OPTIMISING FILTER PERFORMANCE WITH THE 'R/P STAT METHOD'

Filtration background

The manufacturing process for biopharmaceuticals requires filtration steps for the product clarification and purification. For efficient filtration, considerations must be made for the filter porosity, filter area, differential pressures and the selected pump flow rates. With use, however, the filtration devices may clog during the product filtration processes. Clogging, or caking, is a common issue for normal flow filtration (NFF) processes due to the filtered bioburden (including cell debris, particulate, bacteria) settling on the membrane, limiting the processing capability and volume.

The membrane pores, or the feed channels, become obstructed with this bioburden, resulting in a decreased liquid flow rate across the porous filter membrane. This results in a change in system pressure, which can risk damage to the product.

Filtration methods

Filtration is typically controlled by two methods:

1- Constant flow rate – configured flow rate driven by a pump.

2- Constant pressure – determined by valve control and pressure across the filter.

Processing at a constant flow rate maintains the liquid flow rate through the filter at a constant rate, leading to increasing pressure as bioburden builds up on the filter membrane. This can damage the product and reduces the efficiency of the filtration process.

Processing using a constant pressure method can lead to slow filtration times as the increasing pressure, following filter caking, results in pump flow rates progressively decreasing.

Finding the balance to optimise the process

To overcome the filtration challenges and optimise the process, Parker have developed the "Rate/Pressure Static method", referred to as "R/P Stat". This patented method has shown to increase throughput and yield - an innovation that has additionally resulted in significant improvements in the filter life cycle.

During normal flow filtration, the system starts filtering using a constant flow rate until a pressure setpoint threshold is reached. At this point, pressure limited filtration begins, and the pump flow rate reduces. This ensures the pressure threshold can be maintained, but never exceeded, until all material has been filtered, or the pump flow rate reaches a lower threshold cutoff.

By doing this, the pressure can be managed and allows for full utilisation of the existing filter capacity.

This is achieved by selecting three simple process variables: initial flow rate, maximum inlet pressure, and minimum flow rate.

Figure 1 illustrates this method - the pump is set at an initial flow rate, and the pressure is monitored. Over time, the filter membrane clogs and the pressure increases. The R/P stat initiates the pump to slow down. The flow rate dynamically adjusts, and the pressure can be managed.

This encourages more product to pass through the filter membrane, and reduces the likelihood of potential risk of damage to the product caused by increased pressure.

As a result, the R/P Stat method can typically provide a 30% increase in total filter efficiency, compared to constant pressure or constant flow methods.

This method has been configured on the Parker SciLog® NFF, SciLog® NFF+ automated systems, and SciLog® FilterTec™.

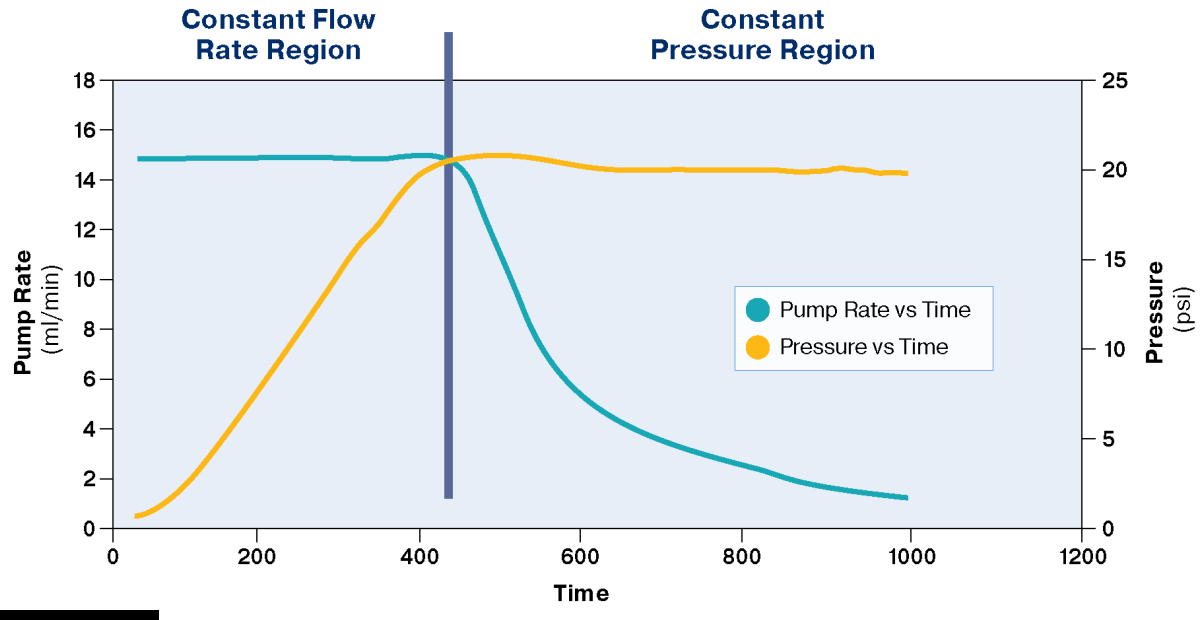

Fig. 1 - Normal Flow Filtration by R/P Stat Method

Reference: Patented-Method_00_EN