STERIBAC®

Hygienic Filtration System

Solid-liquid separation plants for the Pharma and Biotech industries

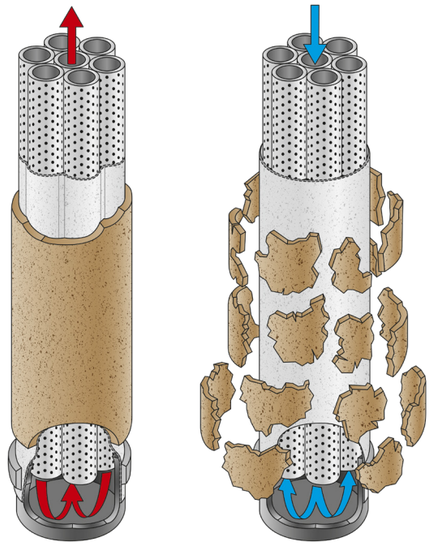
DrM

www.drm.ch

STERIBAC® filter

STERIBAC® is a newly developed filtration system specifically designed for complete CIP technology for GMP and FDA approval. The system is based on the well known FUNDABAC® principle where a suspension containing particles is filtered on one or multiple filter elements inside a pressure chamber. During the filtration the solids collect on the outer surface of the filter medium and a uniform cake is formed. After filtration the solids can be washed, extracted, dried or treated in-situ: due to the concave-convex profile of the filter element the cake remains firmly attached throughout all procedures.

After solids treatment, the filter elements are subjected to a reverse gas flow pres- sure shock. As the filter medium expands, the cake is thrown off. Filter cakes of 3 to 50 mm thickness are completely discharged. The STERIBAC® offers important advantages for the pharmaceutical industries as compared to other solid/liquid separation systems such as centrifuges, separators, nutsches or other filters.



Design advantages

No rotating or otherwise moving parts essentially eliminate maintenance and the shedding of particulate matter and allows easy CIP.

The picture shows an automatic STERIBAC® filtration plant for heel volume filtration, product extraction, cake washing and dry discharge.

Automation of all the filtration steps, from filtration, through washing, down to the enclosed system for the discharge of the dried residue can easily be implemented, even after start-up of the system.

The simple, modular construction of the filtration elements allows adaptation of size, volume and cake thickness in a fully contained system.

Pre-assembled filtration modules (in the case of product dedicated internals) for quick product changes.

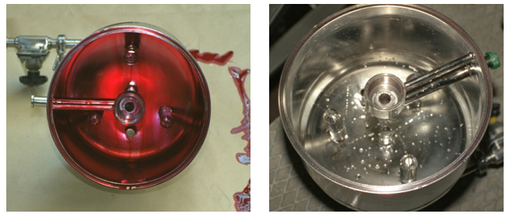
Mobility or flexibility, respectively, is another major criterium in this type of industry. Production cycles are short and batches change frequently. As a result, the equipment must adapt to the required process. Therefore, the machine must be easily transferred from one place to the other. DrM has extensive experience in manufacturing mobile, compact, fully contained and automated filtration systems, which are equipped with the necessary instrumentation, accommodated to the process requirements.

Process advantages

Its entirely enclosed design prevents any contamination of the liquid streams and permits in-situ sterilization. CIP cleaning becomes an easy task, as neither mechanical moving parts nor agitating devices are present. It has been proven that with our applied CIP technology batch integrity can be maintained.

Dry, slurry or reslurried discharge of solids can be changed from batch to batch. Minimizing waste has become an important factor throughout the industries. The patented spray washing system has reduced the required washing liquids and therefore the running costs drastically.

Heel volume treatment (patented) allows an essentially 100% recovery of products, for both solid and liquid heel and assures batch integrity.



CIP performance of the STERIBAC® system:
Filter cover, view of fixed filter parts before and after CIP

Applications options

- Separation of biomass from fermenter slurries
- Separation of precipitated solids in downstream processing lines
- Crystallized product filtration
- Activated carbon treatment of liquid product streams
- Heterogeneous catalyst separation from hydrogenation reactions

Typical design features of the STERIBAC®

Construction material	SS 316L	Check valves	Internal polish RA 0.5 µm and external polish RA 0.8 µm (DrM dead leg free design)
Internal surface	RA 0.4 - 0.5 µm + electro polishing	Pressure gauges	Tubular diaphragm, without dead space and no cross-section restriction
External surface	RA 1.0 - 1.2 µm	Candle connection	DrM CIP design
Vessel flanges	Triclamps	Insulation	Perlite filled jacket
Connections	Triclamps	CIP-Nozzles	Rotating nozzles with pin connection
Interconnecting piping	RA 0.4 - 0.5 µm + electro polishing, 4 - 6° slope, low point drain and high point overflow, connections, orbital weldings with 100 % endoscopic check for FDA validation	Support structure	Square profile pipe frame polished RA 1.2 µm, with integrated stair and antistatic wheels
Gaskets	PTFE or EPDM with FDA-approval	Pressure regulators	Internal polish RA 0.9 µm and external polish RA 1.2 µm
Heel volume spray nozzle	Spiral nozzle with pin connection or removable heel volume distribution pipe	Line sight glass	Aseptic design with O-ring gaskets and triclamp connections
Vessel sight glass	Dead space free design with self cleaning flush	Testing	CIP verification with dye penetrant method (riboflavin test)
Valves	Diaphragm valves with polished bodies, stainless steel valve bonnet and connections. Discharge valve with fill and drain connection to minimize product losses. Alternative: blind cover with swivel support (dry discharge).	Certification	WAZ 3.1.B for ferrite content (< 0.5%) for all wetted stainless steel parts. Laser marking for identification of stainless steel parts. Certificates for surface roughness of stainless steel parts. FDA approvals for all polymer and elastomer parts.

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