

# Albumin Ultrafiltration Cassettes “PESUmax”

## Albumin Concentration

### Description

#### The PESUmax Membrane

The PESUmax membrane is made out of polyethersulfone (PESU). This membrane polymer is well established in the biotechnological and pharmaceutical industries. The PESUmax cassette is designed for use in the blood market, specially for Albumin rejectable applications. The PESUmax membrane is a stable polymer that features a broad pH and

temperature range. Membrane regeneration, storage and depyrogenation can be accomplished by using NaOH even at elevated temperatures. Because of these features, the PESU membrane is ideally suited for blood market applications.



## Product Information

The polyethersulfone membrane has minimal adsorption of proteins, viruses, etc. Membrane retention is unaffected by repeated use. PESU ultrafiltration cassettes have been validated to withstand in-line steam sterilization without any loss or changes in membrane retention.

Feature	Benefits
Low adsorption	Minimal loss of proteins
Low protein-binding	High product yield
Wide pH and a wide variety of temperature range	Chemicals can be used for the removal of foulants
High flow rates	Economical filtration runs
Self sealing cassette	No gaskets needed
Silicone sealing compound	No glue
Enlarged inlet and outlet holes	Lower pressure drop

## Technical Data

### Specifications

#### Materials of Construction

Membrane	Polyethersulfone
Gaskets	PVDF
Spacer	Polypropylene
Sealing compound	Silicone white

### Pore Size | Retention Rate

PESUmax ultrafiltration cassette is available in a retention rate of >99.99% for Albumin.

### Available Sizes

Sartorius crossflow cassettes are available in standard cassette size and Sartocube® size for pilot | production scale, and in **Sartocon® Slice** as well as Sartocon® Slice 200 format for reduced volume handling.

## Available Filter Holder

Sartorius crossflow cassettes are designed for Sartorius filter holders like Sartocon® Slice, Sartocon® 2 Plus, Sartoflow® 10 and 20 holders.

#### Operating parameters

Feed pressure, P <sub>m</sub>	58 psi   4 bar maximum
Operating temperature	50 °C maximum
Air diffusion rates at P <sub>m</sub> = 14.5 psi   1 bar	≤ 2 ml air/min for 0.02 m <sup>2</sup> ≤ 5 ml air/min for 0.1 m <sup>2</sup> ≤ 20 ml air/min for 0.7 m <sup>2</sup> ≤ 20 ml air/min for 3.5 m <sup>2</sup>
Cleaning	NaOH, 1M, 40 °C, 60 min
Disinfection	NaOH, 1 M, max. 50 °C, 30 min
Storage	NaOH, 0.1 M

## Sterilization

NaOH, 1 M, max. 50 °C, 30 min

The Sartorius design “Stress Test” as an indication of cassette cleaning cycles

## Purpose

The goal of this test is to establish that the Sartorius cassette is resistant to NaOH exposure, as is recommended in this guide for cleaning and storage.

## Test Procedure

PESUmax Sartocon® cassettes (Mat. No. 302146AL07K--SW) are tested under stress test conditions according to demonstrate compatibility with caustic. The test conditions are: feed pressure in 4 bar; retentate pressure 0 bar and permeate open; pH is 14 with 1 N NaOH at above 50 °C for minimum 200 hours.

## Results

All released and published Sartocon® cassettes are validated according to this procedure. All cassettes passed the integrity test after minimum 50 hours.

## Regulatory Compliance

All materials have passed the USP Biological Test. The filtrate meets or exceeds the currently valid USP and EP for Sterile Water for Injection, with respect to particulate matter, extractable substances, oxidizable substances, pH dependent conductivity, ammonia, chloride, sulfate, calcium and bacteria endotoxins.

## Quality Control

Each filter cassette is individually assigned a serial number, integrity tested and certified. It complies with cGMP requirements for non-fiber-releasing filters and is filed under the Drug Master File Number DMF 5967 by the Food and Drug Administration, Washington, DC. Validation information is available on request.

If you use holding devices from other suppliers, please contact our Applications Department. A different torque might be needed due to specific variations in design.

For further assistance, please contact your local Sartorius Stedim Biotech field engineer or our Goettingen-based Applications Department in Germany.

## Technical References

Validation Guide  
Publication No.: SPC5701-e

Directions for Use (Sartocube® | Sartocon® |  
Sartocon® Slice | Sartocon® Slice 200 Cassettes)  
Publication No.: SPC6051-a

## Average Dynamic Water Flux

Permeate	Per Slice 200 Cassette 0.02 m <sup>2</sup>	Per Sartocube® Slice Cassette 0.1 m <sup>2</sup>	Per Sartocube® Cassette 0.7 m <sup>2</sup>	Per Sartocube® Cassette 3.5 m <sup>2</sup>
Approx.	7 l/h	50 l/h	250 l/h	1000 l/h

( $P_{\text{feed}} = 29 \text{ psi} | 2.0 \text{ bar}$ ,  $P_{\text{retentate}} = 7 \text{ psi} | 0.5 \text{ bar}$ )

## Retention Coefficient PESUmax

Marker	Retention
Albumin	>99.9%

## Order Information

Available types and order numbers


Cut Off	Sartocube® Slice 200 Cassettes 0.02m <sup>2</sup> Filter Area	Sartocube® Slice Cassettes 0.1 m <sup>2</sup> Filter Area	Sartocube® Cassettes 0.7 m <sup>2</sup> Filter Area	Sartocube® Cassettes 3.5 m <sup>2</sup> Filter Area
Albumin	308146AL02K--SW	305146AL01K--SW	302146AL07K--SW	302146AL35K-BSW

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