

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

BioClean-C Non-Sterile Chemotherapy Protective Sleeve Cover

About

Designed for protection, the BioClean-C™ Chemotherapy Protective Sleeve Covers have been specially developed for maximum protection against a range of chemotherapy drugs, and to be compatible with ISO Class 4 cleanrooms. Constructed from lightweight, low-linting and hard wearing CleanTough™ material, the sleeve covers feature elasticated arms and 100% polyester elasticated cuffs. The 'one size fits all' cover has been tailored for quick and simple donning.

Specifications

MATERIAL:

CleanTough™ material

COLOUR:

Blue

CONSTRUCTION:

Ultrasonically bonded seams covered with protective tape

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Low particulating

COMPATIBILITY:

ISO Class 4

Features

- Tested against ASTM D6978-05 using a minimum of nine cytotoxic drugs
- Ultrasonically bonded seams with protective tape
- · Elasticated for secure fit
- Processed to ensure ISO Class 4 compatibility
- · 100% polyester elasticated cuffs
- Lightweight, low-linting & hard wearing CleanTough™ material

CHEMOTHERAPY
Protective Sleeve Covers
BCSC

LIGHTWEIGHT & LOW-LINTING

TESTED AGAINST ASTM D6978-05

100% POLYESTER ELASTICATED CUFFS

ULTRASONICALLY BONDED SEAMS





Dr Isolator™ represents BioClean's™ GMP compatible Chemo Safety Wear





Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Tested against standard EN ISO 13034 protective clothing against liquid chemicals (Type PB [6])
- Tested against standard EN 14325 protective clothing against chemicals
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment

Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Performance Test Results

TEST	RESUL	Т	PERFORMANCE CLASS (EN 14325)		
Abrasion Resistance	10 to 100 cycle	es	1		
Flex Cracking Resistance	5,000 to 15,000 cy	cles	3		
Trapezoidal Tear Resistance	MD 58.4 N		3		
Trapezoidal Tear Resistance	CD 42.5 N		3		
Tensile Strength	MD 68 N		2		
Tensile Strength	CD 43 N 9 N		1		
Puncture Resistance			1		
Repellence to Liquids	30% H ₂ SO ₄	99.0%	3		
	10% NaOH	98.4%	3		
	O-Xylene	91.4%	2		
	Butan-1-ol	93.9%	2		
Penetration by Liquids	30% H ₂ SO ₄	0%	3		
	10% NaOH	0%	3		
	O-Xylene	0%	3		
	Butan-1-ol	0%	3		
Seam Strength ¹	90 N		3		

¹Seam not destroyed.

Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)	
Particle Shedding (Helmke Drum Test)	<260	Category I	





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CleanTough™ Material - ASTM D6978-05 Test Results

Breakthrough detection time (minutes)

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO-RUBICIN HYDRO-CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

Product Numbers

BCSC

6 pc/bg, 15 bgs/cs



