

Manufacturer of Active Pharmaceutical Ingredients Process Optimization

Customer:	Manufacturer of APIs
Application:	API, BioScience
Products:	Pleated Filter Disc
Primary Motive:	Improve Performance /New Technology
Location:	Italy
Project Date:	2021
Division:	New Milton, UK



Customer Overview:

The end-user is part of a Pharmaceuticals Group, which supplies active pharmaceutical ingredients (API) worldwide. With its state-of-the-art manufacturing facility, it sets a new standard for the manufacture and control of active ingredients extracted from biological tissues.

The team has developed efficient manufacturing methods and controls in accordance with current Good Manufacturing Practices (GMP) assuring the drug's potency, identity, strength, quality, and purity.

In addition, its capability includes QC testing, stability and batch release of biological medicinal products. As due, it is inspected by the major Regulatory Agencies, including AIFA, US-FDA, PMDA and ANVISA.

Its production technology and quality control are continuously aligned with the latest technological standards and international quality requirements. It works hard to ensure that for each batch of drug product or drug substance that is manufactured, a robust and documented traceability chain exists.

Customer's Requirement:

Purpose: Filtration of solvents (acetone CH46 and ETOH CH16-17-6) containing organic residues, batch sizes ranging from 300-5,000l.

The end-user requested a review of their existing process line to ensure it was optimised and assess any potential cost saving.

Working temperature:	Max 60°C
Flow rate:	Max 1500Lph
Working pressure:	Max 3,5bar
Consumption:	50pcs/year

Porvair's Solution:

Our Italian partner requested samples to trial on site:
Hydrofil™ 0,2µm (10")
Hydrofil™ Plus 0,2µm (20")

Project Overview:

Nylon 6.6 is a hydrophilic polymeric membrane which offers an interesting chemical compatibility. Particularly suitable for filtering solvents involved in manufacturing of APIs.

The results showed significant process optimization and were a cost-effective alternative, saving 20% on their existing product.

Product and System Information:

Hydrofil™ 0,2µm (10")
Hydrofil™ Plus 0,2µm (20")

Other Opportunities:

Active Pharmaceutical Ingredients manufacturers, seeking cost saving in their production lines.