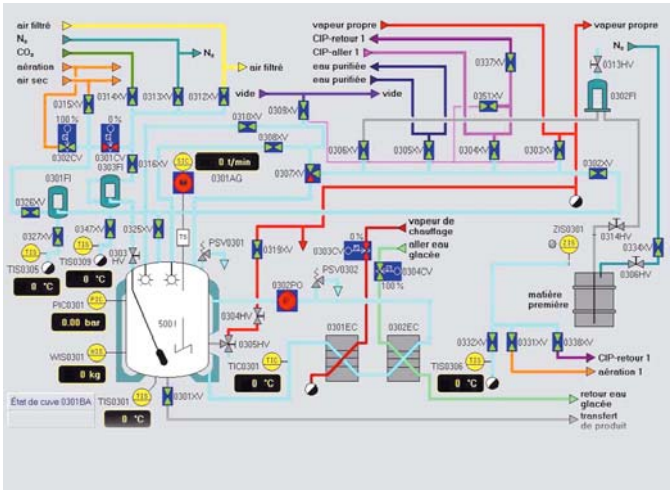
Production plant for liquid pharmaceutical products



Application

In a new and fully automated plant various liquid pharmaceutical products are produced and stored. Each of the three production tanks with a content of 500, 1000 and 2000 litres respectively can be connected with each of the 5 storage tanks (2 x 1000, 3 x 2000 l) by means of a change-over system. Up to three different production steps are possible. As the products are also exported to the USA, the plant is designed to cGMP and approved by FDA. Planning and construction of the plant are based on the latest directives and standards.

Plant technology

Transfer from the preparation tank to the storage tank, cleaning (CIP), sterilization (SIP) or drying in various sections can take place at the same time. Each storage tank is assigned to a filling machine. Automatic cleaning and drying programs ensure that all medium wetted components and transfer sections are included. The total transfer lengths of the plant are 1000 metres. The plant is made from high-grade stainless steel, its medium wetted components have high quality surfaces and all the connections are orbitally welded. Each of the preparation tanks stands on a weigh cell in separate cleanroom cabins thus excluding cross contamination by active substances in the other products. The active substances as well as the basic liquid (WFI water or vegetable oils) are added either via direct connections from the water system or via vacuum suction from barrels. Larger quantities are SPS controlled via a weighing system or a dosing installation.

Solution

All manual and pneumatically controlled valves installed are diaphragm valves in DN 8 to DN 50 (except a few valves in the change-over section). GEMÜ 601, 673, 625 and 687 valves are used. The end positions of over 300 valves are monitored by a GEMÜ electrical position indicator. In the future valves of the GEMÜ *BioStar*® range could be used as an alternative. The external surfaces and actuator materials of this new and innovative generation of valves have again been improved with regard to cGMP requirements. The new electrical position indicator GEMÜ1235 enables very short mounting times and simplified parameterization of end positions. In plants as described above, which have many single components, the simple and safe handling of the GEMÜ 1235 position indicator offers an enormous advantage with regard to time savings and reliability of operation.

Legend:

FDA (Food and Drug Administration): US authority responsible for approval procedures for the manufacture and trade of active substances, food, cosmetics and pharmaceutical products. This can also be compared to the German Health Authority.

GMP (Good Manufacturing Practice): Standards and rules for the proper manufacture of drugs were established for the first time by the WHO (World Health Organisation) in 1968. Since then various national standards have been established with the USA playing a leading role. Above all, preventive quality assurance and the respective documentation (validation) are laid down in GMP.

CIP (Cleaning in Place): Is the internal cleaning of a plant without dismantling or making major changes to it.

SIP (Sterilization in Place): Is the internal sterilization of a plant without dismantling or making major changes to it compared to its operating conditions.

In use:
GEMÜ 601, 673, 625 a. 687 (f. l. t. r)
with electrical position indicator
type 1230 / 1232

Alternative:
GEMÜ ***BioStar***® 653 / 654, 650
and GEMÜ 1235 elctrical
position indicator

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