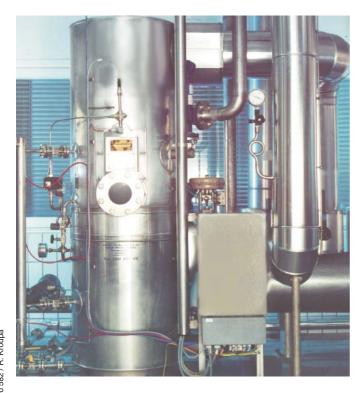
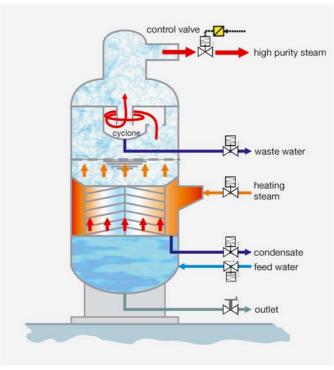
FEML' PRODUCT APPLICATION - ASEPTIC PROCESS

High purity steam generation for sterilization





Application

The quality of standard process steam is not sufficient for the sterilization of installations in the pharmaceutical industry because the portion of contaminants, particles, hydrazine, phosphates and similar components (corrosion inhibitors) is too high. A special process steam must be used for drugs in compliance with relevant regulations e.g. FDA (Food and Drug Administration). This process steam must not contain any of these components and in addition it must be free from volatile matters which cannot be removed by filtration. By feeding the installation with deionized water the percentage purity of the steam is increased so that it is practically free from foreign ionogenic matters. In addition the steam is germ-free, too. When using a cyclone and the centrifugal force it produces, unwanted matter is extracted. The steam produced in this procedure can be used for sterilization and autoclaving of pharmaceutical installations.

Plant technology

The distillation plant described in the following not only produces steam by heat but also uses a cyclone. After the evaporation of the deionized feed water it centrifuges the steam to a 500 fold acceleration using gravity to extract particles it may contain. The separation grade of the cyclone is $5^{1.0}6^{1.0}$. It separates particles down to a diameter of 0.7 μ m. Due to the adhesive and coagulative effect of the water drops even smaller droplets are removed. Thus the highest technically possible quality of high purity steam can be achieved. When using a heating steam of 8 bar, a high purity steam of 6 bar is achieved. If the required pressure of the high purity steam is lower, the productive capacity of the installation is increased. By using an electro-pneumatic control valve the high purity steam can be controlled within a range of 0 to 7.8 bar

gauge pressure, corresponding to 100 to 178°C. The feed water used is deionized water. The materials used are nickel chromium molybdenum steel and PTFE.

Solution

The globe valves GEMÜ 514 and GEMÜ 512 (pneumatically operated and in stainless steel) are used for conducting the heating steam to the heat exchanger, letting off the waste water at the cyclone and tapping the sterile steam. The feeding of deionized water is controlled by the diaphragm valves GEMÜ 625 and GEMÜ 687 (pneumatically operated and in stainless steel).

Summary: Metal globe valves are used for the control/regulation of steam and metal diaphragm valves are used for the control/regulation of feed water.

The GEMÜ 1435 positioner can be adapted to a corresponding globe valve with integrated regulating cone.

Legend:

Hydrazine - chemical compound of nitrogen and hydrogen Corrosion inhibitors - anticorrosive substances FDA - American public health authority Coagulation - flocculation