



# FILTRODISC™ BIO SD

## SINGLE-USE DEPTH FILTRATION SYSTEM

### One-step clarification of fermentation broths with flexible scalability

FILTRODISC™ BIO SD is a filtration system which removes particles (e.g. cells, bacteria, yeast), impurities (e.g. HCP, DNA) and other turbid matter from process liquids (e.g. 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, cleaning validation efforts and downtime during filter changes, making this method the ideal choice for contract manufacturers (CMO) and other operations with a high frequency of product change. All sizes can be ordered gamma sterilized (upon request).

#### Applications

- Cell harvest
- Cell debris removal
- Activated carbon removal
- Removal of toxic substances
- ...

#### Features

- Adaptable in terms of:
  - filter area /space for filter cake
  - retention rates
  - connectors
- Widely scalable from lab (2" capsules, <1 l) to production (16" double module, ~1000 l)
- Very small dead volumes
- Well known and accepted technology (e.g. plasma fractionation)
- Removal of cells and impurities in one step (up to 30–40% HCP's)
- No need for pH changes nor flocculants
- Manufactured in Switzerland
- Variable operation possibilities (diatomaceous earth filtration, sheet filtration)
- Elimination of cleaning validation
- Reduction of cross contamination risks
- Reduction of downtime during filter change
- Reduction of overall production costs

#### Technical data modules

|   | 2" BIO SD  | 5" BIO SD  | 12"K BIO SD |      | 12"S BIO SD |      |      | 12"D BIO SD |      |      | 16"D BIO SD |      |      |
|---|------------|------------|-------------|------|-------------|------|------|-------------|------|------|-------------|------|------|
| Number of filter lenses <sup>1</sup>                    | 1          | 1          | 2           | 3    | 4           | 5    | 6    | 4           | 5    | 6    | 4           | 5    | 6    |
| Filter area for DE filtration [m <sup>2</sup> ]         | 0.002      | 0.0127     | 0.22        | 0.33 | 0.44        | 0.55 | 0.66 | 0.88        | 1.1  | 1.32 | 1.81        | 2.26 | 2.71 |
| Maximum holding volume (cake volume) [l]                | 0.06       | 0.381      | 3.5         | 4.8  | 11.2        | 9.9  | 8.9  | 22.4        | 19.8 | 17.8 | 46.1        | 40.7 | 36.6 |
| Hold up volume after blow out [l] <sup>2</sup>          |            |            | 5.5         | 4.5  | 5.8         | 5.1  | 4.7  | 5.8         | 5.1  | 4.7  | 10.3        | 9.1  | 8.4  |
| Max. amount of DE [kg] <sup>3</sup>                     | 0.017      | 0.109      | 0.99        | 1.38 | 3.2         | 2.8  | 2.5  | 6.4         | 5.7  | 5.1  | 13.2        | 11.6 | 10.5 |
| Max. batch size [l] <sup>4</sup>                        | 0.8        | 5.1        | 65          | 46   | 150         | 132  | 119  | 299         | 264  | 238  | 615         | 542  | 488  |
| Max. filter area for sheet filtration [m <sup>2</sup> ] | 0.002      | 0.0127     | 0.66        |      | 1.8         |      |      | 3.6         |      |      | 7.2         |      |      |
| Size of inlet and outlet connection [DN]                | 4.5        | 6          | 10          |      | 10          |      |      | 15          |      |      | 20          |      |      |
| Inner diameter of inlet and outlet [inch/mm]            | 1/4" / 6.4 | 3/8" / 9.5 | 1/2" / 12.7 |      | 1/2" / 12.7 |      |      | 3/4" / 19.5 |      |      | 1" / 25.4   |      |      |
| Inner diameter of air vent [inch/mm]                    | Luer lock  | Luer lock  | 3/8" / 9.5  |      | 3/8" / 9.5  |      |      | 3/8" / 9.5  |      |      | 3/8" / 9.5  |      |      |
| Min. flow rate [l/m <sup>2</sup> h]                     | 300–350    | 300–350    | 300–350     |      | 300–350     |      |      | 300–350     |      |      | 300–350     |      |      |

<sup>1</sup> For 2" and 5" capsules: number of filter pads

<sup>2</sup> Volume of support system below lowest filter lens; can be reduced by the use of a 5" capsule

<sup>3</sup> Based on wet density of 3.50 l/kg

<sup>4</sup> Based on dosage of 20 g/l DE and 0.5% wet centrifugate in unfiltrate

## Celpure® data

|                                      | C 65  | C 100    | C 300    | C 1000 |
|--------------------------------------|-------|----------|----------|--------|
| Permeability [Darcy]                 | 0.065 | 0.100    | 0.300    | 1.000  |
| Solids removed [micron] <sup>1</sup> | < 0.3 | 0.3–0.45 | 0.45–0.6 | 1–2    |
| Surface area [m <sup>2</sup> /g]     | 6–7   | 5–6      | 3–4      | 1–2    |
| Purity [%]                           | 96–99 | 96–99    | 96–99    | 96–99  |
| Approx. wet density [l/kg]           | 3.5   | 3.8      | 3.9      | 3.9    |

<sup>1</sup> Data is provided for comparison purpose only. Depending on the compressibility of the solids, the values may range by more than an order of magnitude. (Data from Advanced Minerals Validation Guide; Celpure® is an Advanced Minerals brand.)

## Technical data support system

|   | 2" BIO SD | 5" BIO SD | 12"K BIO SD | 12"S BIO SD | 12"D BIO SD | 16"D BIO SD |
|---|-----------|-----------|-------------|-------------|-------------|-------------|
| Hold up volume of empty support system [l]                |           |           | 13.6        | 25          | 51          | 90          |
| Max. hold up volume after filtration run [l] <sup>1</sup> |           |           | 9.9         | 16.4        | 33.0        | 53.7        |
| Max. hold up volume after blow out [l] <sup>2</sup>       |           |           | 5.5         | 5.8         | 5.8         | 10.3        |
| Max. operating pressure at 25°C [bar]                     | 2.5       | 2.5       | 3.0         | 3.0         | 3.0         | 3.0         |
| Max. operating pressure at 60°C [bar]                     | 2.0       | 2.0       | 3.0         | 3.0         | 3.0         | 3.0         |

<sup>1</sup> Hold up volume of empty support system minus maximum cake volume

<sup>2</sup> Volume of support system below lowest filter lens

### Material

- PURAFIX® filter sheets:
  - Cleaned and bleached cellulose
  - Natural filter aid (kieselgur, perlite)
  - Cationic wet strength agent
- Plastic parts module:
  - USP Class VI polypropylene
- Bag material:
  - Multilayer PE
- Tubes:
  - Pharma grade pressure stable tubes
- Connectors:
  - All common types possible, for details please see information from the respective manufacturer

### Retention rates

Please see PURAFIX® technical data sheet

### Leachables & extractables

- Bag material:
  - Please refer to separate validation guide from our bag supplier. Available on request.
- Modules:
  - Please refer to validation guide FILTRODISC™ BIO SD. Available on request.
- Tubes:
  - Please refer to validation guide of the respective tube manufacturer.
- Connectors:
  - Please refer to validation guide of the respective connector manufacturer.

Validation guides for the bag material, modules and tubes can be requested from FILTROX.