SUCCESS STORY

Breaking Barriers: Overcoming Filtration Hurdles in API Production

THE CUSTOMER

A major European pharmaceutical manufacturer, producing purified water, water for injection (WFI), and X-ray contrast media, contacted Global Filter to address a critical supply chain issue. Following the discontinuation of a key product by a competitor, the client needed to replace a filtration element essential to their manufacturing process.

THE CHALLENGE

Regulatory standards set by organizations such as the FDA, EMA, and WHO impose strict limits on substances used in pharmaceutical production, ensuring patient safety and medication efficacy. For this client, the filtration process not only had to meet sterility and microorganism-free requirements but also provide a reliable barrier against pyrogenic endotoxins.

Before reaching out to Global Filter, the client relied on a product that was no longer available on the market. This posed a threat to the continuity of their production, particularly for WFI and X-ray contrast media. The replacement solution needed to comply with stringent industry standards and withstand demanding steam sterilization procedures.

THE SOLUTION

Global Filter provided a standard solution from its range of charge-modified polyamide membrane filter cartridges (BRHNY+0.2A30C7E-I and BRHNY +0.2A30C7S-I). This technology uses electrokinetic separation effects to create an effective barrier against endotoxins. The BRHNY+ filter elements have indeed demonstrated capability to remove bacterial endotoxin to below a 0.005 EU/milliliter detection limit in independent testing. The cartridges meet all pharmaceutical industry requirements, including bacterial filtration of Brevundimonas diminuta (with a log reduction value >9) and chemical compatibility with the client's processes and is compliant to AAMI Standard ST108: Water (AAMI ST108:2023, Water for the processing of medical devices, revises and replaces AAMI TIR34:2014/(R)2021).

Extensive testing was conducted, including validated compliance with the client's production procedures. These tests included:

- Steam sterilization at 134°C for 30 minutes.
- Automatic diffusion integrity tests (pressure decay test).
- Performance evaluation under normal and extreme operational conditions.

THE RESULTS

After six months of continuous use, Global Filter's filtration elements met all expectations. They reduced filtration and maintenance costs by 20% compared to the previous solution while ensuring perfect sterility and mechanical integrity.

Thanks to this successful qualification, the client integrated the product into their WFI production line and plans to use it for X-ray contrast media production in the near future. This solution ensured production continuity, compliance with industry standards, and improved medication availability for patients.

LOOKING AHEAD

This partnership with Global Filter has not only resolved immediate challenges but has also positioned the customer for long-term success. The improved filtration system ensures ongoing compliance with regulatory standards and sustained cost savings.

Global Filter is ready to collaborate with you to enhance your products and streamline the processes that fuel your success.

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