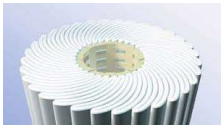
# Klarwin Pharma Technology

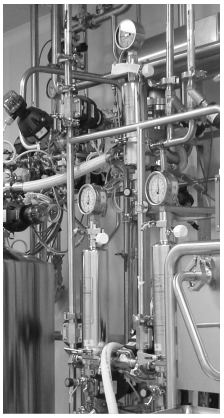
# CASE STUDY

## REDUCING OVERALL FILTRATION COSTS USING INNOVATIVE ULTIPLEAT DESIGN

(1)



(2)



(3)

## Application:

A Romanian pharmaceutical plant manufactures millions of ophthalmic, ampoules, prefilled syringes and other sterile and non-sterile products every year.

A high viscosity ophthalmic product, containing an excipient with big molecular weight (~ 250 kDa) was filtered in batches of 25-100 L. Currently, the work is done in campaign, including approx. 3 batches, with 2 hours break between batches. Integrity tests of the sterilizing filter media are performed at the beginning and at the end of the campaign.

Process parameters:

- CIP, SIP for the filter cartridge;
- Aseptic filtration of the ophthalmic product;
- Ambient temperature;
- Pressure 2 bar (const.).

## Problem:

Based on a long collaboration, customer asked for a filtration improvement under process conditions, to decrease costs and work time.

## Solution:

Pall 0.2 micron-rated sterilizing grade filters retain *Brevundimonas diminuta* at $10^7$ CFU/cm² effective filter area (EFA). The current filtration solution, **Pall Fluorodyne II DFL** (1), a PVDF double layer, symmetric membranes ensure very low extractables and adsorption. They are recommended for sterilizing filtration of pharmaceutical fluids like solutions with active ingredients, biologicals, biotech proteins, ophthalmics and other dilute preservative solutions.

The proposed solution was **Pall Supor EX Grade ECV**, a high capacity, high flow rate, 0.2µm sterilizing grade filter with PES asymmetric double layer membrane. Due to the **Ultipleat** (2) design of the filter media, which gives double the surface area/cartridge, a bigger batch volume was filtered, using one filter cartridge for more batches, increasing 6 times the filtered volume (3).

| | BEFORE | AFTER |
|---|---|---|
| Filter type | Pall Fluorodyne II DFL | Pall Supor EX Grade ECV |
| Effective filter area | 1.53 $m^2$ | 3.12 $m^2$ |
| No of cartridges/batch | 1 cartridge/ 1 batch | 1 cartridge/ 3 batch |
| Batch volume | 50L | 100L |
| **Filtration cost/L** | **15€** | **4.5€** |

## Benefits:

- ✓ Reducing 3x **filtration costs** due to higher flux, bigger filtration area and high dirt capacity/cartridge.
- ✓ Lower **operating costs,** considering less filter handling and CIP & SIP cycles, decreasing WFI consumption/campaign.
- ✓ Production capacity/campaign increased, as the volume/batch was doubled.