

Pharmastill multi effect Stills





STILMAS

MASCO GROUP

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

Pharmastill multi effect Stills

The Pharmastill multiple effect Stills produce distilled water for injectable use which meets the latest requirements of the International Pharmacopeias including USP, EP and JP.

The Pharmastill modular construction offers a wide choice of configurations allowing optimum payback times.

Standard models range is from 60 to 22.000 lts/h output.

Main features of Stilmas Pharmastill

- **Rapid start up.** The distillate is produced after only few minutes from switch on.
- **Energy Savings:** the best performance in terms of energy savings, due to an extremely accurate design of the condenser/evaporators and heat recovery system.
- **High Flexibility:** the production capacity can be varied by up to 80% without any plant modification.
- **Unique purification system:** gravitational purification principle for better guarantee of distillate purity.
- **Simple and clean mechanical construction:** baffle free decontamination chamber - no welding. Granting the best inspectability, minimized corrosion risk, for the longest expected life of equipment.
- **Extremely limited maintenance.** No moving parts, expansion joints or mechanical seals.
- **Compact construction and low weight.** Little extra head room needed for dismounting and inspection.
- **Up to ten effects,** for maximum energetical efficiency.



Pharmastill MS 505 HPS increasing of condenser height

Look closely..

Operating principle

The Pharmastill HPS is based on the “Thin Falling Film” and Multi-stage principles ingeniously combined. The first effect is fed by an external energy source (Industrial Steam or Electrical energy).

The pure steam generated in the each effect and the non evaporated water are fed to the subsequent one operating at lower pressure; pure steam is condensed into WFI vaporizing a new portion of feed water.

Pharmastill's are provided with one pre-heater for each column recovering the sensible heat of the distillate, and two final exchangers. In the final condenser a degassing system is also integrated.

WFI conductivity is continuously measured and, in case of “out of spec”, the produced WFI is automatically discharged to the drain. On line TOC monitoring is also possible.

The production capacity can be adjusted in the range of 60-100% by simply acting on the industrial steam pressure.

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. Product (WFI) contact parts are manufactured with surface finishing 0.6 microns Ra mechanically polished, with piping orbitally welded with sanitary flanges and pharmaceutical grade Teflon gasket.

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.

Pre-heaters and exchanger are shell-and-tube type; double tube sheet execution is foreseen where contamination of the distillate is possible. The pipes are expanded into the plates, avoiding any welding for a totally hygienic execution, and a better resistance against dilatation stress.

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



Pharmastill MS 505 ES electrical heating

a unique and original design

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.

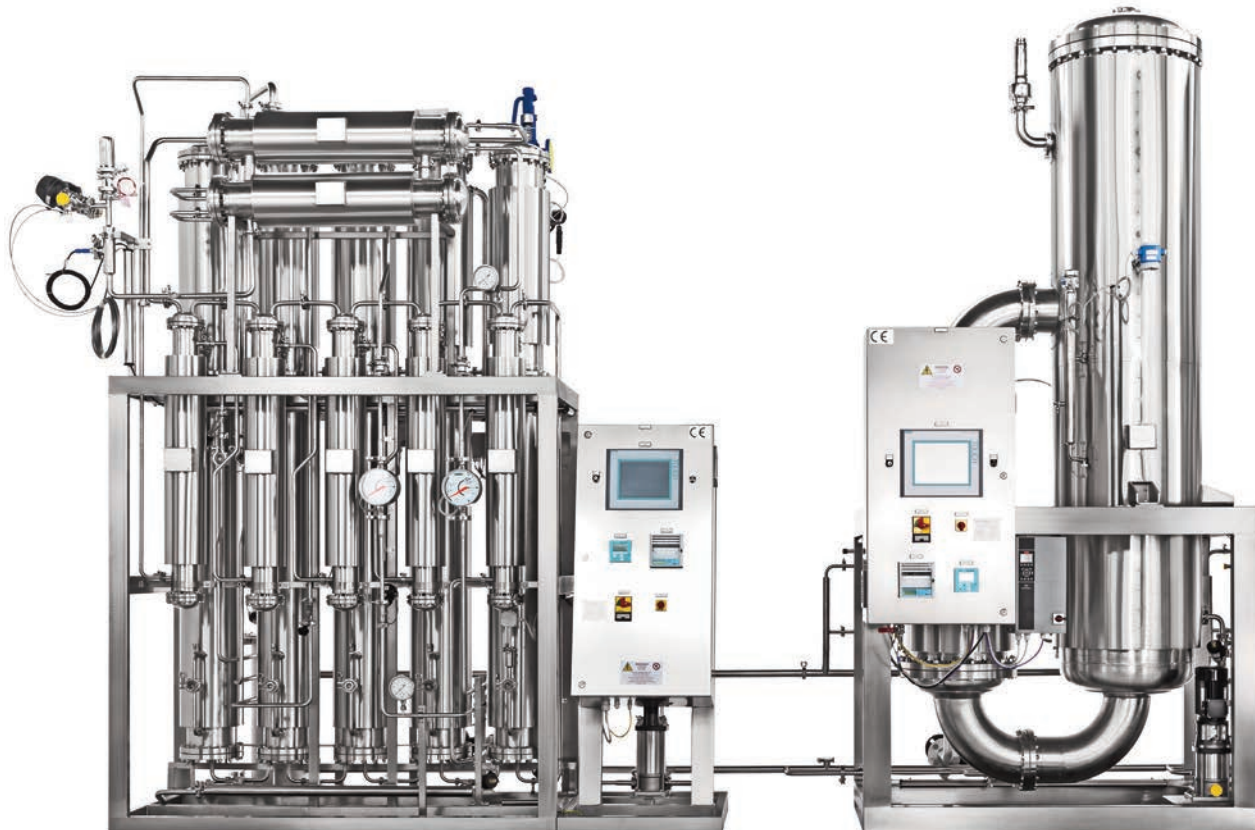
Challenging the system with increased endotoxin levels in the feed water has proven the capability of Stilmas Pharmastill to reduce endotoxyn level by log 6 (1.000.000 times).

Pharmastill effect design

Pharmastill are equipped with effect of unique and original design. Each effect consists of a tube condenser on top and a decontamination chamber below, joined by a flanged connection which also has the function of Support. The column is therefore free to expand without any restraint.

The decontamination chamber is a completely empty column without any baffle or mechanical separation device. The decontamination of the steam is obtained by exclusively gravitational separation: the produced steam separates into pure vapour ascending the height of the decontamination chamber at low speed, allowing the impure water droplets to fall to the bottom of the column under simple gravitational force.

The contaminants remain thus in the feed water.



Pharmastill MS 1005 HPS coupled with Pure Steam Generator

THERMODYNAMIC PRINCIPLE - HEAT RECOVERY

The heat recovery system in Stilmas Pharmastill is the result of a careful mechanical and thermodynamic study.

The thin falling film process inside the evaporators/condensers grants the highest efficiency in heat and mass transfer. This process is coupled with the short tubes technology, which ensures the best wettability of the exchange surface.

In addition, Stilmas Pharmastill is equipped with individual and separate pre-heaters for each effect, independent from the evaporators/condensers, thus achieving the highest sensible heat recovery, and finally the best energetical efficiency.



Pharmastill MS 704 HPS: seven effects and no cooling water needed

MORE.....

- **Pure steam production:** by diverting the steam produced in the first effect of the Pharmastill it is possible to obtain a stream of Pure Steam to be used for SIP processes, autoclaves, etc.
- **Feed water degassing:** Stilmas has designed a feed water degassing system which can be installed upstream the Pharmastill. This system is recommendable when extremely low Non Condensable Gases content (and / or conductivity) is required for the WFI, or when a residual pressure is required at WFI outlet (usually atmospheric).
- **WFI pressurizing:** in certain cases, due to layout constraints, WFI cannot be fed by gravity to the storage tank. Stilmas has designed a WFI pressurizing system integrated into the Pharmastill, able to provide required WFI pressure.
- **Pharmastill MS COMBI:** the innovative Pharmastill MS - COMBI integrates into one system the possibility of simultaneous and independent production of WFI and Pure Steam in different capacities and ratios. Dedicated design can be performed to fit production needs.



Pharmastill MS 705 COMBI: simultaneous production of WFI and PS

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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