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1. Product Description

This specification document applies to Newform™ Cleansteam™ bags.

1.1. Shelf life

The shelf life of the product is limited to 3 years after manufacturing date. Unused bags should be stored in the closed package as received from Pall at 10 - 40°C and RH < 70%.

1.2. Sterility

Cleansteam™ bags can be subjected to steam sterilization. Steam sterilization processing temperatures should not exceed 124°C.

1.3. Dimensions

Description	Value
Inner width of the bag	xxx ± 10 mm
Inner length of the bag	xxx ± 10 mm
Thickness of the Tyvek film	185 µm[1]
Thickness of the HDPE film	80 ± 10 µm

2. Compliances

Tyvek layer

- The film complies with the requirements of US Pharmacopoeia USP <87>, USP <88> (USP Class VI) and USP <661>.
- The film complies with the requirements of the European Pharmacopoeia 3.1.5.
- The film complies with the requirements for use in contact with food of FDA regulation 21 CFR 177.1520 and 21 CFR 178.2010.
- The film complies with the compositional requirements for use in contact with food of Commission Regulation (EU) No 10/2011.
- Tyvek may contain up to 500 ppm of a stearic acid salt where the stearate group may be derived from tallow. Processing conditions of the raw materials used in manufacturing of Tyvek meet or exceed the recommended conditions by Commission Regulation (EU) 722/2012, European Commission 2011/C 73/01 or ISO 22442-1 Annex C for protection against TSE (Transmissible Spongiform Encephalopathy)/BSE (Bovine Spongiform Encephalopathy). As such, to the best of our knowledge, Tyvek does not contain substances having the risks of transmitting TSE/BSE.

HDPE layer

- The film complies with the requirements of the US Pharmacopoeia USP <87>, USP <88> (Class VI) and USP <661>.
- The film complies with the requirements of the European Pharmacopoeia 3.1.5 section "tests"
- The resin complies with the requirements for use in contact with food of FDA regulation 21 CFR 177.1520 (c) 3.1 a
- The resin complies with the compositional requirements for use in contact with food of Commission Regulation (EU) No 10/2011.
- The material is Animal Derived Component Free (ADCF).

[1] Typical value

3. Production process

3.1. *General*

Manufacturing and assembly of Cleansteam™ bags is performed under ISO Class 5 at rest cleanroom conditions (ISO 14644-1). The extrusion of the HDPE film is done in an ISO Class 8 environment (ISO 14644-1).

3.2. *Process Steps*

Step 1: Blow extrusion of HDPE film
Step 2: Winding of HDPE film
Step 3: Unwinding of HDPE and Tyvek, followed by automatic cutting and sealing of the bags
Step 4: Packaging of finished bags
Step 5: Labelling of packaged bags

3.3. *In Process Controls*

Test	Method	Frequency
Dimensions	Internal	Per batch
Visual control	Internal	100%
Sealing strength	ASTM-F88	Per batch
Seal integrity test	Internal	Per batch
Cleanliness	IEST-STD-CC1246D	Per batch

Visual control
No disconformities which affect the functionality or quality of the bag.

Seal strength
The seal strength of the film/film weld is tested according to ASTM-F88.
Seal strength film/film: ≥ 20 N/15mm

Seal integrity test
No leaks detected with seal pinhole test (dye-penetration test with methylene blue).

Cleanliness
Cleanliness level 200 according to IEST-STD-CC1246D.

4. Packaging & Labeling

Finished Cleansteam™ bags are double packed into sealed bags under cleanroom conditions. Each pack is labelled as follows:

- Product type(= item number)
- Description
- Quantity
- Batch number
- Package number
- Manufacturing date
- Expiry date
- Warning statements

Packs are packed into cardboard boxes. Each box is labelled as follows:

- Product type(= item number)
- Description
- Quantity
- Batch number
- Package number
- Manufacturing date
- Expiry date

5. Traceability

There is traceability of raw materials for each lot. There is traceability of the product through Pall Life Sciences processes.

6. Certificates

A certificate of conformity (COC) is supplied with each shipment stating that the requirements of this specification have been met.

Cleansteam™ Technical properties

1. Tyvek layer (Tyvek 1073B)[1]

Property	Test method	Unit	Value
Basis weight	ASTM D3776 EN ISO 536	g/m²	71.2 – 78.0
Delamination	ASTM D2724	N/2.54 cm	1.8 – 3.6
Gurley Hill Porosity	TAPPI T460 ISO 5636-5	sec/100 cc	8 – 36
Miscellaneous property	Test method	Unit	Typical value[2]
Microbial barrier	ASTM F1608 ASTM F2638	log reduction value (LRV) % pMax	> 5 < 0.3
Bendtsen Air Permeability	ISO 5636-3	mL/min	513
Moisture vapor transmission rate	TAPPI T523	g/m²/24h	> 1600
Hydrostatic head	AATCC TM 127 EN 20811	cm H_2O	159
Tensile strength, MD	ASTM D5035 EN ISO 1924-2	N/2.54 cm	221
Tensile strength, CD	ASTM D5035 EN ISO 1924-2	N/2.54 cm	219
Elongation, MD	ASTM D5035 EN ISO 1924-2	%	20
Elongation, CD	ASTM D5035 EN ISO 1924-2	%	24
Elmendorf Tear, MD	ASTM D1424 EN 21974	N	3.2
Elmendorf Tear, CD	ASTM D1424 EN 21974	N	4.0
Mullen Burst	ASTM D774 ISO 2758	kPa	1234
Spencer puncture	ASTM D3420	J/m²	10324
Opacity	TAPPI T425 ISO 2471	%	92

2. HDPE layer

Property	Test method	Unit	Value
Thickness	Internal	µm	70 – 90
Property	**Test method**	**Unit**	**Typical value[2]**
Max Tensile strength, MD	ASTM D882-02	N/mm²	41
Max Tensile strength, CD	ASTM D882-02	N/mm²	37
Yield strength, MD	ASTM D882-02	N/mm²	28
Yield strength, CD	ASTM D882-02	N/mm²	30
Tear strength – initial max load, MD	ASTM D882-02	N	13
Tear strength – initial max load, CD	ASTM D882-02	N	21
Tear strength – avg force, MD	ASTM D882-02	N	12
Tear strength – avg force, CD	ASTM D882-02	N	20
Chord modulus at 0.5 and 1 mm, MD	ASTM D882-02	MPa	840
Chord modulus at 0.5 and 1 mm, CD	ASTM D882-02	MPa	930
Elongation at break, MD	ASTM D882-02	%	900
Elongation at break, CD	ASTM D882-02	%	900
Puncture resistance, maximum load	FTMS 101C	N	39
Puncture resistance, deflection at maximum load	FTMS 101C	mm	19
Dart drop impact	ASTM D1709	g	130
Oxygen transmission rate	ASTM D3985	cc/m²/24h	678
Water vapor transmission rate	ASTM F1249	g/m²/24h	0.409
Seal strength (to Tyvek layer)	ASTM F88	N/15 mm	≥ 20

[1] Tyvek properties are according to Dupont Technical reference guide for medical and pharmaceutical packaging. Miscellaneous properties are subject to slight changes from normal process drift. For more information, consult Dupont Technical reference guide.

[2] Typical values for properties are calculated from lot averages measured on validation lots. These properties are not subjected to process control and should not be used as specifications.