



## Pure Steam generator

Pharmaceutical Pure Steam for direct contact with sterilization material is produced in a compact single-stage pressure column distillation with natural circulation evaporation. Consistent monitoring of the process parameters and sufficient system volumes ensure compliance with the requirements. An upstream degassing system (optional) removes non-condensable gases.

GMP-compliant system design and maintaining high temperatures in all system areas form the basis for the hygienic condition of the Pure Steam generator. We also offer twin systems for the production of WFI and Pure Steam.





## Anti-Rouging Concept

In order to comply with EN 285, we use thermal degassing to remove CO2 and other gases that can condense.. By removing  $CO_2$ , we can significantly reduce the effect of rouging.

## Technical Data

Material	Stainless steel 1.4404 with roughness Ra < 0.8/ 1.6 $\mu m$ or 1.4435 with roughness Ra < 0.6 $\mu m$ and electropolished
Process engineering	Circulation/heating of the feed water, degassing (optional), pressure column distillation, Cooling of blowdown, vapor and sampling volumes
Available performances	Steam heating: up to 3,600 kg/h, electrical heating: up to 700 kg/h
Combination option	Condensation of partial quantities of Pure Steam when small quantities of WFI are required
Desludging	1 % discontinuous
Degassing	Thermal degassing (optional), membrane degassing (optional)
Heat exchanger	DTS heat exchanger for heating and evaporation
Sanitization of the entire system	Self-sanitization through permanently high temperatures (> 70 $^{\circ}$ C) and internal circulation
Connections	Clamp connection in accordance with DIN 32676, use of safety clamps in accordance with AD-2000, aseptic flange in accordance with DIN 11864-2
Valves	Seat valves suitable for Pure Steam, diaphragm valves
Inline / Online Process monitoring	Conductivity, TOC (optional), temperature, pressure, level, flow rate
Pure Steam parameters	Connections for measuring parameters in accordance with DIN 285 and DIN 58950-7 in pure steam
Control and visualization	System control via Simatic S7 PLC, operation and visualization via Siemens TIA Portal
Computer validation	According to GAMP 5

Technical changes and errors excepted.