

AseptiBag APT

Antistatic Powder Transfer Bags

mdi AseptiBag® APT single use antistatic powder bags are designed to provide reliable and effective solution for powder containment and delivery systems in biopharmaceutical processes. These are manufactured using high strength LDPE film with antistatic properties which helps in maximum powder recovery while also ensures sterility. The antistatic properties of the film significantly reduce the risk of static charge buildup, making these bags ideal for handling sensitive powders.

These are available with 6" sanitary flange ports to facilitate easy and secure fitment during powder transfer to bioprocess systems such as mixers.

Sizes Available

Ports	3", 4" and 6" sanitary flange ports
Bag	1 L, 2 L, 5 L, 10 L, 20L and 25 L

Applications

Storage and transfer of high value drug substances and Chemically defined proprietary media

Special Features

- High powder recovery and minimum product loss
- Reduce costs
- High strength film

Materials of Construction

Bag Film	LDPE with antistatic properties
Port	HDPE
TC Blind	HDPE
Gasket	Silicone
TriClamp	ABS



Specifications

Sterilization by Gamma Irradiation

mdi AseptiBag® APT single use antistatic powder bags are Gamma Sterilizable upto 50 kGy.

Sterility

The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6} .

Bioburden Levels

Bioburden level is < 1000 cfu/device as per ISO 11737-1:2018

Bacterial Endotoxin Levels

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amoebocyte Lysate (LAL) test as per USP <85>

Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release

Particle Release

The filtrate complies with USP <788> test for particulate matter in injections

Quality Management System

mdi AseptiBag® APT antistatic powder bags are well designed products with in-built quality assurance. ISO-9001:2015 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality bags.

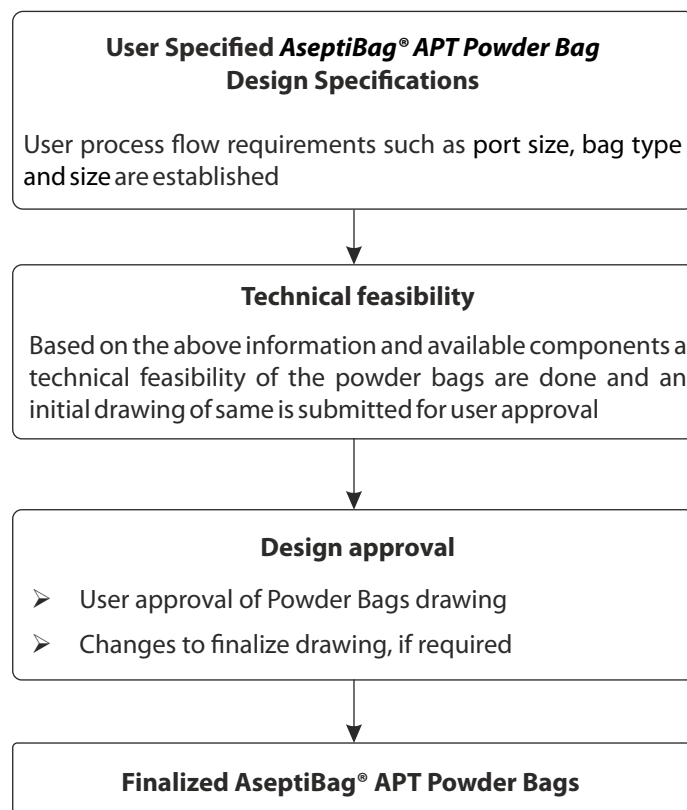
Manufacturing Facilities

mdi AseptiBag® APT antistatic powder bags are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

Customization

mdi AseptiBag® APT antistatic powder bags can be customized to suit user requirements in terms of ports, size and capacity.

Product Realization Flow Chart



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