

Isofield Steridon Single-Use Garment

Sterile coverall with hood and
integrated facemask

PRODUCT INFO

GMP Grade A & B compatible
ISO Class 4 & 5 compatible
Aseptic fold
Donning in less than one minute

DESIGN

Integrated facemask with guided tie-on system
Enclosed and elasticated face, wrists and ankles
Ergo-fit design at back and shoulders
Bound seams

FABRIC

52gsm tri-laminate fabric
Excellent fluid and viral protection
Soft, comfortable, and breathable

ASEPTICALLY PACKED

Aseptically presented fold
Colour coded left & right inner tabs
Removable external tabs at zipper to maintain
sterile field

STERILIZATION

Validated for sterility by X-Ray
Sterility Assurance Level (SAL) 10⁻⁶

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
Aseptic filling and labelling
Medical device manufacturing
Blending operations for biotechnologies
Handling of active materials
Maintenance of equipment and instruments



First cleanroom garment
validated for sterility by **X-Ray**



BARRIER TEST/PERFORMANCE

BARRIER TEST/PERFORMANCE	TEST METHOD	TYPICAL VALUES
Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities /clothing for protection against contact with blood and body fluids-test Method using synthetic blood	ANSI/AAMI PB70 ISO 16603:2004 ASTM F1670	Level 4 Class 6
Viral penetration test (liquid challenge : bacteriophage Phi-X174)	ASTM F1671 ISO 16604:2004	Pass Class 4
Material resistance to wet bacterial Penetration	ISO 22610	Class 6
Resistance to penetration by biologically contaminated aerosols	ISO 22611	Class 3
Resistance to dry microbial penetration	ISO 22612	Class 3

PHYSICAL PROPERTIES

PHYSICAL PROPERTIES	TEST METHOD	TYPICAL VALUES
Basis weight	ASTM D3776	52 g/m ²
Dry mullen burst strength	TAPPI T403 om-02	2100 g/cm ²
Tensile strength	ASTM D5034 (Grab CD)	7500 g (16.5 lbf)
	ASTM D5034 (Grab MD)	11000 g (24.5 lbf)
Trapezoid tear MD	ASTM D5733-95	2400 g
Hydrostatic head with screen	AATCC 127	200 cm
Wet peel CD (inner/outer)	ASTM F904-98	50/100 g/2 in
Moisture vapor transmission rate (MVTR)	ASTM E96 Procedure D	1400 g/m ² /day
Helmke drum particle count	IEST-RP-CC003.4	Class I (<2000)
Static decay MD/CD	WSP 40.2	0.5/0.5 seconds

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	TEST METHOD	TYPICAL VALUES
Blenoxane	ASTM D 6978-05	> 240 mins
Cisplatin	ASTM D 6978-05	> 240 mins
Cytarabine	ASTM D 6978-05	> 240 mins
Dacarbazine	ASTM D 6978-05	> 240 mins
Ellence	ASTM D 6978-05	> 240 mins
Fludarabine	ASTM D 6978-05	> 240 mins
Gemcitabine	ASTM D 6978-05	> 240 mins
Idarubicin	ASTM D 6978-05	> 240 mins
Ifosfamide	ASTM D 6978-05	> 240 mins
Irinotecan	ASTM D 6978-05	> 240 mins
Mechlorethamine HCL	ASTM D 6978-05	> 240 mins
Melphalan	ASTM D 6978-05	> 240 mins
Methotrexate	ASTM D 6978-05	> 240 mins
Mitomycin C	ASTM D 6978-05	> 240 mins
Mitoxantrone	ASTM D 6978-05	> 240 mins
Vincristine Sulfate	ASTM D 6978-05	> 240 mins



PACKAGING

- 1 piece per sealed inner cleanroom bag
- 1 inner bag per sealed outer bag
- 20 outer bags per carton liner with twist tie
- 20 pieces per carton (S-XXL)
- 15 Pieces per carton (3XL-5XL)

SHELF LIFE

Three (3) years from date of manufacture

STORAGE

Store in a cool, dry place (<40°C) away from direct sunlight
Do not expose opened cartons to prolonged direct fluorescent light

PRODUCT CODE

REF 80231

SMALL	80231S
MEDIUM	80231M
LARGE	80231L
XLARGE	80231XL
XXLARGE	80231XXL
3XLARGE	80231XXXL
4XLARGE	80231XXXXL
5XLARGE	80231XXXXXL