

Isofield Overboots

Non-sterile Cleanroom Overboots

Last updated 25 Mar 2024





80760

SIZE UNIVERSAL



PRODUCT INFO



Non-sterile Cleanroom overboots 50cm knee height Two ties for added security Anti-slip PU sole Aseptically folded

CLEANROOM COMPATIBILITY



ISO Class 4 cleanroom ISO Class 5 cleanroom

Class 10 cleanroom Class 100 cleanroom

QUALITY ASSURANCE



Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

APPLICATIONS 👺



Pharmaceutical product preparation Cleanroom cleaning and preparation Medical device manufacturing Blending operations for biotechnologies Handling of active materials Maintenance of equipment and instruments

STORAGE & SHELF LIFE 🗃



Store in a dry, cool place (<40°C) away from direct sunlight

Do not expose open cartons to prolonged direct fluorescent light

Three (3) years from date of manufacture

PACKAGING 📮



10 pairs per double bag, 8 sealed outer cleanroom bags, 80 pairs per carton

MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight	g/m²		±2	60
Machine Direction Strength	N/5cm	ISO 9073-1-1989	≥50	69
Machine Direction Elongation	%		≥100	109
Cross Direction Strength	N/5cm		≥25	43
Cross Direction Elongation	%		≥100	111
Hydrostatic Head	mmH ₂ 0	ISO 811-1981	≥100	213
Air Permeability	I/m²/S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	1	107
Slip Resistance	Coefficient of Friction (COF)	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

HELMKE DRUM TEST RESULT

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	TYPICAL
≥ 0.3µm	547	less than 2000	<400
≥ 0.5µm	222	less than 1200	<1000

ASTM F739-20 TEST METHOD

CHEMOTHERAPY DRUGS TESTED	MEAN BREAKTHROUGH TIME (MBT), MINUTES BREAKTHROUGH OF THE TEST CHEMICAL IS DEEMED TO HAVE OCCURRED WHEN THE PERMEATION RATE HAS REACHED 0.11 µG/CM²/MIN*	
Carmustine	30 mins	
Cisplatin	> 480 mins	
Cyclophosphamide	> 480 mins	
Doxorubicin HCI	> 480 mins	
Etoposide	> 480 mins	
Fluorouracil	> 480 mins	
Methotrexate	> 480 mins	
Paclitaxel	> 480 mins	
Thiotepa	60 mins	
*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory		

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	7.0kg	7.0kg
Carton size	W43 L28 H31cm	W43 L28 H31cm
Nett weight	6.0kg	6.0kg
Air freight pallet	Max height: 139cm Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 Cartons: 40

DOCUMENTATION



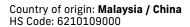
CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF IRRADIATION (COI)

View sample of COC, COA, COI



FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate, please email us



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