



FILTRODISC™ BIO SD

Single use clarification in a new dimension
Disposable high performance microfiltration system
Easy scalable from lab to process

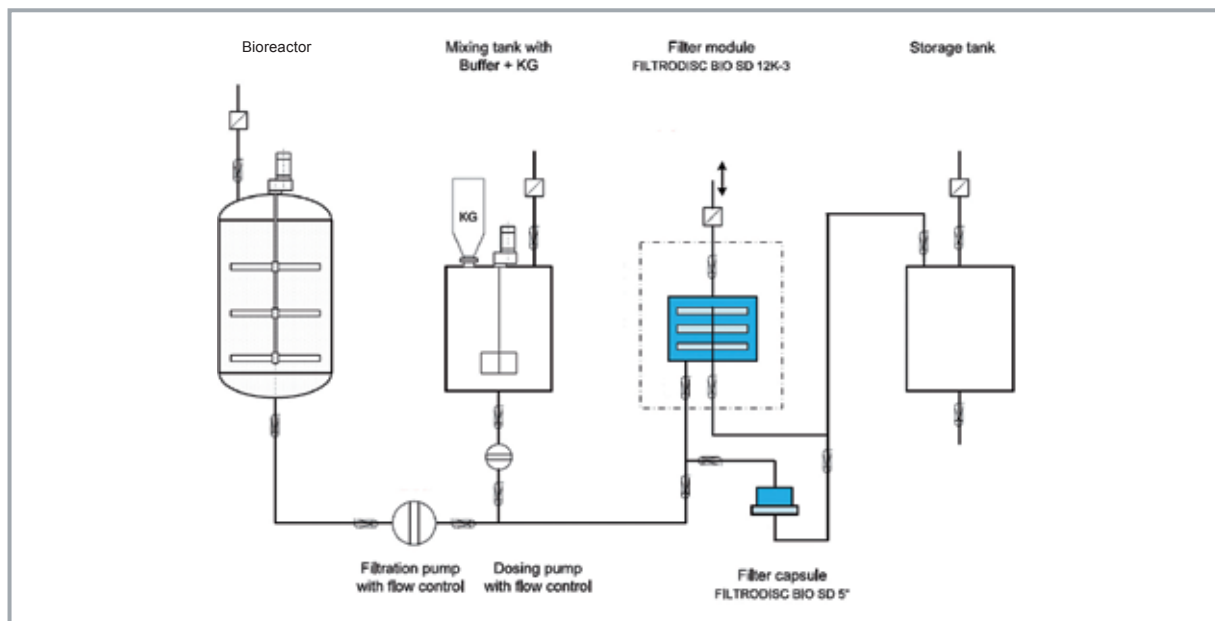
FILTRODISC™ BIO SD

Introduction

Clarification of fermentation broths is one of the most important steps in downstream biotech processes. Optimized fermentation processing leads to dramatically increased cell densities over the recent decade. Standard technologies (centrifugation, depth and membrane filtration) can no longer handle the high particle loads in an economical way. Membranes are very cost intense and their scale up is not practical. The required footprint for standard depth filtration increases with the particle load. Centrifugation, an application in which mechanical stress is applied to cells, increases the turbidity through fine particles which have to be re-

moved further downstream through separation and purification. Alternatively, a depth filter with higher capacity per area can solve these issues.

Alluvial filtration is a well-established method in pharmaceutical industries. Until recently, however, it has not been used for cell separation as it was unavailable as a scalable and disposable system fulfilling all validation requirements. FILTRODISC™ BIO SD is the first depth filter using the advantages of the alluvium technology in a disposable format. It is further useful for other applications like activated carbon removal or processes with highly staining or toxic material creating high cleaning requirements.



Applications

FILTRODISC™ BIO SD comprises of a filtration system which removes particles (e.g. cells, bacteria, yeast) and other turbid matter (e.g. activated carbon) from process liquids like fermentation broths. This system is completely disposable; all material that comes in contact with the product is meant for single use and can be disposed of after the filtration is completed. This "disposability" or "single use" reduces cross contamination risks, eliminates cleaning validation efforts and reduces the downtime during module changes, making this method the ideal choice for contract manufacturers (CMO) and other operations with a high frequency of product change. All systems can be delivered sterile (gamma irradiation, upon request).

The system is scalable from lab size to industrial size filtration. The transfer from method development to large scale processes can be easily achieved.

For alluvial filtration, the pharma grade DE (Celpure®, an Advanced Minerals brand) will be provided from FILTROX in single use transfer bags. These can be easily connected

directly to the single-use bioreactor or mixing device. The fermentation broth is mixed with DE in a bioreactor or mixing bag and then pumped over the filter unit. The DE and the cells form a filter cake, extend the filtration capacity and avoid blocking of the filter media. After the filtration is done, the remaining liquid in the bag can be pumped over a FILTRODISC™ BIO SD 5" capsule to recover the last drops of the valuable liquid. After both filtrations are finished, the module and the capsule can be disposed of.

Performance

The turbid matter of a cell broth is caused by cells, the feed and other degraded ingredients. In order to evaluate the feasibility and to obtain orientation values, tests with *E. coli* bacteria (cell density 6.6×10^6) and *Pichia* yeast (density 4×10^7) have been carried out. In both cases the turbidity after filtration with 5" FILTRODISC™ BIO SD capsules was lower than after a standard centrifugation procedure.

Scalability

We recommend the versions of the FILTRODISC™ BIO SD for the following batch sizes:

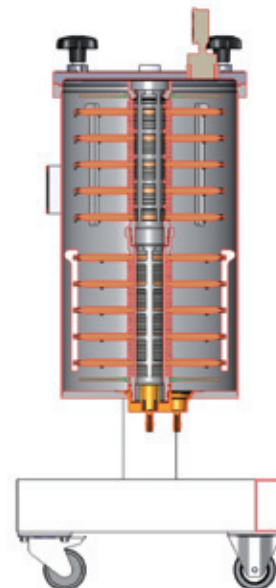
FILTRODISC™ BIO SD	Batch range [litre]	Sludge volume [litre]	Filter area m ²	Application
2" capsule	± 1	0.06	0.002	Proof of technology, evaluation of DE grade
5" capsule	± 5	0.38	0.0127	Dosage of DE and flux
12" short module	± 65	4.8	0.22	Pilot scale
12" single module	± 125	9.9	0.55	Bio process scale
12" double module	± 250	19.8	1.10	Bio process scale
16" double module	± 500	40.7	2.26	Bio process scale

Since all applications are unique, the table above is meant as a preliminary guidance only. Please contact a FILTROX application engineer for customized advice regarding your specific application.



DISCSTAR® BIO SD support systems

Reusable stainless steel shells allow to homogeneously fill the FILTRODISC™ BIO SD bags and to protect them against pressure shocks. The heavy larger modules can be tilted horizontally to allow easy discharge of the used bags. All DISCSTAR® BIO SD housings (except version 12K) will be delivered with a separate trolley for module discharge. A pressure gauge is installed on the top of the support system.



Order information

Part number	Media grade	Size	Code of module version only for 12" and 16"	Number of cells only for 12" and 16"	Hose (inside diameter) only for 12" and 16"	Hose connector only for 12" and 16"	Sterilization																					
BSD	Media grade	Code	2" 5" 12" 16"	Code	Version	Number of cells	<table border="1"> <thead> <tr> <th colspan="3">Inlet/Outlet-Vent</th> </tr> <tr> <th>Code</th> <th>Hose type</th> <th>Module type</th> </tr> </thead> <tbody> <tr> <td>V</td> <td>1/2"-3/8"</td> <td>Code S and K</td> </tr> <tr> <td>W</td> <td>1/2"-3/8"</td> <td>Code D</td> </tr> <tr> <td>X</td> <td>3/4"-3/8"</td> <td>Standard for 12" D</td> </tr> <tr> <td>Y</td> <td>1"-3/8"</td> <td>Standard for 16" D</td> </tr> <tr> <td>Z</td> <td>No hose</td> <td>For all types</td> </tr> </tbody> </table>	Inlet/Outlet-Vent			Code	Hose type	Module type	V	1/2"-3/8"	Code S and K	W	1/2"-3/8"	Code D	X	3/4"-3/8"	Standard for 12" D	Y	1"-3/8"	Standard for 16" D	Z	No hose	For all types
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CH 15P	15	K	Semi high only in 12"	2 or 3																								
CH 23P	23																											
CH 33P	33																											
CH 43P	43																											
CH 53P	53																											
CH 73P	73																											
CH 103P	103																											
CH 113P	113																											
CH 133P	133																											
CH 143P	143																											
CH 153P	153																											

Examples: BSD 113 2" (BIO SD with CH 09P sheet, 12" semi high, 2 lenses, 1/2"-3/8" hose, CPC connector, irradiated)
 BSD 09 12K 2 VCI (BIO SD with CH 53P sheets, 12" double, 10 lenses, 3/4"-3/8" hose, TC connector, not irradiated)
 BSD 53 12D 10 XTH

CPC = Colder Products Company Connector
 TC = Tri Clamp Connector

Material

PURAFIX® P (Pharma grade) filter media

Purified and bleached cellulose, filter aid and polyamido-amine (< 3 %); with low ion and pyrogen content.

2" and 5" capsules

Polypropylene encapsulation.

12" and 16" modules

Backbone and bag material: Polypropylene, Polyethylene or Polyamide.

Gasket material: Silicone, others on request.

Connections

- Hose fittings (lab scale).
- All modules are delivered in a bag equipped with 3 x 25 cm Pharma grade tubing (inlet, outlet, venting).

All materials are FDA approved.

Operating conditions

Max. operating temperature: 60 °C

Max. differential pressure: 2.4 bar

Max. system pressure: 3.0 bar

Recommended rinsing volume: 50 l/m²

Sterilization: only Gamma sterilization available

Filtrox quality assurance

Filtrox assures the best quality control according to international standards:

- ISO 9001:2008 (Quality management)
- ISO 14001:2004 (Environmental management)
- ISO 22000:2005 (Food safety incl. HACCP)
- FDA drug master file: #16418
- EN ISO 3834-2
- DGR 97/23/EG
- China Pressure Vessel Certification
- ASME Code Section VIII Division 1

External tests of lenticular modules and filter sheets were performed and certified according to

- USP plastic class VI (BSL, Munich).
- other CFR requirements by the NAMSA.

A comprehensive validation guide can be ordered from FILTROX.