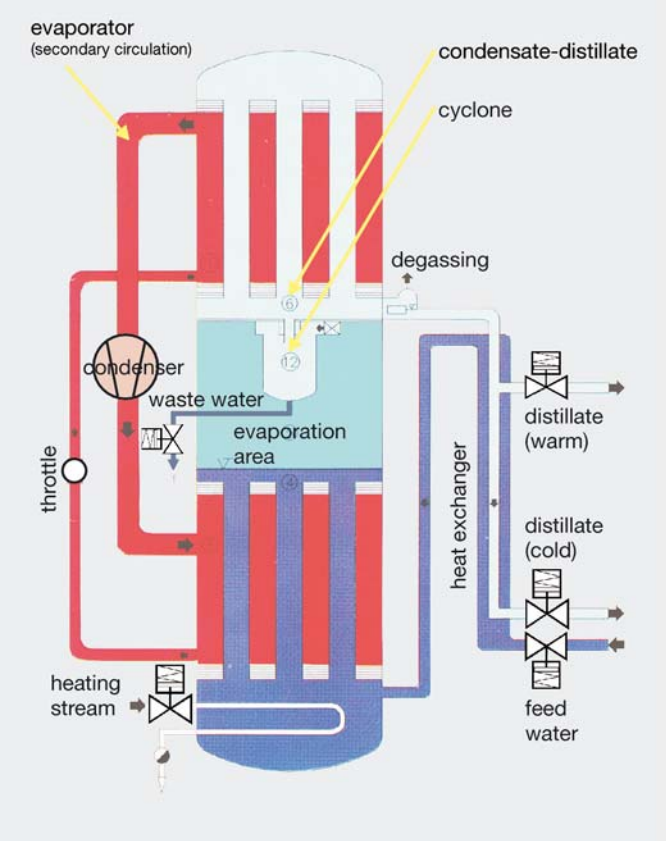
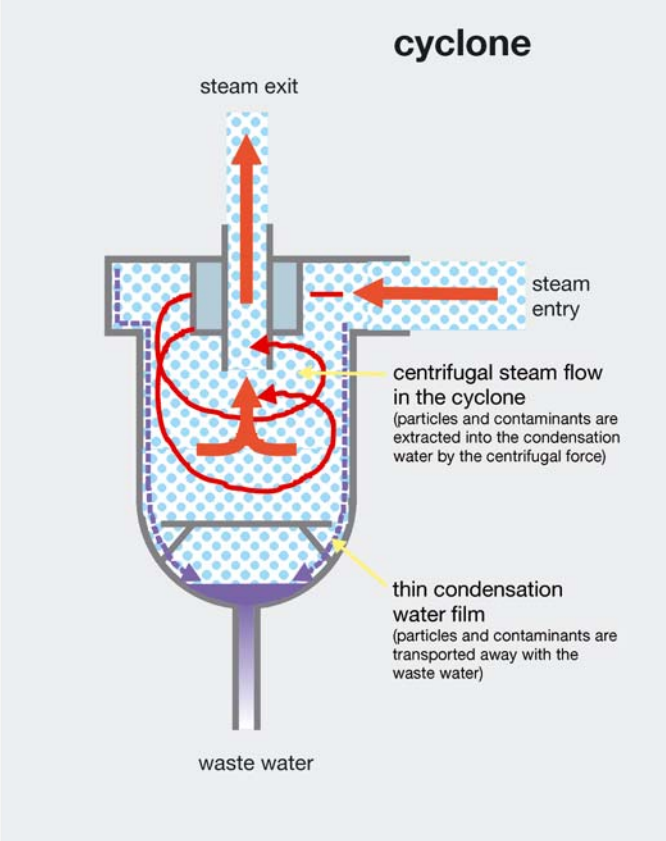
GEMÜ® PRODUCT APPLICATION - ASEPTIC PROCESS

Distillation Unit for WFI Water





Application

For the manufacture of drugs administered to the human body by injection or transfusion only specially purified water known as Water for Injection (WFI) may be used according to the relevant regulations e.g. FDA (Food and Drug Administration). It must not contain any components damaging to one's health, must be highly pure and free from volatile matters. Especially those which cannot be removed by filters. If the distillation feed water is high purity and/or deionized water, the percentage purity of the steam is considerably increased and it is practically free from foreign ionogenic matters, germs and pyrogens. When using a cyclone and the centrifugal force it produces, unwanted matters are extracted and the steam produced in this procedure is degassed and cooled. The condensate of this sterile steam can then be used as WFI water for pharmaceutical processes and the manufacture of drugs.

Plant technology

The distillation plant described below 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^{10}-6^{10} and separates particles down to a diameter of 0.5 µm. Due to the adhesive and coagulative effect of the water drops even smaller droplets are removed which are moved to a collector at the bottom of the cyclone and carried off the plant as waste water. Then the steam is degassed so that the liquid portion of the steam can be conducted through the spiral double pipe heat exchanger and cooled down. The new incoming feed water flows round the outlet pipe. On the one hand the outgoing high purity water is cooled to the required temperature, on the other hand the feed water is heated so that a lower energy supply required for the evaporation is possible. This results in a saving of energy and a reduction in costs. 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 and letting off the waste water at the cyclone. The feeding of deionized water and the tap points of the cold and warm distillates are 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 waste water and metal diaphragm valves are used for the control/regulation of high purity water.

Legend:
FDA - American public health authority
Pyrogens - substances decomposed by heat / substances causing fever
WFI water - water for injections
Coagulation - flocculation

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