

Isofield Beta Kit

Sterile Cleanroom Coverall with Mandarin Collar,
Hood with 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



OVERBOOTS

Extra long — 50cm knee height
Two ties for added security
Anti-slip 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,

20 outer bags per carton liner with twist tie (XS-2XL),

15 outer bags per carton liner with twist tie (3XL-5XL)



Three items are aseptic fold

PRODUCT CODE

REF

80451

XSMALL 80451 XS
SMALL 80451 S
MEDIUM 80451 M
LARGE 80451 L
XLARGE 80451 XL

2XLARGE 80451 2XL
3XLARGE 80451 3XL
4XLARGE 80451 4XL
5XLARGE 80451 5XL



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	
In-house AQL 1.5	Test plan for major defect	Pass	
EN ISO11137 Part 2:2015	Sterility validation	SAL 10 ⁻⁶	



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	6.84 - 8.44kg	6.84 - 8.44kg
Carton size	W28.5 L47 H38cm	W28.5 L47 H38cm
Nett weight	5.53 - 7.13kg	5.53 - 7.13kg
Air freight pallet	Max height: 128cm Layers: 3 Cartons: 18	Max height: 129cm Layers: 3 Cartons: 24
Sea freight pallet	Max height: 167cm Layers: 4 Cartons: 24	Max height: 167cm Layers: 4 Cartons: 32

DOCUMENTATION



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

View [sample](#) of COC, COA, COP



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

Country of Origin: China
HS Code: 6210109000

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EUROPE

ISOFIELD (IRELAND) LTD
Charter House, 5 Pembroke Row, Dublin 2
Dublin, D02 FW61, Ireland

ASIA

ISOFIELD SDN BHD
6 Jalan Gudang 16/9, Seksyen 16, 40200, Shah Alam,
Selangor, Malaysia, T +603 5512 1709

CONTACT

www.isofield.com
enquiries@isofield.com