

Case Study: Pharmaceutical Gel Capsules

GYLON BIO-PRO®



INDUSTRY

Pharmaceutical Processing - Excipients

CUSTOMER

A global manufacturer of pharmaceutical-grade gelatin for capsules

BACKGROUND

The customer's USA facility was using both EPDM and PTFE sanitary gaskets throughout their process, but they had encountered issues over the years with both materials. The EPDM gaskets were typically over-tightened which created gasket intrusion and physical degradation, and upon replacement they were also found to be stuck to the ferrules, creating further problems when maintenance technicians had to use hard tools to scrape away any residue. The PTFE gaskets were easier to remove, but showed considerable evidence of creep and cold flow which created process leaks, resulting in build-up of crystallised gelatin around the tri-clamp connections. Worryingly, in both cases, there was evidence of downstream contamination from gasket fragments which frequently led to un-scheduled downtime, additional cleaning, as well as batch quarantine and disposal.

OPERATING CONDITIONS

1. Media (process): Liquid Gelatin
2. Media (cleaning): 3% Caustic Solution @ 356°F (180°C)
3. Size: Various 1" to 6"
4. Temperature: 392°F (200°C)
5. Pressure: 200psi (13.8 bar) with spikes up to 800psi (55.2 bar)

SOLUTION AND BENEFITS

Production of pharmaceutical-grade gelatin involves some challenging process conditions - alkaline or acid extraction, deionization, sterilization, concentration - as well as harsh cleaning regime to ensure that the process cleanliness and sterility is maintained. In order to meet these conditions and overcome the ongoing problems with both standard EPDM and PTFE materials, GYLON BIO-PRO® sanitary gaskets were recommended as a universal solution across the entire plant. Despite some initial reluctance to specify a more expensive component, the customer's extensive testing program demonstrated that the modified PTFE used in GYLON BIO-PRO® solved all their problems and thus provided much higher value than the commodity gaskets they had been using. Superb compatibility with all process and cleaning conditions, elimination of process leaks without the need to re-torque, and easy installation were all factors that support the customer's decision to change their long-standing specification.

Since the whole plant was converted to BIO-PRO® sanitary gaskets, the customer has not experienced a single contamination event and is enjoying the benefits of longer service life and reliable performance. As an example, in one area of the plant they were replacing EPDM gaskets due to failure every 6-8 weeks, but the maintenance program has already been extended to more than one year with GYLON BIO-PRO® gaskets without any problems.

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

GARLOCK

an EnPro Industries family of companies
Tel: 1-877-GARLOCK / 315.597.4811
Fax: 800.543.0598 / 315.597.3216
www.garlock.com

Garlock
GPT
Garlock Australia
Garlock de Canada, LTD

Garlock China
Garlock Singapore
Garlock Germany
Garlock India Private Limited

Garlock de Mexico, S.A. De C.V.
Garlock New Zealand
Garlock Great Britain Limited
Garlock Middle East