

Klercide™ 70/30 IPA

Advantages

■ High quality product

The Klercide 70/30 IPA Aerosol (stream aerosol) is IPA blended with highest grade (EP – which requires a distillation process) Water for Injection, with guaranteed endotoxin levels below 0.25 EU/ml. Triple bagged for easy transfer into Grade A and B cleanrooms and gamma irradiated to ensure a sterile, spore free product.

■ Guaranteed sterility during use

The aerosol has also been validated to maintain sterility for three months during use so there is no need to discard unused product.

■ Reduction in atmospheric alcohol

A lower level of airborne alcohol is generated by the concentrated jet of the stream aerosol compared to a standard aerosol. This results in a reduction of the atmospheric alcohol if the same quantity of product is used.

■ Optimum surface coverage

The choice of aerosol formats allows the user to select the most appropriate method of application, either the fine mist of the standard aerosol or the concentrated spray pattern of the stream aerosol.



■ GMP compliant

This stream aerosol minimises particulates generated whilst in use, making it highly suitable for use in Grade A environments. In line with the latest update to Annex 1 of the EU Guidelines for Good Manufacturing Practice, the stream aerosol can be used during the continuous monitoring that is necessary for the full duration of critical processing.

A custom made detachable and autoclavable wall mounted hands free dispenser allows for hands free glove disinfection. This ensures compliance with standard operating procedures is maintained and that out of specification readings as a result of aerosol usage are avoided providing more meaningful monitoring results.

Description

Klercide 70/30 IPA is a blend of 70% isopropyl alcohol with Water for Injection. Endotoxin levels for this product are guaranteed to be below 0.25 EU/ml.

The nozzle is designed to provide a steady stream of alcohol instead of a jet or a spray. The flow of fluid creates no particles so does not set off a particle counter.



Standard Aerosol

Stream Aerosol

The alcohol blend is 0.2 micron filtered, filled and triple bagged under Grade B (ISO Class 5) Laminar Air Flow in a Grade C (ISO Class 7) cleanroom, before irradiation using a validated process at no less than 25 kGy. The aerosol has been validated to preserve the sterility of the contents for 3 months.

Klercide 70/30 IPA Aerosol can also be wall mounted using the Klercide Wall Mounted Spray Adaptor.

Use biocides safely. Always read the product information before use.

Particulates generated by the Klercide 70/30 IPA Aerosol (stream)

All trigger sprays and standard aerosol cans, even when set to jet, create aerosolised alcohol particles which are picked up by a standard cleanroom air particle counter. This can lead to false positives, creating an out of spec result which has to be justified when used in a Grade A environment where GMP requirements call for continuous particle monitoring.

Type of Product	Particle Size (μm)		
	0.3 – 0.5	0.5 – 1.0	1.0 – 5.0
Trigger spray mist setting IPA	67 – 69% Average 68%	27 – 29% Average – 28%	3 – 4 % Average – 4%
Trigger spray mist setting Denatured Ethanol	61 – 65% Average 63%	30-35% Average 32%	6 – 11% Average 8%
Trigger spray jet setting IPA	36 – 90% Average 69%	10 – 29% Average 14%	0 – 36% Average 14%
Non adjustable trigger spray IPA	85 – 93% Average 89%	7 – 15% Average 11%	<1%
Nitrogen pressurised aerosol can	25 – 34% Average 29%	47 – 50% Average 48%	19 – 26% Average 22%
Aerosol can with stream aerosol	0%	0%	0%

Peer reviewed data

Recent peer reviewed data highlights the requirement for an alternative aerosol delivery system¹.

This work covered three major areas, these were:

- Establishing the particulate levels associated with cleanroom activities.
- IPA aerosol residence time.
- Comparison of particulate levels for manufacturing operation with and without the use of the stream aerosol.

The cleanroom activities highlighted the levels of particulates generated from a standard alcohol product with 10 fold greater particulates generated through the use of a standard aerosol product than those generate by vigorous personnel movements. In addition to this it takes twice the time for the aerosol particles to reduce to consistent low levels as opposed to those generated by personnel.

The IPA residence time showed that a 5 second release from a standard aerosol product would release as many as $3 \times 10^5 \geq 0.5\mu\text{m}$ particles. These can then take up to 14 minutes to disperse, (in the experimental chamber established for measurement).

This means that there is a risk that any cleanroom activity which generates particles is likely to be masked by the particles generated through aerosol usage. This is aggravated by the residence time of the alcohol.

The comparison of manufacturing activities; transfer of equipment contact parts, set-up, production operation, environmental monitoring, clean-down and glove disinfection every ten minutes, were repeated the next day using the stream aerosol as opposed to a standard aerosol.

This highlighted a significant reduction in both $\geq 0.5 \mu\text{m}$ and $\geq 5 \mu\text{m}$ particles when using the stream aerosol.

Results from the comparison of manufacturing activities:

Delivery System	Number of Particles per ft ³			
	Particles $\geq 0.5 \mu\text{m}$		Particles $\geq 5 \mu\text{m}$	
	Statistically Derived Operational Alert Limit	Class Limit	Statistically Derived Operational Alert Limit	Class Limit
Standard Aerosol	9,000	10,000	>100	83
Stream Aerosol	3,000	10,000	60	83
Reduction in Number of Particles (per ft ³) Stream Aerosol vs Standard Aerosol				
Total average number of particles	86%		69%	
Operation Alert Limit	67%		>40%	

The use of the stream aerosol brought both the $\geq 0.5 \mu\text{m}$ and $\geq 5 \mu\text{m}$ statistically derived alert limits down to within the class limits (the $\geq 5 \mu\text{m}$ were previously exceeded by the standard aerosol product). This means that more meaningful alert limits can be set and compliance with Good Manufacturing Practice guidelines can be obtained.

Protocol

Ready to use, so can be sprayed directly onto the surface to be sanitised. Always ensure the whole surface is in contact with the liquid. For optimum results, wipe the surface to physically remove any contaminants.

Validation

Supplied by a ISO 9001:2008, ISO 13485:2012 and European Medical Device Directive 93/42/EEC accredited company.

Passes EN test 1276 for bactericidal efficacy and EN 1650 for fungicidal efficacy.

Certificates of analysis, irradiation and quantitative endotoxin levels <0.25 EU/ml with every batch. Endotoxin tested to an approved pharmacopœial method.

3 year shelf life.

Product Codes

CODE	OLD CODE	LANGUAGES ON LABEL	DESCRIPTION	WATER QUALITY	STERILE / FILTERED	SIZE	UNIT OF SALE
3078550	3050930	GB;DE;FR;IT; ES;NL	Klercide 70/30 IPA Aerosol	WFI	Sterile	360ml	24 cans x 0.36L
	3057910		Klercide Wall Mounted Spray Adaptor				1

References

1. Tim Eaton. Cleanroom Airborne Particulate Limits of 70% Isopropyl Alcohol: A lingering problem for Pharmaceutical Manufacturing? PDA J Pharm Sci and Tech 2009, 63 559-567

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