

Case Study: BIO-PHARMACEUTICALS

GYLON BIO-PRO®



INDUSTRY

Pharmaceutical – Bio-Processing

CUSTOMER

A global biopharmaceutical company focusing on neurology and immunology drug therapies, based in Europe but with a global manufacturing network.

BACKGROUND

EPDM sanitary gaskets had been specified for all their buffer/surge tanks. However, due to the pre-sterilization process in autoclave, EPDM sanitary gaskets exhibited both sticky behaviour and premature degradation when they were placed in their ferrule. This sticky behaviour led to major difficulties in dismounting the tank lid prior to cleaning – often with operators requiring tools to prise open the lid. Gasket degradation also created potential risk for fragments/particles to contaminate the process, and again made cleaning and pre-sterilization very difficult.

CHALLENGES FACED

The challenge was to find a sanitary gasket that would not exhibit any sticky behaviour, would not show premature degradation, and would be easy to use. Three different sizes of sanitary gasket were required for the different sizes of buffer/surge tank used in the process. Excellent resistance to process temperatures, pressures and cleaning detergents was also mandatory, as was full compliance to FDA and USP Class VI standards.

OPERATING CONDITIONS

1. Media (process): Solvent + Organic Chemicals
2. Media (cleaning): detergents (NaOH 6M)
3. Size: 8" and 10" tri-clamp (ASME-BPE)
4. Temperature: 123°C (253°F) max.
5. Pressure: 2 bar (29PSI) max.

SOLUTION AND BENEFITS

As a trusted advisor to this industry, Garlock was offered full access to the customer's manufacturing facility. The solution was to specify GYLON BIO-PRO® sanitary gaskets for the tri-clamp fittings on their buffer/surge tank lids. Two standard sizes (8" & 10") and one customized 10" profile were implemented to provide better fit across their different tank sizes. The customer observed immediate benefits across many areas:-

- » Easier installation - improved repeatability.
- » Easier dismantling - no sticky behaviour, no residue.
- » No degradation - avoid impurities/batch contamination.
- » Operator Safety - no sharp tools required to remove tank lid.

While GYLON BIO-PRO® easily meets all the process, performance and compliance requirements from the customer, the major benefit is that it has allowed the customer to enjoy time-saving (~30 min/day) during each cleaning process cycle.

For more information, please visit:
<http://www.garlock.com>

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