

Pre-coat Filtration BECO® PR ENDURA® S

Support Sheets for the Pharmaceutical Industry

BECO PR ENDURA S support sheets are specially developed for the exacting requirements of the pharmaceutical industry. Low endotoxin content is ensured through the use of particularly pure raw materials and a special production process.

The specific advantages of BECO PR ENDURA S support sheets:

- Extremely low content of extractable components.
- Low endotoxin content through special production process.
- Comprehensive quality assurance for all raw and auxiliary materials and intense in-process controls ensure consistent quality of the finished products.
- Increased product yield during cake harvesting due to the extremely smooth and hydrophobic surface.
- Easy past recovery (harvest) and secure handling due to high wet bursting strength.
- Reduced product loss due to the low hold up volume (small thickness and optimized permeability).
- A Validation Guide is available upon request.

Special Low-Endotoxin Filter Sheet for Pre-coat Filtration with Minimum Loss of Product

The application of BECO PR ENDURA S support sheets in pre-coat filtration, particularly for cake harvesting as part of plasma fractionation, ensures safe and economic filtration results.

Product loss during cake harvesting is minimized due to the extremely smooth and hydrophobic surface. The high mechanical resistance and stability further simplifies cake harvest through secure handling.

Even if the intention is to extract the filtrate as a resource substance during pre-coat filtration, product loss is minimized due to the low suction volume (small thickness and hydrophobic matrix) of BECO PR ENDURA S support sheets.



Pyrogens/Endotoxins

Prior to delivery, the BECO PR ENDURA S support sheets are controlled routinely for their endotoxin content. For the quantitative proof of endotoxins the LAL test (**L**imulus **A**mebocyte **L**ysate) is used. The endotoxin content of the samples is specified in EU/ml (endotoxin unit). A certificate is available upon request.

Application Examples

- Cake recovery and removal in pharmaceutical industry
- Cake harvest as part of the plasma fractionation
- Pre-coat filtration and valuable product recovery in the fine/specialty chemistry

Physical Data

This information is intended as a guideline for the selection of BECO depth filter sheets.

Type	Article no.	Thickness in (mm)	Ash content %	Bursting strength wet psi (kPa*)	Water throughput at $\Delta p = 14.5 \text{ psi}$ gpm/ft ²	$(\Delta p = 100 \text{ kPa}^*)$ l/m ² /min)	Endotoxin content** EU/ml
PR ENDURA S	29450	0.06 (1.5)	< 1.0	> 58.0 (400)	18.9	(770)	0.08

The water throughput is a laboratory value characterizing the different BECO support sheets. It is not the recommended flow rate.

* 100 kPa = 1 bar

**Endotoxin content analysis after rinsing with 1.23 gal/ft² (50 l/m²) of WFI (Water for Injection)

Compliance Notice

BECO support sheets fulfill the requirements of Regulation (EC) 1935/2004, the FDA Guideline 21 CFR § 177.2260 test criteria as well as the requirements of the USP Plastic Class VI – 70 °C test. For further details on individual components and material see the declaration of conformity.

Components

BECO PR ENDURA S support sheets are made from particularly pure materials. Finely fibrillated cellulose fibers from deciduous and coniferous trees, cationic charge carriers, and synthetic fibers are used.

Instructions for Correct Use

When inserting the support sheets into the sheet filters, handle carefully. Avoid knocks, distortion or abrasion. Never use a damaged support sheet.

Insertion

Support sheets have one rough side and one smooth side each. The rough side faces the liquid to be filtered (upstream). The smooth side is the filtrate side of the support sheet (downstream). When inserting take care to ensure that the smooth side is facing the filtrate plate.

Filter Preparation

Prior to the first filtration, Eaton recommends pre-rinsing the closed filter with 1.23 gal/ft² (50 l/m²) of water at 1.25 times the flow rate. As a rule, this equals a rinsing time of 10 to 20 minutes depending on the application. Test the entire filter for leakage at maximum operating pressure.

High-proof alcohol solutions and chemical products that cannot be used with water for pre-rinsing should be circulated for 10 to 20 minutes. Dispose of the solution after rinsing.

Sterilization (Optional)

Wetted support sheets may be sterilized with saturated steam of **249.8 °F (121 °C)**. The pressed packed filter has to be slightly loosened. Make sure to sterilize the entire filtration system thoroughly. Final pressure should be applied to the filter package once the entire filter has cooled down.

Sterilizing with Hot Water

The flow velocity should at least equal the filtration capacity. The water should be softened and free of impurities.

Temperature: 185 °F (85 °C)

Duration: 30 minutes after the temperature has reached 185 °F (85 °C) at all valves

Pressure: At least 7.2 psi (50 kPa, 0.5 bar) at the filter outlet

Sterilization with Steam

Steam quality: Steam has to be free of foreign particles and impurities

Temperature: Max. **249.8 °F (121 °C)**
(saturated steam)

Duration: Approx. 20 minutes after steam has exited from all filter valves

Important Notice:

All vent and discharge valves must be slightly opened for optimal sterilization effect and to avoid the steam shock.

Safety

When used and handled correctly, there are no known unfavorable effects associated with this product.

Further safety information can be found in the relevant Material Safety Data Sheet, which can be downloaded from our website.

Waste Disposal

Due to their composition, support sheets can be disposed of as harmless waste. Comply with relevant current regulations, depending on the filtered product.

Storage

Support sheets consist of strongly adsorbing materials. Careful handling is necessary during transportation and storage. Support sheets must be stored in a dry and odor-free place that is well aerated.

Do not expose the support sheets in direct sun light.

Support sheets are intended for immediate use and should be used within 36 months after production date.

Available Formats

Support sheets can be supplied for all current filter sizes, square or round. Special formats are available at request.

Quality Assurance According to DIN EN ISO 9001

The Quality Management System of Eaton Technologies GmbH has been certified according to DIN EN ISO 9001.

The certification confirms the functioning of the total system of Quality Assurance from product development through contract controls, choice of suppliers as well as acceptance controls, production and final examination all in the way to storage and dispatch.

Extensive quality assurance measures comprise the adherence to technical criteria regarding the function as well as the confirmation of chemical purity and quality recognized as safe under the German law governing the production of foodstuffs and beverages.

All information is given to the best of our knowledge. However, the validity of the information cannot be guaranteed for every application, working practice and operating condition. Misuse of the product will result in all warranties being voided.

Subject to change in the interest of technical progress.

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