



Ultra-Pure Pyrogen-Free Steam Generators





STILMAS

Stilmas is an industrial and engineering Company specialized in the research, design, development and construction of high technology plants for the pharmaceutical, electronic, cosmetic and food processing industries.

The business scope is the design, the production, the assembly, the sale and installation of such plants, of special equipment and instruments, as well as the exploitation of alternative powers and energy saving achievements.

The modern and exhaustive equipment, the dynamic organization and the available financing means, allow the completion and extension of both activity and study in addition to a closer relationship with C.N.R. and the most important universities.

pure technology, pure water

Pure Steam Generators

Stilmas' PSG - DTS Pure Steam Generators are designed and constructed according to the latest International Pharmacopeias and the latest cGMP FDA. They are capable of solving any problem of sterilisation of pharmaceutical equipment and process lines. Standard models range is from 50 to 6.000 kgs/h output.

Main features of Stilmas PSG - DTS

- **The Immediate start up:** due to the design as per "accumulating boiler" technology, the pure steam is immediately available. The unit is able to pass from stand-by to full capacity in a few seconds.
- **High Flexibility:** the production capacity can be varied automatically from 0 to 100% according to the demand.
- **Unique purification system:** gravitational purification principle for better guarantee of steam, purity.
- **High Quality Steam:** the quality of produced steam is constant in terms of pyrogen contents, superheat value and dryness fraction, independently from pressure and production flow rate.
- **Simple and clean mechanical construction:** baffle free decontamination chamber - no welding. Granting the best inspectability, minimized corrosion risk, for the longest expected life of the equipment.
- **Extremely limited maintenance.** No moving parts, expansion joints or mechanical seals. No extra space in height is needed.
- **Compact construction and low weight.** Little extra head room needed for dismounting and inspection.

Pure Steam Generator PSG 1000 DTS



Look closely...

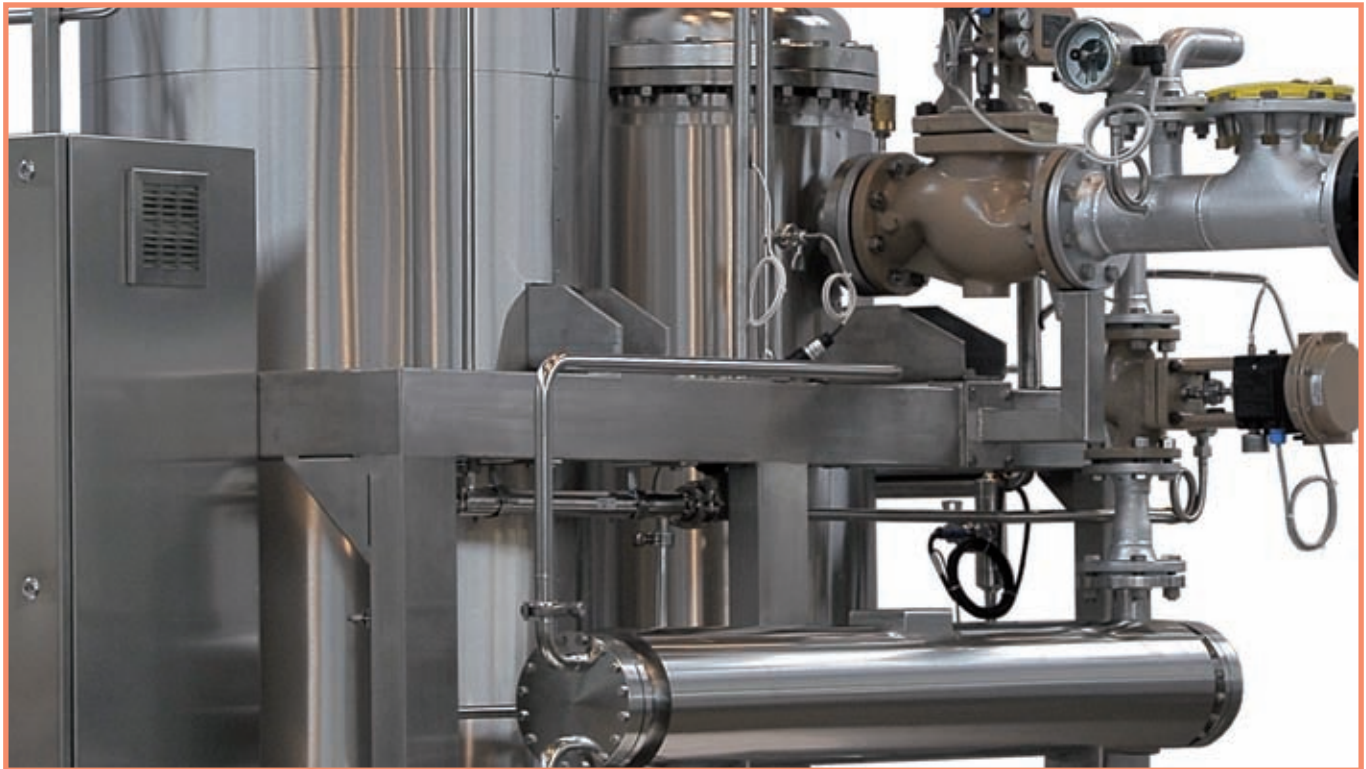
Operating principle

Stilmas' PSG - DTS Pure Steam Generators design is based in the "accumulating boiler" technology. The system is composed by two parallel bodies: the heat exchanger and the evaporator - decontamination column. Feed water is fed to the decontamination column (main body), while industrial steam is fed to the heat exchanger, shell side. Industrial steam heats the feed water to evaporation temperature, so creating a strong circulation inside the two bodies. The steam develops in the evaporator: steam low velocity and the height of the decontamination column eliminate any possible impure water droplets entrainment.

A pressure transducer, installed in the evaporator, controls the feed of industrial steam to the heat exchanger, thus granting constant pressure of the produced pure steam.

The feed water flow is controlled by a level transmitter installed in the evaporator.

On request it is possible to provide pure steam generators fed by electrical energy (Stilmas series PSG - E).



Pure Steam Generator with Gasbuster® - Detail

a unique and original design

Construction Characteristics

The plant is completely made in AISI 316L stainless steel. Standard finishing of the active surface is pickled and passivated; mirror or electropolishing can be made on request.

The heat exchanger is a DTS type; the pipes are expanded into the plates, avoiding any welding for a totally hygienic execution, and a better resistance against dilatation stress.

The design and construction of the decontamination chamber, which is a totally empty column, ensure the best inspectability. The absence in this area of welding dramatically reduce the risk of corrosion, for a very long expected life of the equipment.

The general construction design, coupled with the described decontamination process, ensure a very compact layout, together with an extremely limited space needed for maintenance.



Pure Steam Generator - Detail of decontamination chamber and heat exchanger

ADVANTAGES

- Maximum operation flexibility. The unit produces automatically in the range of 0-100% according to the demand.
- The pyrogen free steam quality is always perfect independent from pressure and production flow-rate.
- The temperature and water volume in the decontamination chamber allow the unit to respond rapidly. in a few seconds from stand-by to maximum production capacity.
- The compact design and the silent operation allows the unit position even in the production departments.
- No extra height is required for maintenance.

Endotoxyn reduction

A unique and careful design of the decontamination chamber allows Stilmas to grant the highest performances in terms of endotoxyn content reduction. The gravitational separation system has proven to be an extremely simple and simultaneously effective process for the separation of the contaminants from the pure steam. Challenging the system with increased endotoxin levels in the feed water has proven the capability of Stilmas PSG-DTS to reduce endotoxyn level by log 6 (1.000.000 times).

WFI production

In case limited amount of WFI production is required, it is possible to provide the Pure Steam Generator with a condensing unit (PSC) constituted an a Double Tube Sheet heat exchanger, complete with automatic regulation system. The PSC units allows for partial or total Pure Steam flow conensation, into WFI.



Detail of double tube sheet heat exchangers

Non-condensable-gases (NCG) reduction

Stilmas has developed two alternative solutions, in case compliance with international rules (EN285, HTM2010) is required for the NCG content.

The first solution foresees the installation of an external degassing tank, in which preheated feed water is sprayed for NCG removal.

The second solution is based on a Stilmas patented system - Gasbuster®. In this case pre-heated feed water is fed directly to the PSG-DTS decontamination column, where a special device is installed granting the contacting between the preheated water and a small stream of pure steam: the stream of pure steam degasses the water by stripping out the NCG.

With both solutions Stilmas' PSG-DTS is able to grant NCG content much lower than what is required by the international rules.

Electrically heated Pure Steam Generator

Stilmas' range of production even includes Pure Steam Generator electrically fed. In this case the main body of the equipment is provided with electrical heaters made in a resistant alloy, which grant the heating of the water. Typically electrical steam generators are applied for capacity up to 500 Kg/h.



Pure Steam Generator: PSG-E

a full range of special devices

AUTOMATION

Stilmas pure water production plants are equipped with a PLC controller and HUMAN machine interface. A wide range of configurations are available based on the use of widely applied brands of PLC models. All the PLC controllers have the possibility to be connected with a factory supervisory system via the most common communication system. Software is developed according to the latest GAMP. Complete SCADA system CFR 21 - Part 11 Compliant is available on request.

DOCUMENTATION AND VALIDATION

The Documentation Package supplied by Stilmas for its Plants is conceived and organized to be in compliance with:

- to provide documented evidence of the Project Life-cycle, from the design phase up to the final Site Acceptance Test runs.
- to collect all the necessary information as needed to consistently feed and support the Validation Activity.

With regards to the Validation Activity, Stilmas is able to provide a fully comprehensive Validation Service Package, including Validation Protocol Preparation, Site Tests execution, Instruments calibration and Validation Reports organization.

The Validation Activity is performed by a dedicated Validation Team.



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