No. **43**	Dose Map 3 Tote No. **44**	Average	Location
D_{Min}	25.9	25.9	26.1	26.0	M5
D_{Max}	32.6	32.8	33.0	32.8	M8
D_{Refer}	–	–	–	–	–

2. Variance calculation

$Var(D_{Min}) = [(25.9 - 26.0)^2 + (25.9 - 26.0)^2 + (26.1 - 26.0)^2]/(3 - 1) = 0.015\ (kGy)^2$

$Var(D_{Max}) = [(32.6 - 32.8)^2 + (32.8 - 32.8)^2 + (33.0 - 32.8)^2]/(3 - 1) = 0.04\ (kGy)^2$

3. Standard deviation calculation

$S(D_{Min}) = \sqrt{Var(D_{Min})} = 0.122\ (kGy)^2$

$S(D_{Max}) = \sqrt{Var(D_{Max})} = 0.2\ (kGy)^2$

4. Uncertainty at 95% confidence level

For D_{Min} : 2S $(D_{Min})/(D_{min})$ avg = (2 × 0.122 kGy/26.0 kGy) × 100 = 0.94 %

For D_{Max} : 2S $(D_{Min})/(D_{Max})$ avg = (2 × 0.2 kGy/32.8 kGy) × 100 = 1.22 %

5. Dose Uniformity Ratio

D_{Max} / D_{Min} : 32.8 kGy / 26.0 kGy = 1.26 kGy

6. Routine monitoring position & Correction factor

Routine monitoring location : D_{Min} (M-5)

Correction factor (D_{Min}) : $D_{Min} - (D_{Min} \times 0.0094)$ = $D_{Min} \times 0.99$

Correction factor (D_{Max}) : $(D_{Min} \times 1.26) \times 1.0122$ = $D_{Min} \times 1.28$

7. Dose Distribution

Dose Distribution Records

Dosimeter Position		ABS (Absorbance)	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Upper	U-1	0.869	0.308	2.82	31.1
	U-2	0.894	0.317	2.82	31.1
	U-3	0.860	0.304	2.83	31.3
	U-4	0.749	0.287	2.61	27.5
	U-5	0.833	0.319	2.61	27.5
	U-6	0.710	0.271	2.62	27.7
	U-7	0.934	0.329	2.84	31.5
	U-8	0.855	0.301	2.84	31.5
	U-9	0.948	0.335	2.83	31.3
Middle	M-1	0.895	0.312	2.87	32.0
	M-2	0.884	0.307	2.88	32.2
	M-3	0.827	0.287	2.88	32.2
	M-4	0.753	0.299	2.52	26.1
	M-5	0.836	0.333	2.51	25.9
	M-6	0.693	0.274	2.53	26.2
	M-7	0.968	0.335	2.89	32.4
	M-8	0.792	0.273	2.90	32.6
	M-9	0.934	0.322	2.90	32.6
Lower	L-1	0.778	0.272	2.86	31.8
	L-2	0.775	0.270	2.87	32.0
	L-3	0.935	0.327	2.86	31.8
	L-4	0.747	0.285	2.62	27.7
	L-5	0.731	0.279	2.62	27.7
	L-6	0.768	0.293	2.62	27.7
	L-7	0.884	0.310	2.85	31.6
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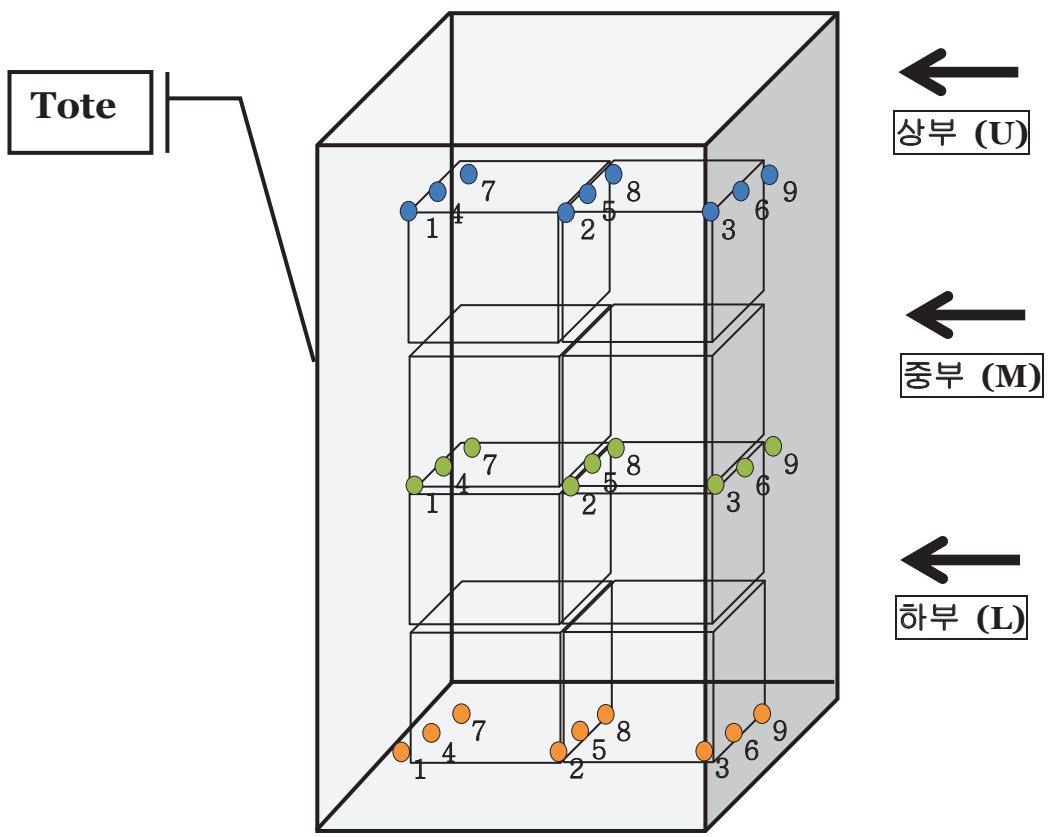
Dosimeter Locations



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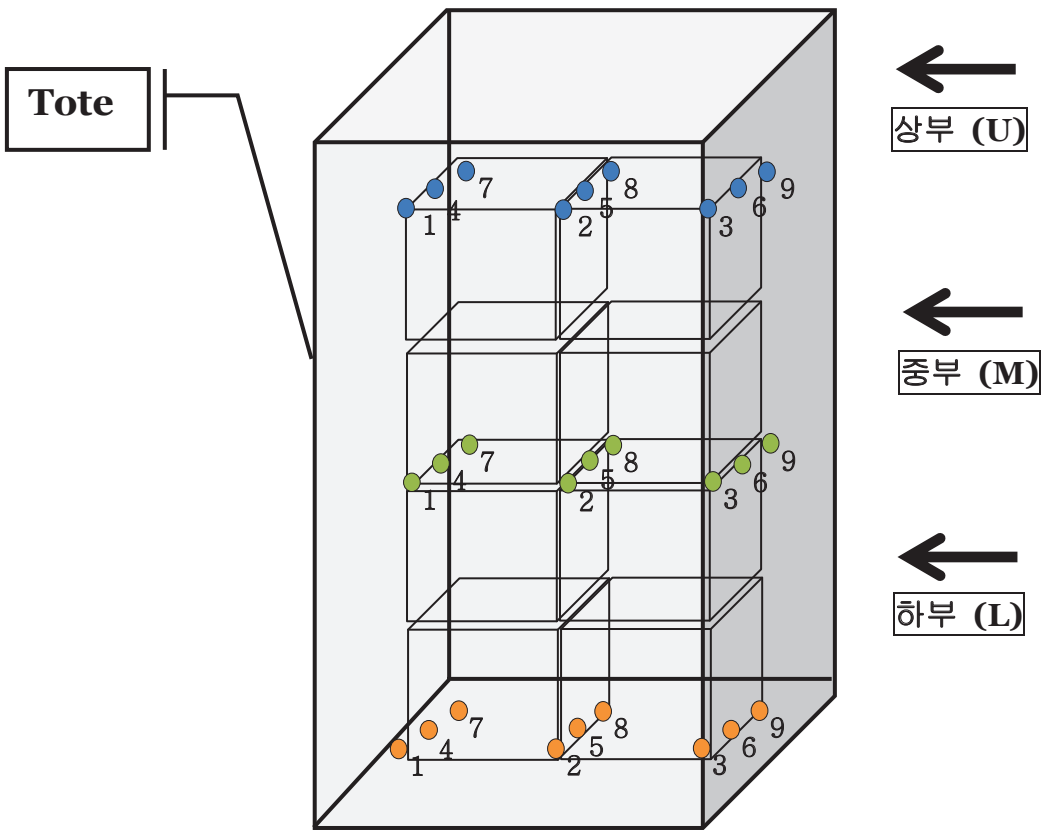
Dosimeter Locations



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	U-6	0.777	0.299	2.60	27.3
	U-7	0.770	0.271	2.84	31.5
	U-8	0.949	0.333	2.85	31.6
	U-9	0.832	0.292	2.85	31.6
Middle	M-1	0.948	0.328	2.89	32.4
	M-2	0.867	0.300	2.89	32.4
	M-3	0.931	0.321	2.90	32.6
	M-4	0.772	0.305	2.53	26.2
	M-5	0.794	0.315	2.52	26.1
	M-6	0.787	0.310	2.54	26.4
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	M-9	0.812	0.279	2.91	32.8
Lower	L-1	0.959	0.334	2.87	32.0
	L-2	0.829	0.288	2.88	32.2
	L-3	0.939	0.325	2.89	32.4
	L-4	0.731	0.281	2.60	27.3
	L-5	0.710	0.275	2.58	27.0
	L-6	0.808	0.312	2.59	27.2
	L-7	0.924	0.321	2.88	32.2
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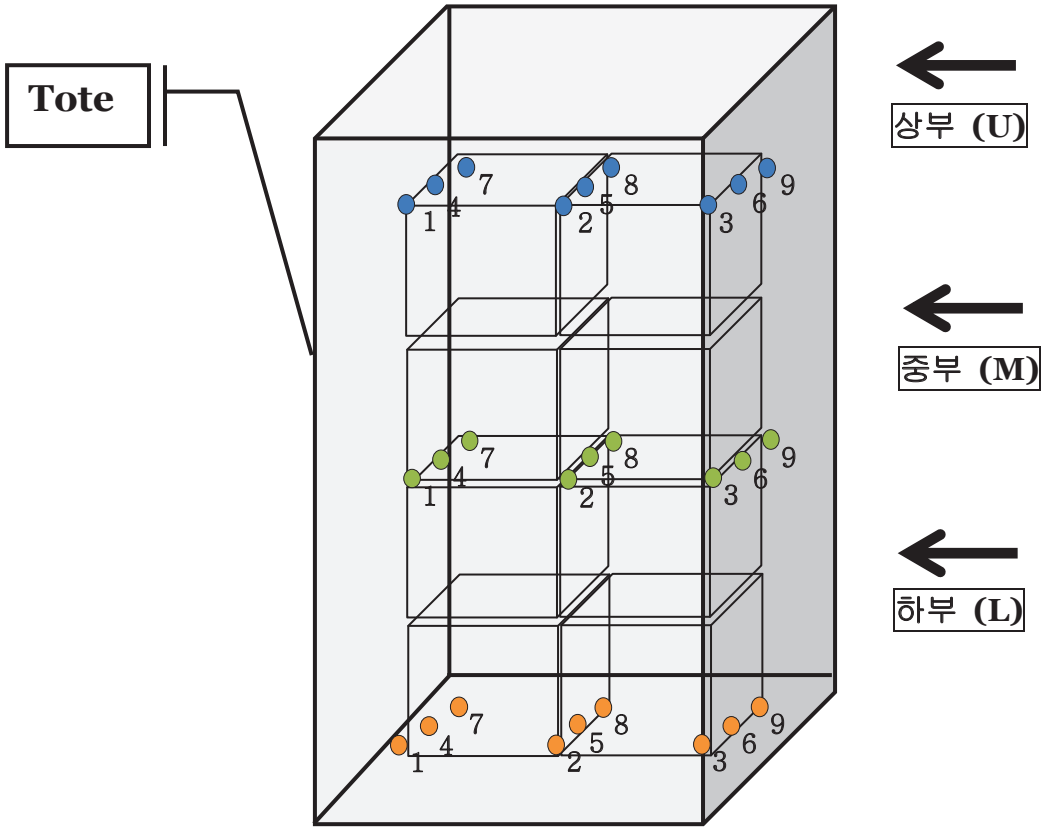
Tote Number		**42 ~ 44**		**44**	

Dosimeter Locations



Dose Distribution Records

Dosimeter Position		ABS Absorbance	Thickness (cm)	ABS/cm	Abs. Dose (kGy)
Location	M-1	0.929	0.316	2.94	33.4
	M-2	0.988	0.335	2.95	33.5
	M-3	0.885	0.302	2.93	33.2
	M-4	0.882	0.299	2.95	33.5
	M-5	0.929	0.314	2.96	33.7
	M-6	0.800	0.273	2.93	33.2
	M-7	0.950	0.322	2.95	33.5
	M-8	0.941	0.318	2.96	33.7
	-	-	-	-	-
-	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
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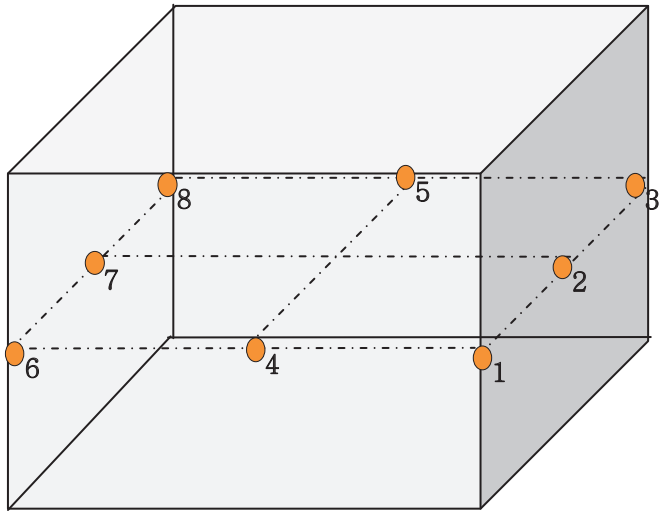
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
	-	-	-	-	-
Min. Dose		-	-	-	-
Max. Dose		0.941	0.318	2.96	33.7
Tote Number		**45**		-	

Dosimeter Locations

A box Part load



* Central Dosimeter Position (5) located in the middle of the Carton outside.
* Dosimeter Position in order to enhance the understanding and create larger picture of Carton .

Attachment 13.

Master record for Gamma irradiation process

Master record for gamma irradiation process

1. Receipt of product & Review for irradiation request

Irradiation Batch No.	

고객명/Customer		승 인/Approved by	(서명)
제품명/Product Name		수 령/Received by	(서명)
수 량/Quantity	Carton	수령일자/Received Date	20 년 월 일
중 량/Unit Weight.	kg	출고 희망일	월 일 시
제조일련번호/Lot No			
Special Handling Requirement			

2. Determination to be applied

외관검사	정상( ), 이상( )	승 인/Approved by	(서명)
특이사항:		검 토/Checked by	(서명)
		검 사/Tested by	(서명)
요구선량 Specified Dose	D(Max) kGy D(Min) kGy	적재방식지침/ Loading configuration	SYL -

3. Irradiation of products

3.1공정 파라메터 조정/ Adjustment of Process Parameter	M/T(min sec) Set Cycle( )	승 인/ Approved by	(서명)
3.2제품적재/Product Loading(Start Cycle)		적재/Loaded by	(서명)
적재일시/Date	월 일 시 분	적재토트번호/Loading Tote Number	~ ( )
적재수량/Loading Quantity	Carton	Dosimeter 종류 (batch Number)	Red 4034( ) Amber 3042( )

선량계 부착위치 및 수량/ Dosimeter Location & Quantity	Tote No.	A( )	B( )	C( )
	Location 1			
	Location 2			
부분적재 Tote/Partial Loading Tote	(Tote No : Carton/Tote)			

3.3작업공정/Process Running

Cycle(예상선량)	시간(Time)	확 인			
1(kGy)	일 시 분		8(kGy)	일 시 분	
2(kGy)	일 시 분		9(kGy)	일 시 분	
3(kGy)	일 시 분		10(kGy)	일 시 분	
4(kGy)	일 시 분		11(kGy)	일 시 분	
5(kGy)	일 시 분		12(kGy)	일 시 분	
6(kGy)	일 시 분		13(kGy)	일 시 분	
7(kGy)	일 시 분		14(kGy)	일 시 분	
			15(kGy)	일 시 분	

공정정지 /Process interruption	**1**	월 일 시 분	**제품위치 /Container Position**	~
YES( ) NO( )	**2**	월 일 시 분	**제품위치 /Container Position**	~

3.4 제품하역/Product Unloading(Finish Cycle)

하역일시 /Unloaded Date	월 일 시 분	**하 역/Unloaded by**	(서명)
하역수량 /Unloading Quantity	Carton	**도시메타 부착위치 확인 /Identification of Dosimeter Location & Frequency**	YES( ) NO( )
제품손상 및 상태확인 /Identification of Product damage & status	정 상( ) 이 상( )	**이상내용/Note**	
검 토 /Checked by	(서명)	**승 인 /Approved by**	(서명)

4. Release of product & Certification of dose

판정일시/Date	20 년		월		일	
선량평가/Dosimetry analysis		**측 정/Measured by**		(서명)		
Dosimeter location	A-1	A-2	B-1	B-2	C-1	C-2
ABS						
Thickness	cm	cm	cm	cm	cm	cm
ABS/cm						
Delivered dose	kGy	kGy	kGy	kGy	kGy	kGy
최대 최소 선량비 D(Max)/D(Min) Ratio			**표준편차**		Maximum(kGy) Minimum(kGy)	
참조 최소 선량비 D(Ref)/D(Min) Ratio			Calculation 최 소 : kGy 최 대 : kGy			
참조 최대 선량비 D(Ref)/D(Max) Ratio						
Absorbed Dose Range	**최 소**(kGy) / **최 대**(kGy)					
감마선 조사증명서 번호 /Gamma Irradiation Certificate number						

검 토 /Checked by	(서명)	**승 인 /Approved by**	(서명)	합격/Acceptance	불합격/Rejection

Attachment 14.

Certificate of Gamma irradiation

CERTIFICATE

of gamma irradiation

Certificate No. : S 120101 0001

Customer : Company name

Item Specification	QTY	Product (Lot No)	Specified Dose	
			D_{min}(kGy)	D_{max}(kGy)
Product name	–	–	0	0
TOTAL	–			

Irradiated Date : 1-Jan-12

Irradiation(Batch No.) : -

Plant : Master Irradiation

Irradiation Container (Tote) No : 1 ~ 55

Irradiator : Cobalt 60 gamma irradiator (JS-10000 High performance tote type)

Dosimeters for Monitoring (Batch No) : Harwell PMMA Dosimeter (Red 4034 JT)

Dosimetry Results (Dmin to Dmax) : 0 ~ 0 kGy

Date : 1-Jan-12

Approved : ki Hwan, Kim *Signature* _____

Title : Q.M.R / Director

We hereby certify that the above specified goods have been duly irradiated by gamma-ray.

Technology for better life!
SOYAGREENTEC

900-3, Sangsin-Ri, Hyangnam-Eup, Hwasung-Si, Kyoungki-Do, Korea

TEL : +82-31-353-6999 FAX : +82-31-353-6979 URL : http://www.soyagreentec.co.kr

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