Telstar® Puretech™

WFIS

Water For Injection Stills

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A choice of quality

Telstar Puretech Multiple Effect Water for Injection Stills are designed and constructed to produce pyrogen-free sterile water (WFI) in full compliance with cGMP guidelines as per FDA and EMEA requirements.

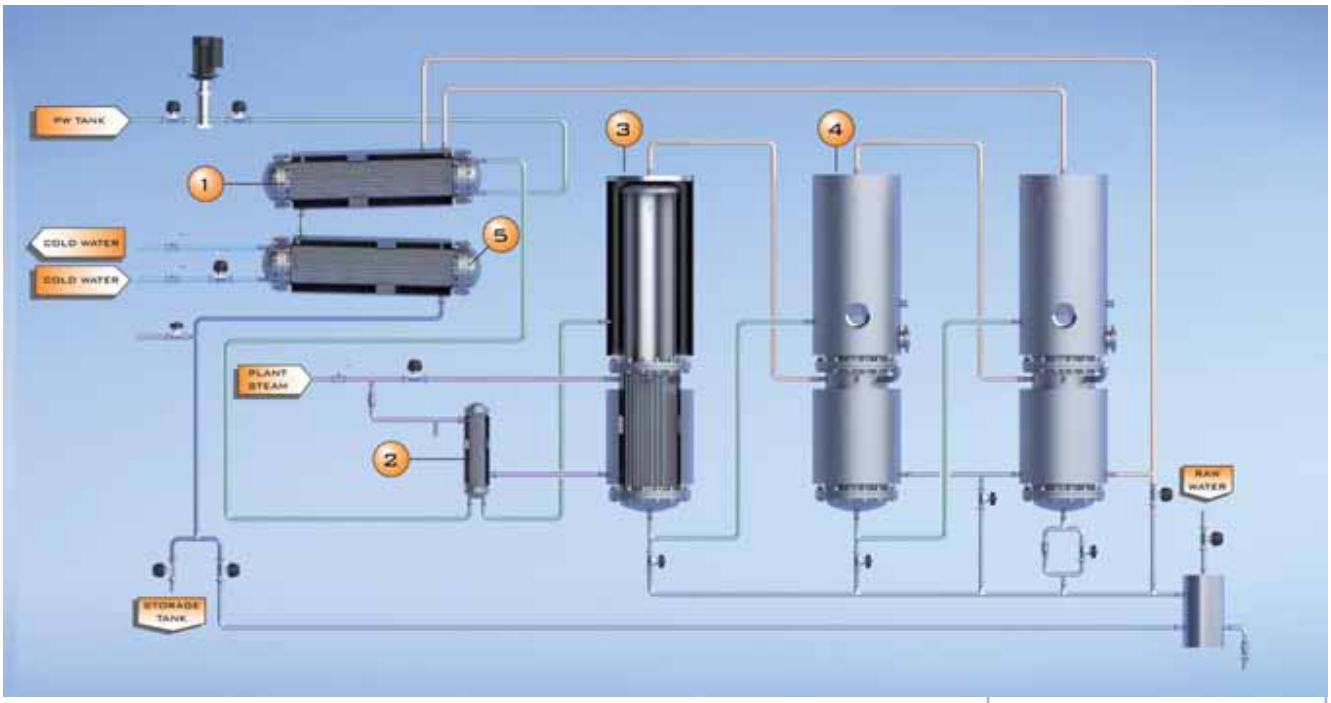
Engineering and manufacturing practices follow ISO 9001 procedures, ASME BPE criteria, GAMP guidelines, etc. Design and construction meets the most stringent Regulations and Codes from Europe, USA and others concerning safety and pressure vessels.

To ensure the equipment meets your requirements, we work in partnership with you and a dedicated team follows your order as a unique project. We develop specific Quality Plans (DQ, IQ and OQ) and undertake factory acceptance testing (FAT) to give assurance, performance and quality.

WFI applications

WFI water for injection, as defined in the Ph Eur and the USP, is used for the preparation of medicines for injectable administration, where water is used as a vehicle (water for injections in bulk), to disolve or dilute substances or preparations for injectable administration before use (sterile water for injections). According to the Ph. Eur water for injections can only be produced by distillation, of drinking water or purified water.

Operating principle



Feed water (PW) is pre-heated by means of two DTS heat exchangers, which use respectively the heat of the pure steam and distillate water outlet and the plant steam outlet. The first column of the CS water still is equal to our CPS steam generators, heated also with plant steam.

The pure steam produced in the first column is used as the heating medium for the next one, so it condenses and turns into WFI. Simultaneously, the partial amount of non-evaporated water goes to the next column, so it is also partially evaporated as pure steam and used as heating energy for the next column.

Here, the pure steam also condenses (resulting in WFI distillate) and it is transferred by pressure to the successive columns.

1. **DTS PRE-HEATER**
2. **DTS HEAT EXCHANGER**
3. **PLANT STEAM HEATED COLUMN**
4. **PURE STEAM HEATED COLUMN**
5. **CONDENSER**

Control system

The control system is based on a PLC wire operator supervision via a user-friendly touch-screen HMI with the following menu:

- Mimics of the equipment, showing the operational state in real time
- Process parameters (temperature, pressure and conductivity)
- Setting up of parameters
- Alarm information
- Start-up and alarm recognition.

Options include: paper or electronic chart recorder for pure steam conductivity, temperature, extra feed water conductivity meter, on-line TOC monitoring, etc.

Design & construction features

Compact and Modular

The unit and all its components such as feed water pump, pre-heater and condensers are mounted on a stainless steel AISI 304 skid.

All parts in contact with the media are made of stainless steel AISI 316L, insulated with mineral wool (asbestos-free material) with external cladding made of stainless steel AISI 304. Inner surfaces are polished to Ra ≤ 0.64 µm and electro polishing is an available option.

Hygienic design: Including clamp connections, orbital welding techniques for tubing and components, minimisation of dead legs and proper piping slopes for self-drainability, double tube sheet construction in first column, condenser and pre-heaters, diaphragm valves for distillate/reject, etc.

Simple and Efficient Design

The lower part of the column consists of a double tube sheet shell heat exchanger with a large central pipe surrounded by a bundle of peripheral seamless pipes. This arrangement produces a natural fluid circulation: ascendant inside the peripheral pipes and descendant inside the central one. Steam flows up very slowly but droplets cannot reach the top of the column as they fall down simply by gravity. Thus, impurities such as particles and pyrogens contained in the droplets are dragged down towards the bottom of the column where they are automatically blown down. Pure steam from the first column serves as heating energy in the next column where it condenses as WFI. This can be reproduced several times, so called multiple effects, up to 7 columns. The more effects we install, the less heating energy and cooling water required.

Ease of Maintenance and Installation

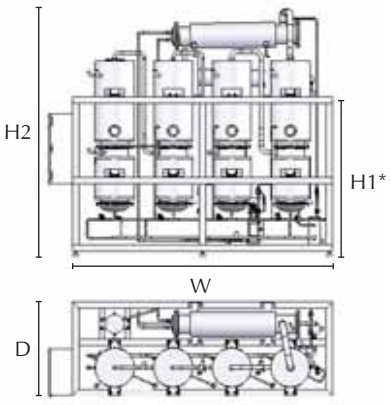
The heat exchangers are totally accessible and no internal elements are located within the column. This makes inspection much easier than other designs, with long pipes or internal heat exchangers.

The replacement of column gaskets can be done easily and quick, without needing to dismantle the column, which removes the need for very high technical areas in order to take off any internal part.

Heat exchanger pipes are always totally immersed in water, so there is a very low tendency to build up scale inside the tubes. Moreover, as they are shorter than other designs, they are less stressed by vibrations and risk of corrosion is significantly reduced.

Technical data

MODEL	No. of effects	Overall dimmensions				Main Utilities			Approx. Weight Kg
		Width (W) mm	Height (H1) mm	Height (H2) mm	Depth (D) mm	Distillate output l/h	Heating steam @ 8 bar kg/h	Cooling water (25-50º C) l/h	
WFIS 3-250	3	2.140	2.000	2.900	1.300	270	130	1.095	800
WFIS 3-500	3	2.105	1.900	2.875	960	500	235	2.030	1.000
WFIS 4-500	4	2.500	1.900	2.875	960	500	190	1.185	1.200
WFIS 4-750	4	2.910	2.100	3.100	1.100	775	295	1.835	1.350
WFIS 4-1250	4	3.040	2.230	3.090	1.180	1.200	460	2.840	1.500
WFIS 5-500	5	2.915	1.900	2.875	960	500	165	650	2.100
WFIS 5-750	5	3.420	2.100	3.070	1.100	775	255	1.005	2.300
WFIS 5-1250	5	3.590	2.230	3.090	1.180	1.200	390	1.555	2.500
WFIS 5-2000	5	3.700	2.400	3.550	1.500	2.075	680	2.690	3.000
WFIS 5-3000	5	4.200	2.685	3.830	1.500	3.065	1.000	3.970	3.400
WFIS 5-4500	5	4.400	2.950	3.975	1.600	4.585	1.500	5.940	3.800
WFIS 6-2000	6	4.270	2.400	3.550	1.500	2.075	605	1.150	4.200
WFIS 6-3000	6	4.880	2.980	3.830	1.500	3.065	890	1.695	4.700
WFIS 6-4500	6	5.315	2.950	3.975	1.548	4.585	1.335	2.540	5.200
WFIS 6-6500	6	5.900	3.080	4.420	1.630	6.535	1.900	3.615	5.800
WFIS 6-9000	6	6.900	3.080	4.420	1.800	9.060	2.635	5.015	6.500
WFIS 6-12000	6	6.675	3.170	4.500	2.100	12.640	3.680	11.665	7.200
WFIS 7-3000	7	5.560	2.980	3.830	1.500	3.065	815	0	6.000
WFIS 7-4500	7	6.050	2.950	3.975	1.550	4.585	1.220	0	7.400
WFIS 7-6500	7	6.710	3.080	4.420	1.630	6.535	1.740	0	8.800
WFIS 7-9000	7	7.510	3.080	4.420	1.800	9.060	2.410	0	10.300
WFIS 7-12000	7	7.700	3.170	4.500	2.400	12.645	3.365	0	12.500



** WFIS OUTLET*

Options and accessories

- Feed water conductivity monitoring
- Pure steam take from the first column
- Elevated WFIS condenser
- Hot standby mode
- Sanitisation/Sterilization of the separator columns and WFIS condensers
- Protective mesh guarding
- On-line TOC monitoring device
- WFI storage and distribution skid.

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