GEMÜ® PRODUCT APPLICATION - ASEPTIC

Nanometer Filter Cascade for virus removal

Plant design

The nanometer filter cascade consists of two basic modules. A storage tank with a contents of 500 litres and an agitator is the first module where the protein solution for the cascade is stored under aseptic conditions. During the CIP process the tank serves as a storage tank for the cleaning agent. The tank itself can be cleaned by a mobile CIP pump. The second module is the actual cascade filter in which the product is conveyed via three pressure accumulators with 20 litres each and passed through 75 nanometer preliminary filter elements and 35 nanometer filter elements. The continuously increasing blockage is compensated by increasing the pump speed. In order to protect the 35 nanometer filter elements against overload which would endanger the product, the accumulated flow is counted and when the permissible quantity is reached the respective filter system is turned off and secured. Then the product is conveyed through an identical parallel system to enable a continuous filtration process. After filtering the product can be distributed into one of three sterile collecting tanks.

Solution

The respective tank inlets and outlets, the filter systems and the cleaning lines are automatically operated by GEMÜ type 625 diaphragm valves in control function 1 (normally closed). The manual valves used are GEMÜ type 612 diaphragm valves. EPDM diaphragms with reference number 13 are used as sealing elements. At exposed points the valves are installed at a specified draining angle. The body material is 1.4435 / 316 L. GEMÜ 601 manual diaphragm valves are used for the condensate outlet. The seal adjuster integrated as standard in the manual GEMÜ valves ensures optimized diaphragm service life.

Application

When processing human plasma protein solution an unacceptable virus enrichment must be prevented. The nanometer filter cascade described in this application is used for this purpose. It ensures that existing viruses and/or viruses introduced by a later contamination are removed so that the human plasma is suitable for further use and that the final product cannot cause any damage to health. A special requirement of this process technology is to ensure that the medium is transported pulsation-free and that the flow speed of the product is as gentle as possible. The plant must be CIP cleanable and sterilizable. Another important requirement is that during the cleaning operation a 15-fold performance is possible. In addition to requirements complying with GMP and FDA directives, it must also be ensured that the nanometer filter elements are pressurized under validation conditions. The fully automated operation must guarantee maximum safety and the volumetric flow, differential pressure, product quantity and change-over of the filters must be permanently monitored and controlled. The required batch size is 500 litres.

Legend:
Human plasma protein solution: human blood plasma
Nanometer: 1 nm = 10^{-9} m (0.000001 mm)

GEMÜ 612 diaphragm valve, manually operated

GEMÜ 625 diaphragm valve, pneumatically operated, normally closed

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