

APPLICATION NOTE

3.02 PHARMACEUTICAL & BIOTECH

ULTRAFILTRATION

- Real time continuous measurement
- Non-invasive analytical method
- Processes Optimization
- Quality control
- Concentration monitoring
- Dual-wavelength measurement
- Zero cell hold up volume

Ultrafiltration (UF) is a type of membrane filtration in which pressure and concentration gradients lead to a separation through a semipermeable membrane. Suspended solids and solutes of high molecular weight are retained in the retentate, while water and low molecular weight solutes pass through the membrane in the permeate (filtrate).

APPLICATION

The main purpose of tangential flow filtration in bioprocessing is to concentrate a product previously filtered in an earlier step in the production process. The feed solution is circulated in a closed loop, passing through the filter.

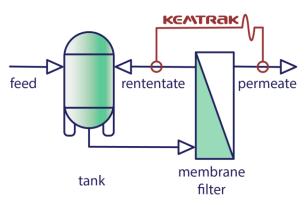
This filter is selected to provide retention of the product being concentrated while allowing unwanted/excess buffer and/or background material in the circulating solution to permeate through the filter material to drain away.

INSTALLATION

The installation of Kemtrak analyzers at strategic points in the filtration system, gives real-time measurement information, that can be used for maximizing product yield in any given batch.

Permeate

A <u>Kemtrak DCP007-UV</u> or <u>Kemtrak TC007</u> analyzer on the permeate stream allows the user to monitor filter failure and ensure its integrity, to increase



throughput and reduce product loss, and accurate determination of concentration end points.

Retentate

A <u>Kemtrak DCP007-UV</u> or <u>Kemtrak TC007</u> analyzer on the retentate stream provides a real time concentration signature of product retained in the circulation loop. It can be used in cascade with feed absorbance to optimize the amount of feed into the recirculation system, keeping the concentration at an optimal level for filter operation.

The analyzer provides a measurement used to indicate retained product concentration. When the rate of change reaches a "plateau", the process end point has been reached.

Hygienic Kemtrak measurement cells are available with FDA and UPS Class VI approved seal materials. The zero dead-volume design assures a fast response without cross contamination. A NIST validation accessory is available to verify analyzer performance without process interruption.



A <u>Kemtrak DCP007-UV</u> photometer is the recommended instrument to accurately measure protein concentration. A <u>Kemtrak TC007</u> turbidity meter is recommended for measuring turbidity and suspended solids.



