

ChargeBag® PE-S

The ChargeBag® PE-S is a single use, cost effective container for the handling, storage and transfer of bio-pharmaceutical powders.

Made with HiPure ULP7, a new pharma ready LLDPE film from ChargePoint Technology, to meet the demands of the most critical aseptic processing environments.

ChargeBag® PE-S

Features & Benefits

Reduce costs and control risks

- Reduce cross contamination, time and expense associated with cleaning and validation with a single use container.

Easy to integrate

- A HDPE reinforced handle for manual handling and safe for connection to lifting hoists
- Standard tri-clamp connection provides extensive compatibility with existing systems

Maximise powder recovery

- Optimal funnel shape and electrically dissipative film maximises powder flow, speed and ultimately recovery

Comprehensively qualified

- Pressure tested to verify the integrity of each bag
- Highly compliant; Rigorously tested to the most up to date standards.

Built for aseptic processing

- Manufactured with high levels of quality control within an ISO6 cleanroom environment
- Can be supplied gamma sterilised ready to use in aseptic and other GMP or bioburden-controlled processes.

Safety for personnel and product

- Manufactured from HiPure ULP7, a proprietary LLDPE film with extremely high levels of integrity with optimised purity and robustness characteristics.



A complete powder transfer system

The ChargeBag® is now available with a ChargePoint® Single Use SBV (Split Butterfly Valve) interface directly welded to the ChargeBag® offering high levels of dust containment and sterility assurance performance in conjunction with the ChargePoint SBV.

Applications

Chemical Synthesis	Seed, Intermediates, Actives, API
Solid Dose Formulation	API, Excipients, Formulations, Tablets, Capsules
Aseptic Processing / Filling	API, Closure Components (vial stoppers)
Bioprocessing	Buffer / Media Powders

Specifications

		ChargeBag® PE-S	ChargeBag® PE-SBV
Standard Volumes		10, 15, 25, 40L	10, 15, 25, 40L
Materials	Film	HiPure ULP7, 250 micron (10mil) single layer LLDPE with a permanent anti-static additive	HiPure ULP7, 250 micron (10mil) single layer LLDPE with a permanent anti-static additive
	Connection	HDPE	HDPE, TPE, PA (GFR)
	Handle	HDPE	HDPE
Connection Interface		50mm (2"), 100mm (4"), 150mm (6") BS4825 Tri-Clamp ferrule welded directly to bag liner	100mm (4") ChargePoint Single Use Passive SBV welded directly to bag liner
Operation Temp Range		0 to 40°C (32 to 104°F)	0 to 40°C (32 to 104°F)
Pressure Rating		None	None
Hazardous Areas		Electrically dissipative and therefore suitable for use in Zones 0, 1 & 2 and Explosion Groups I, IIA and IIB provided it is suitably earthed during gravity filling and discharging	Suitable for use in Dust Zones 20, 21, 22, explosion group III.
Sterilisation		Gamma Irradiation at 25-50 kGy	Available non-sterile or Gamma Irradiated at 25-50kGy
Maximum Loading		15 kgs (33lb)	15 kgs (33lb)
Regulatory Compliance		HiPure ULP7 Film: FDA 21 CFR 177; USP Class VI; EP 3.1.3 Polyolefins; EU 10/2011; REACH; Free from animal derivatives. Tested in accordance to: USP <85> Bacterial endotoxins USP <87> Biological reactivity, In Vitro USP <88> Biological reactivity tests, in Vivo ISO10993 Biological evaluation of medical devices Part 1, 4 and 5. USP 661.1 Plastic Materials of Construction	
		Tri-Clamp Ferrule Material: FDA 21 CFR 177 USP Class VI	Passive SBV Materials: FDA 21 CFR 177 USP Class VI
Manufacturing		ChargeBag® manufactured in ISO6 cleanroom as per ISO14644 under certified ISO9001 Quality Management System.	
Packaging		Each ChargeBag® individually packed within a sealed secondary PE sleeve. 10 bags packed in additional protective liner per carton.	Each ChargeBag® is individually packed within a sealed secondary PE sleeve. 5 bags packed in additional protective liner per carton.
Labelling		Each ChargeBag® and shipping carton labelled with Lot number, manufacturing date, part number.	
Verification Testing/ Inspection		100% visual inspection Pressure tested to verify integrity	
Shelf Life		5 years	