

Isofield Beta Kits

Sterile Cleanroom coverall with mandarin collar, hood with integrated facemask & overboots

PRODUCT INFO



MANDARIN COLLAR COVERALL

Two-layer mandarin collar provides secure fit at neck area
Zip flap with double-sided tape prevents ingress and egress of particles

Low-linting, anti-static fabric suitable for chemo handling

Elasticated thumb loops

Back elastic to prevent bellows effect



HOOD WITH INTEGRATED FACEMASK

Integrated mask with two ties for quick and easy donning

Latex-free enclosed elastic face opening for comfort fit

Extra-long yoke for added protection

Three panel hood design to minimize skin exposure



OVERBOOTS

Extra-Long 50cm, knee height

Two-ties for added security

Anti-slip PU sole



QUALITY ASSURANCE

Type 5/6 certified

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

Processed in a NEBB certified ISO Class 5 cleanroom

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

Five (5) years from date of manufacture

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom

GMP Grade B cleanroom

ISO Class 4 cleanroom

ISO Class 5 cleanroom

Class 10 cleanroom

Class 100 cleanroom

APPLICATIONS

Pharmaceutical product preparation

Cleanroom cleaning and preparation

Aseptic filling & labelling

Medical device manufacturing

Handling of active materials

Blending operations for biotechnologies

Handling Chemotherapy in

Hospital Pharmacy

PACKAGING

1 set (hood/coverall/boots) per sealed inner bag,

1 inner bag per sealed outer bag,

40 outer bags per carton liner with twist tie (S-XXL),

35 sets per carton (3XL-4XL)



All three items are aseptically folded

PRODUCT CODE

REF

80451

XSMALL
SMALL
MEDIUM
LARGE

80451XS
80451S
80451M
80451L

XLARGE
2XLARGE
3XLARGE
4XLARGE

80451XL
80451XXL
80451XXXL
80451XXXXL



STERILE R

MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight PP/PE Film Laminate	g/m ²	ISO 9073-1-1989	±2	60
Hydrostatic Head	mmH ₂ O	ISO 811-1981	≥100	213
Air Permeability	l/m ² /S	GB/T5453	≥	2000
Surface Resistivity	Ω / sq	ASTM D257	Static Dissipative	10 ¹⁰
Overboot Slip Resistance	Coefficient of Friction (COF)	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS	TEST METHOD
≥ 0.3µm	743	less than 2,000	1	IEST-RP-CC003.4
≥ 0.5µm	318	2,000 - 20,000	1	IEST-RP-CC003.4
≥ 5.0µm	43	20,000 - 200,000	1	IEST-RP-CC003.4

*Test carried out on coverall and hood. Typical results.

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	30 min	ASTM F739-20
Cisplatin	> 480 min	ASTM F739-20
Cyclophosphamide	> 480 min	ASTM F739-20
Doxorubicin HCl	> 480 min	ASTM F739-20
Etoposide	> 480 min	ASTM F739-20
Fluorouracil	> 480 min	ASTM F739-20
Methotrexate	> 480 min	ASTM F739-20
Paclitaxel	> 480 min	ASTM F739-20
Thiotepa	60 min	ASTM F739-20

*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory

**Mask not tested

TECHNICAL PROPERTIES

TEST REFERENCE		EXPLANATION	TEST RESULTS	
EN 14325:2004 EN ISO 6530:2005		Repellency to chemicals	10% Sodium Hydroxide	Level 3
			30% Sulphuric Acid	Level 3
			O-Xylene	Level 2
			Butan-1-ol	Level 2
			70% Isopropyl Alcohol	Level 2
			70% Ethanol	Level 2
EN 14325:2004 EN ISO 6530:2005		Resistance to Penetration by chemicals	10% Sodium Hydroxide	Level 3
			30% Sulphuric Acid	Level 3
			O-Xylene	Level 3
			Butan-1-ol	Level 3
			70% Isopropyl Alcohol	Level 3
			70% Ethanol	Level 3
EN 14325:2004 EN ISO 9073-4:1997		Trapezoidal Tear Resistance	Machine Direction	Class 2
			Cross Direction	Class 2
EN 14325:2004 EN ISO 13934-1:2013		Tensile Strength	Machine Direction	Class 1
			Cross Direction	Class 2
EN ISO 13982- 2:2004 EN ISO 13982- 1:2004 (Type 5)		Inward Leakage of aerosols and fine particles into suits	Pass	
		IL _{82/90}	0.544%	
		IL _{8/10}	0.233%	
EN 14325:2004 EN ISO 12947-2:2016		Abrasion Resistance	Class 2	
EN 14325:2004 EN ISO 7854:1997, Method B		Flex Cracking Resistance	Class 6	
EN 14325:2004 EN 863:1995		Puncture Resistance	Class 1	
EN 14325:2004 [5.5]		Seam Strength	Class 2	
EN 13034:2015 + A1:2009 ISO 17491-4:2008 (Type 6)		Resistance to penetration by a spray of liquid (Spray Test)	Pass	



Hood with Integrated Tie-on Facemask

FACEMASK MATERIALS

Outer layer	Non-woven spunbond polyester
Filtration Layer	Non-woven meltblown polyester
Inner facing layer	Non-woven polypropylene / polyethylene
Tie-tapes	Non-woven polyester

FACEMASK FILTRATION PROPERTIES

Particle Filtration Efficiency (PFE) @ 0.1 Micron	94%
Bacterial Filtration Efficiency (BFE) @ 0.3 Micron	97%
Differential Pressure (ΔP), mm H ₂ O/cm ²	6.8

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	13.31 - 16.76kg	13.31 - 16.76kg
Carton size	W38 L58 H47cm	W38 L58 H47cm
Nett weight	10.51 - 13.96kg	10.51 - 13.96kg
Air freight pallet	Max height: 109cm Layers: 2 Cartons: 8	Max height: 109cm Layers: 2 Cartons: 15
Sea freight pallet	Max height: 156cm Layers: 3 Cartons: 12	Max height: 156cm Layers: 3 Cartons: 15

DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF PROCESSING (COP)

Please [email us](#)



FACTORY RELATED CERTIFICATIONS
To request ISO9001 Certificate,
please [email us](#)

Country of origin: **China**
HS Code: 6210109000

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