Multiple-effect Water Stills

CS Series

Product Concept

Standard specifications

Options and accesories

Associated services

What's a multiple-effect still?

- A multiple-effect still shall provide pyrogen-free, water-for-injection (WFI) quality water for use in pharmaceutical manufacturing.
- The system shall operate automatically and provide a "safe state" in which likelihood of injury to personnel and damage to the unit is minimized.
- In addition, it must be equipped with alarms and warnings in order to guarantee and report product constant quality.

When to use a multiple-effect still?

- Whenever the pharmaceutical manufacturer shall use high purity water as stated in the EU and US Pharmacopoeias.
- Whenever the amount of water required is higher than 100 l/h, the use of multiple-effect configuration starts being more profitable.
- Whenever the water loop has to be maintained at 80ºC in order to keep sterile conditions of the same.

Main concerns when producing WFI

- Keep constant quality of water regarding USP requirements.
- To achieve a safe level of endotoxin reduction (no lower than 3 log) in case of incident.
- Quick response to variable demands of distillate water.
- Reliability and trouble free system in terms of operation: no leaks, no cross contaminations, no rust, etc.
- Ease of maintenance: easy to replace seal gaskets, no extra space required and avoid dismantling the unit.
- New concerns about roughing; trend to demand electropolishing of internal surfaces.

WATER: ANALYTICAL PARAMETERS

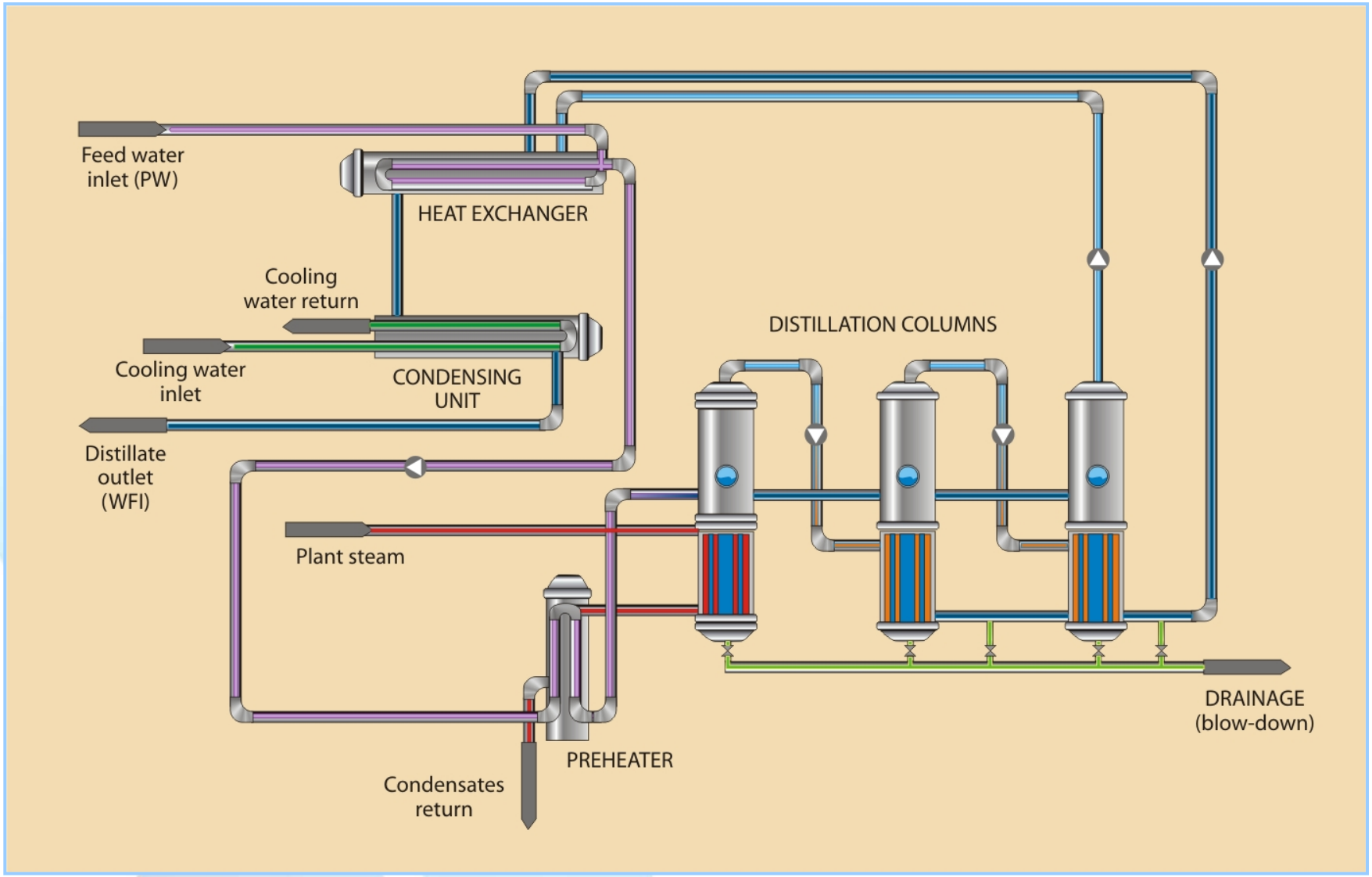
Purify Water Specifications (PW).

PARAMETERS	USP 25	EUROPEAN PHARMACOPOEIA addendum 2001
ORIGIN	potable water/CEE regulation	potable water
CONDUCTIVITY	≤ 1,3 µS/cm at 25 °C (in the 1st phase/3)	≤ 4,3 µS/cm at 20 °C
TOC	≤ 500 ppb	≤ 500 ppb
NO_3 / NO_1		≤ 0,2 ppm
HEAVY METALS		≤ 0,1 ppm
ALUMINIUM		≤ 10µg/l
MICROBIAL CONTAMINATION	≤ 100 UFC/ml	≤ 100 UFC/ml

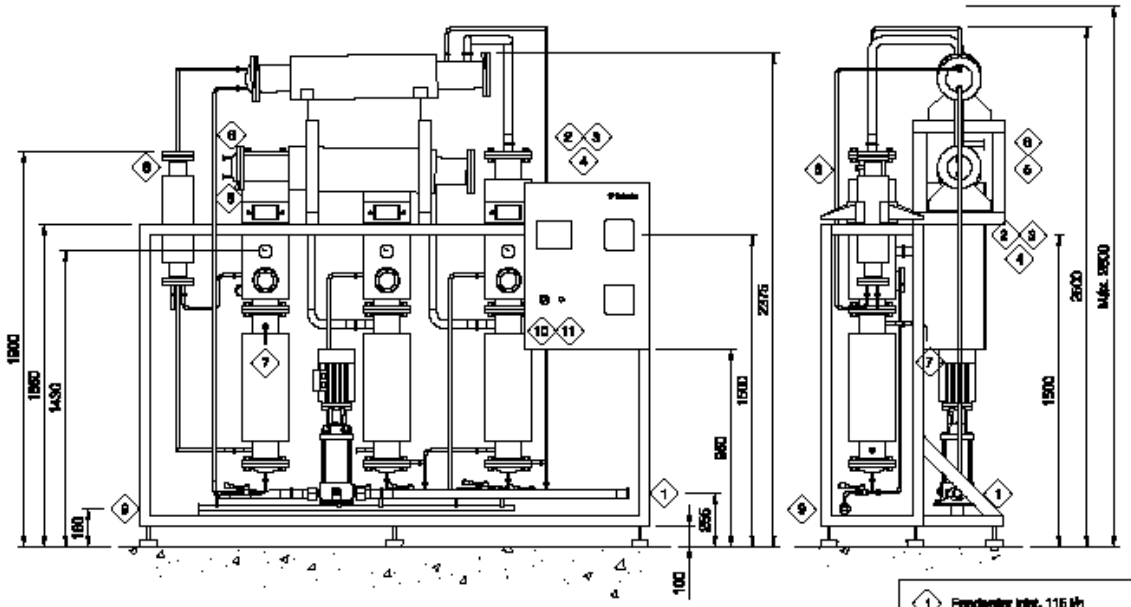
Water for Injections Specifications (WFI).

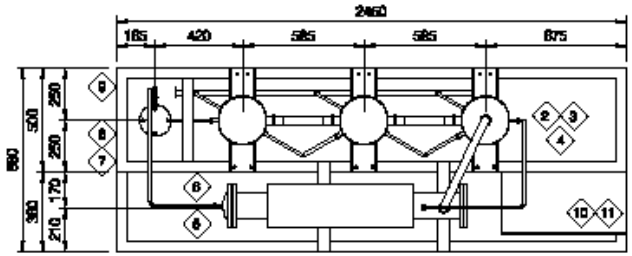
PARAMETERS	USP 25	EUROPEAN PHARMACOPOEIA addendum 2001
ORIGIN	potable water / CEE or EP	potable water / CEE or EP
PREPARATION METHOD	Distillation or reverse osmosis	Distillation
CONDUCTIVITY	≤ 1,3 µS/cm at 25 °C (in the 1st phase/3)	≤ 1,1 µs/cm at 20 °C
TOC	≤ 500 ppb	≤ 500 ppb
NO_3 / NO_1		≤ 0,2 ppm
HEAVY METALS		≤ 0,1 ppm
ALUMINIUM		≤ 10 µg/l
ENDOTOXINES	< 0,25 EU/ml	< 0,25 EU/ml
MICROBIAL CONTAMINATION	≤ 10 UCF / 100 ml	≤ 10 UCF / 100 ml

Working principle



Plant Layout





1. Feedwater inlet, 115 l/h
2. Pure distillate outlet, 100 l/h
3. Distillate divert outlet
4. Distillate sample outlet
5. Cooling water inlet, 480 l/h
6. Cooling water outlet, 480 l/h
7. Plant steam inlet, 50 Kg/h, 8 bar
8. Condensate return
9. Drain outlet
10. Electrical supply, III 220/380 V, 50 Hz, 2 KW
11. Compressed air, 6 bar, 1 Nm/h

The right is reserved to be able to modify the measures to facilitate the production or to improve the design and to adapt it to the specifications required

TITLE	Layout
PROJECT	CS-3 100
CLIENT	
ISSUED FOR	Preliminary drawing
SCALE	1:20
DRAWING NO.	D.H.R.

Celester

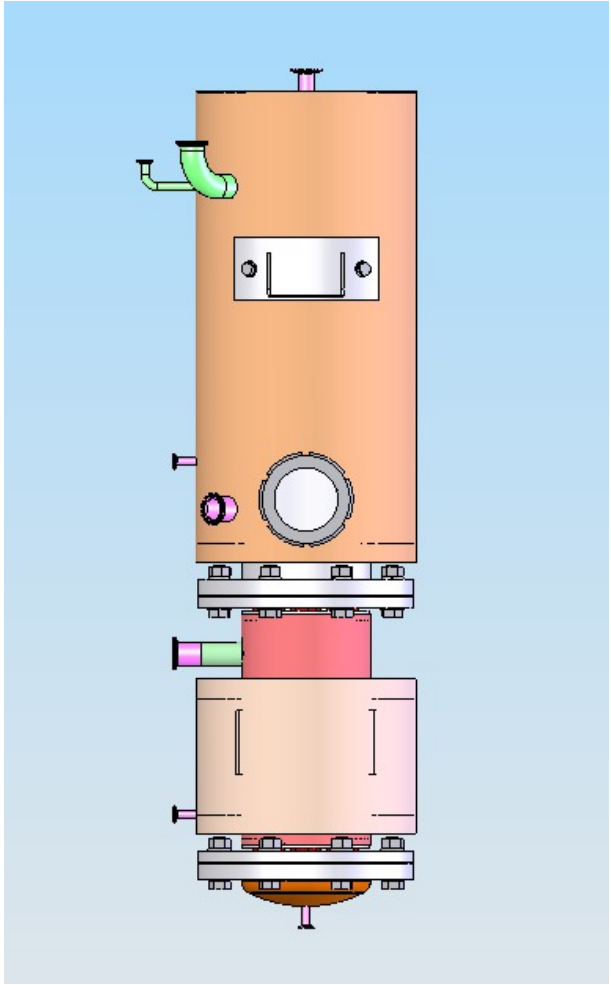
CS 3-250 basic unit

Design and construction features

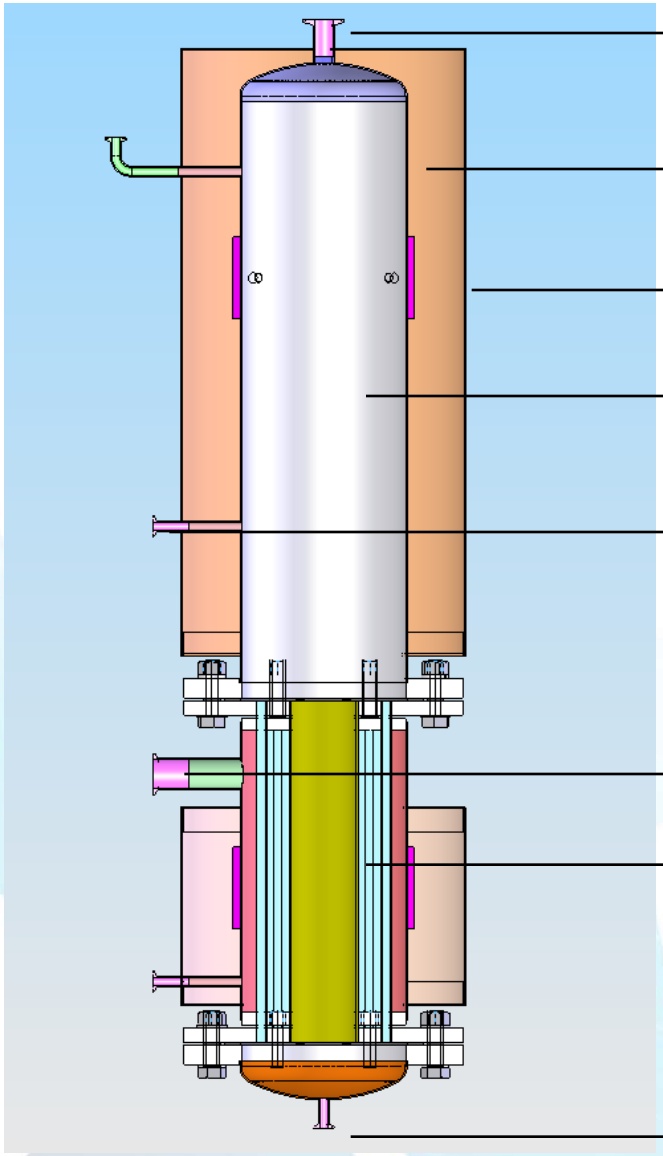
- All process materials (pressure vessels, tubes, valves, etc.) are stainless steel AISI 316 L and the active surfaces are mechanically polished giving a superficial interior roughness Ra $\leq$ 0.64 µm.
- Diaphragm type valves and diaphragm isolated instrumentation installed in the process pipework.
- TIG welding, orbital execution always when it's possible.
- Removable connections with in-line sanitary fittings.
- Minimization of dead legs.

Column design (I)

- Two sections:
  - Upper section constitutes the separator chamber. The column has been designed to allow water droplet separation by gravity due to low velocity up flow principle. Non-evaporated water goes down to the bottom and it is finally discharged.
  - Lower section is a heat exchanger, where the water is heated by plant steam and evaporates, flowing up to the upper section.



Column design (II)



Pure steam outlet to heat up next column

Insulation

External cladding

Separation chamber

Feed water inlet

Heating steam inlet

DTS Heat exchanger

Non-evaporated water to next column

Column design (III) – Heat exchanger

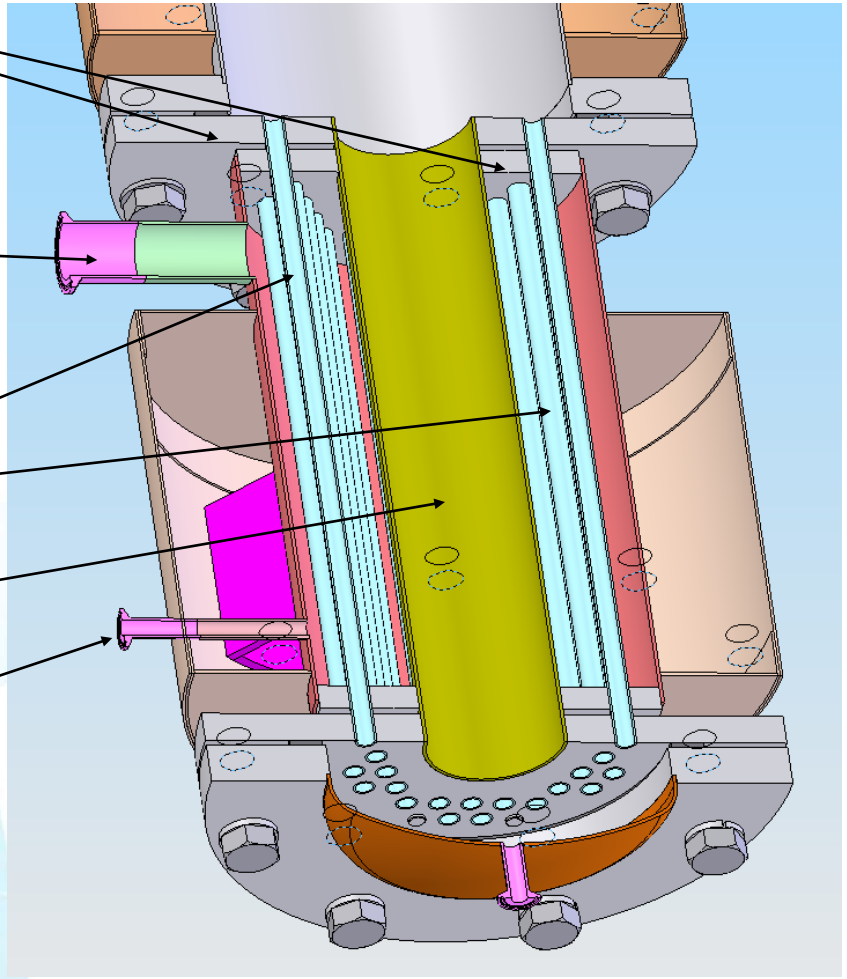
Double sheet

Plant steam inlet

Seamless pipes
(upward flow)

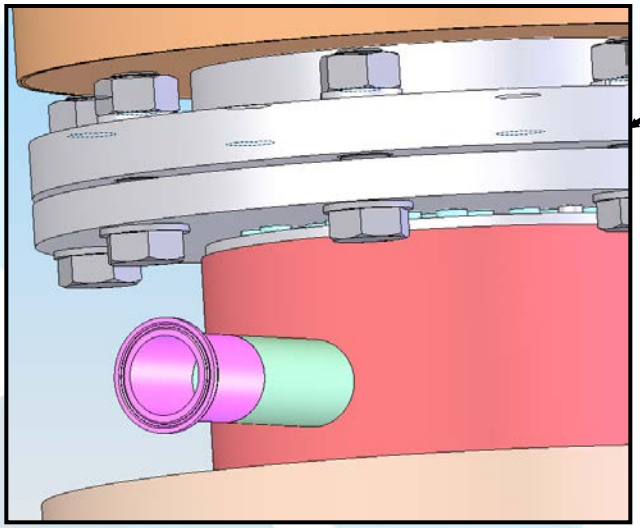
Seamless big pipe
(downward flow)

Plant steam outlet

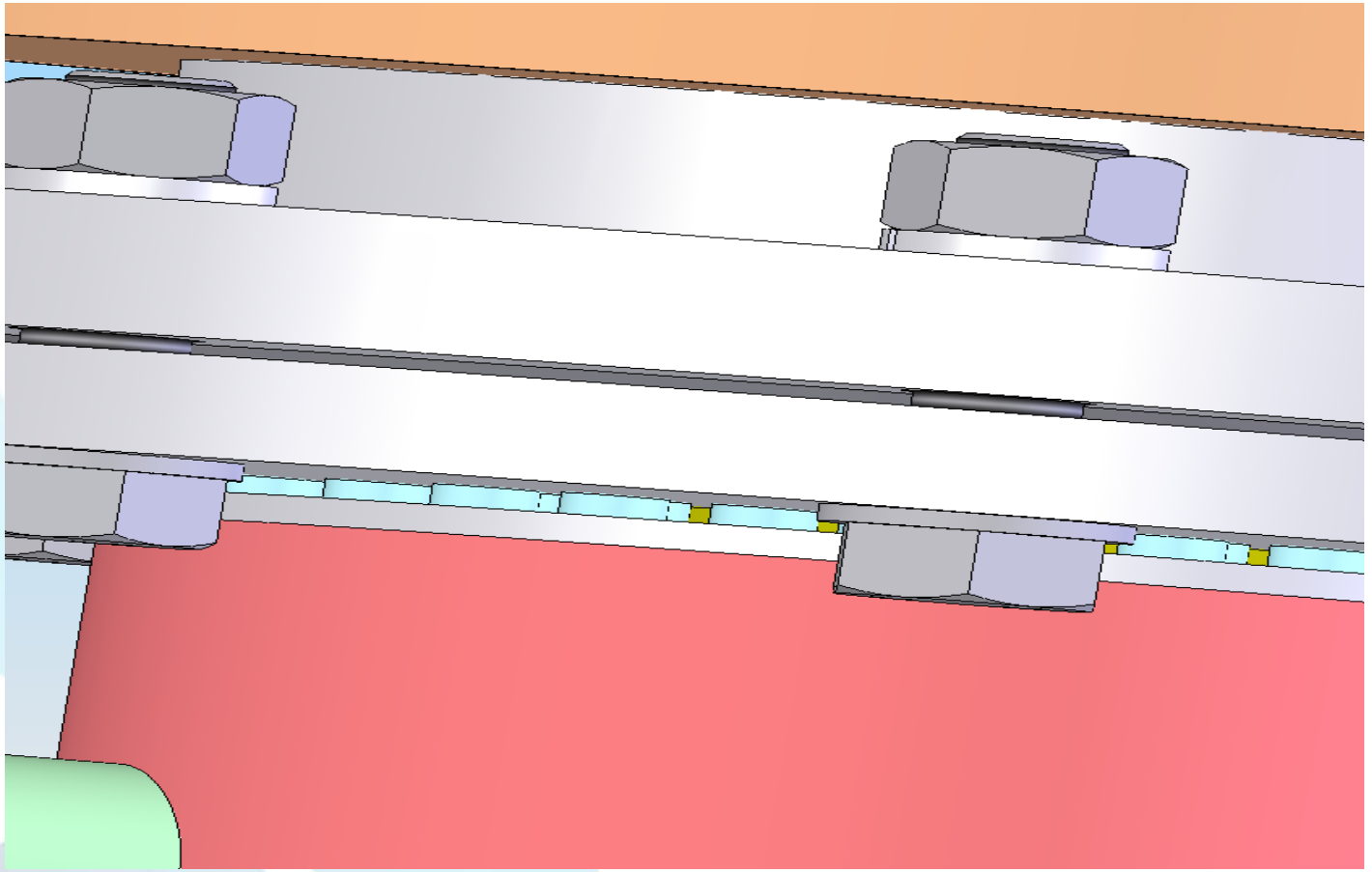


1st Column (I)

- DTS (Double Tube Sheet) design, heated by plant steam (3-8 bar) outside the tubes.
- Condensates of plant steam are used to heat up the inlet water by means of a pre-heater, also DTS design.



Double Tube Sheet Heat Exchanger – cGMP design



1st Column (II)

- A PID valve regulates plant steam pressure so the production can be adjusted according to the consumption demands.

2nd, 3rd... Column performance

- Same design as 1st column, but without DTS. The outside of the tubes are filled with pure steam and distilled water, which serves for heating up the inlet water flowing inside the tubes.
- Last column sends the fluid to the horizontal pre-heater and condensing units.
- Number of columns may change as per desired energy and cool water savings, initial investment budget, etc.

Horizontal heat exchangers

- There are two of them, both U-Type DTS:
  - Pre-heater: The purified water flows in the interior of the tubes and pure steam outside of the same.
  - Condensing unit: The cooling water flows inside the tubes and the WFI (pure steam condensate or distillate) outside of the same.

Advantages of Telstar design (I)

- Engineered with simplicity to pass endotoxin reduction test
  - A clever design is a simple design. The endotoxin reduction test in our design has proven to reduce the level of endotoxines with 3 log, which is totally enough considering that the water source is PW.
- No baffles, spirals or demisters – sources of contaminations
  - The operating principle for separation of particles and endotoxines is simply by gravity. The separator column is designed in diameter and height in order to avoid droplets going out from the top of the column, where there's the outlet of pure steam. As the particles and endotoxines are carried by droplets, they are separated from the pure steam and thus, at the end, from the distillated water.
  - The impurities are then accumulated in the bottom of the column and blown down from time to time.

Advantages of Telstar design (II)

- Wide range of production rates with decontamination effectiveness
  - The design has been proven for the worst case, which it is in the last column where the pressure is the lower and steam velocity is higher, but never goes above 1 m/s.
- Columns with “Tension free” heat exchanger
  - The heat exchanger is totally immersed in the feed-water with equal temperature inside all tubes (small pipes and big central tube) and heating steam is flowing with equal temperature inside the shell and outside all tubes.
  - As a result, when heated up/cooled down (by start and stop), the shell and the tubes will expand/contract equally and thus, no tension at all occurs in pipes, shell and welding. This also reduces the risk of corrosion by tension.

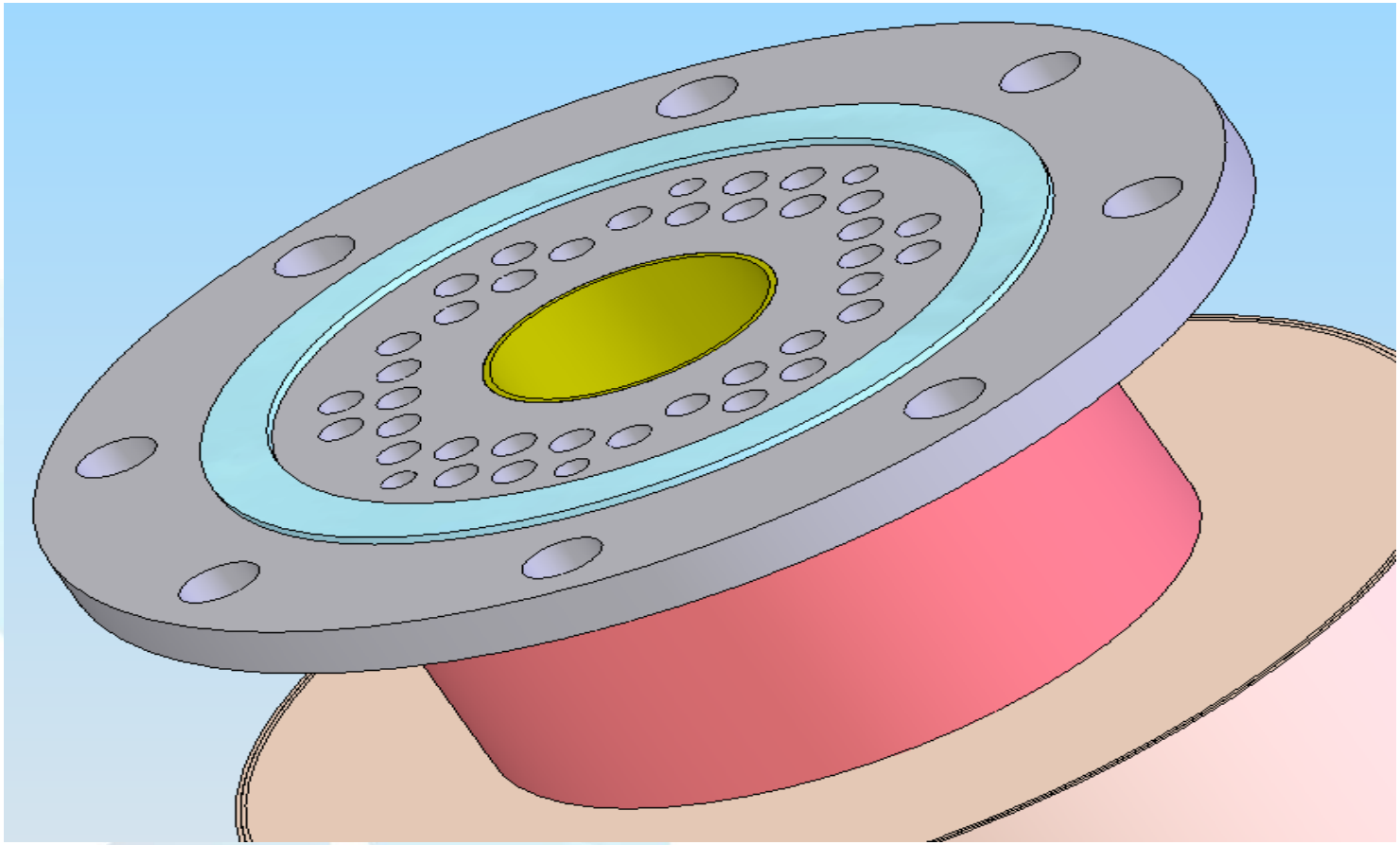
Advantages of Telstar design (III)

- Short tubes length
  - This reduces even more the risk of dangerous effect of vibrations.
- Very low tendency to built up scales inside the tubes
  - Thanks to the fact that the tubes are totally immersed in the feed water, it is guaranteed that all tubes operate in a wet condition. In addition, the generated steam makes a continuous flow upwards, reducing even more scale formation.
- Possibility to check tightness of the heat exchanger without dismantling
  - Thanks to the columns construction (sight glasses placed higher than the top tube plates), the tightness can be tested regularly by applying compressed air to the heat exchanger shell and checking the column water level for air bubbles.

Advantages of Telstar design (IV)

- Ease of maintenance – no dismantling, no extra height required
  - The heat exchanger is totally visible from the outside and no internal elements are located within the column. This makes inspection much easier than other designs, with long pipes or internal baffles, demisters, spirals, or heat exchangers (such as Stilmas, Finn-Aqua or Kemiterm).
  - In addition, replacement of gaskets is much easy and fast. It is only necessary to elevate a little bit both bodies, each one having its own supporting frame. Other designs involve dismantling the column, which is a tedious job and in addition, needs very tall technical areas to take off the internal parts.

Gasket between Heat Exchanger – Expansion chamber



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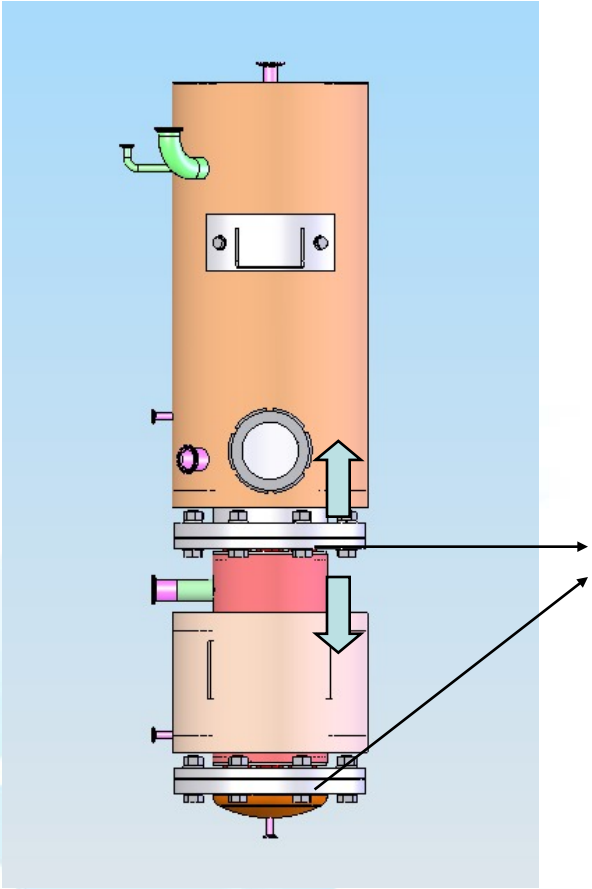


Gasket position:

Easy replacement

Supervision, Control and Recording System

- Emergency Stop
- Colour touch-screen
- Control lights
- Push buttons
- Conductivity meter
- Chart recorder

SCADA PharmaSter control system

- Host PC computer for data logging and supervision
- Computer, PLC and chart recorder interconnected
- Synoptic diagrams
- Self diagnostics
- On-line variables and alarms display
- Variable trends stored in historic files

Options and accessories

- Break tank
- Electropolish of inner surfaces
- 3-Channel recorder
- Feedwater monitoring system
- Heating steam pressure reducing valve
- Set of spareparts for 1/2 year/s

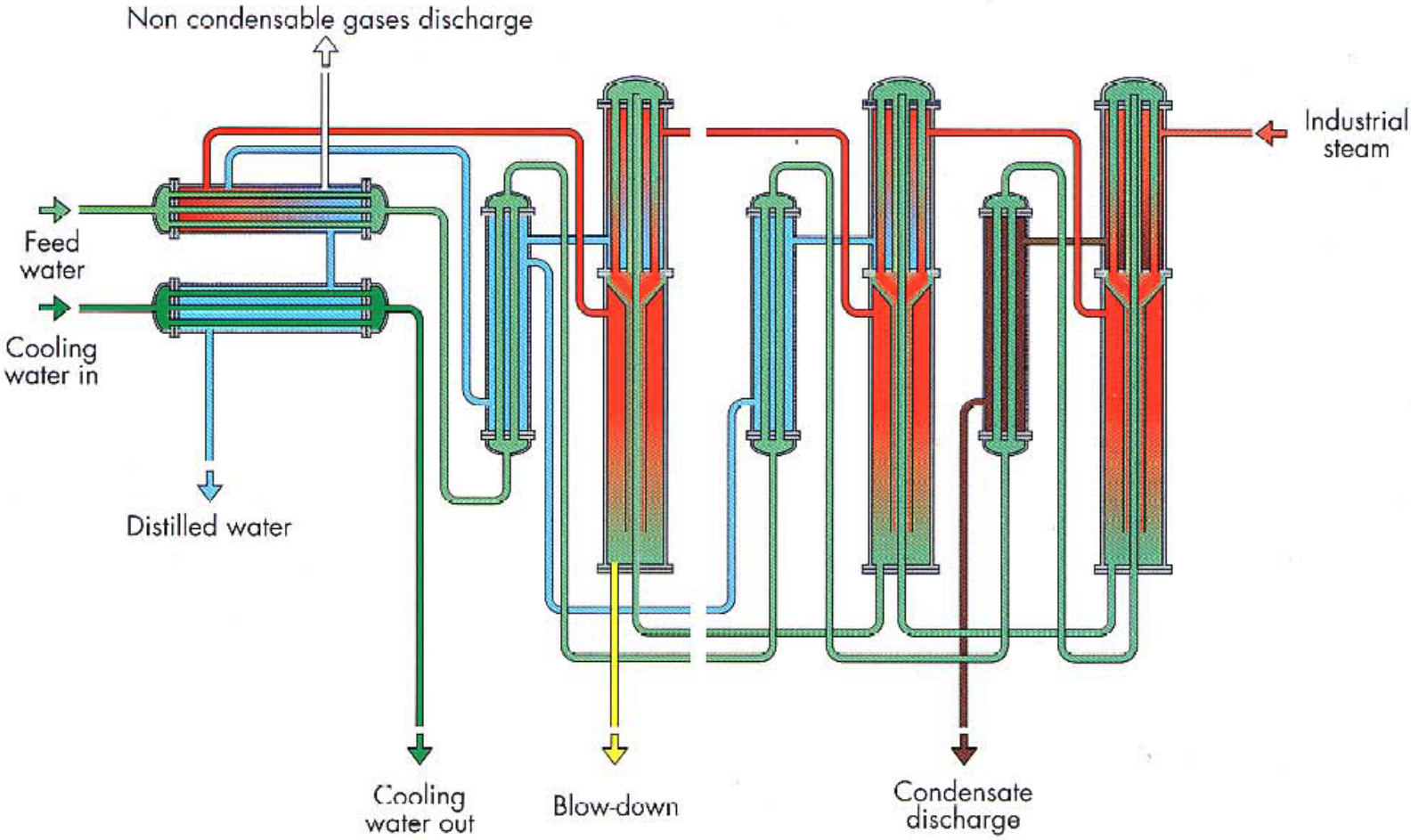
Start up and training

- The unit is fully tested at our facilities simulating working conditions
- User's manual to set up, connection to utilities and start up.
- Start up and training is necessary when the customer is not very familiar with the process and sterilization technology

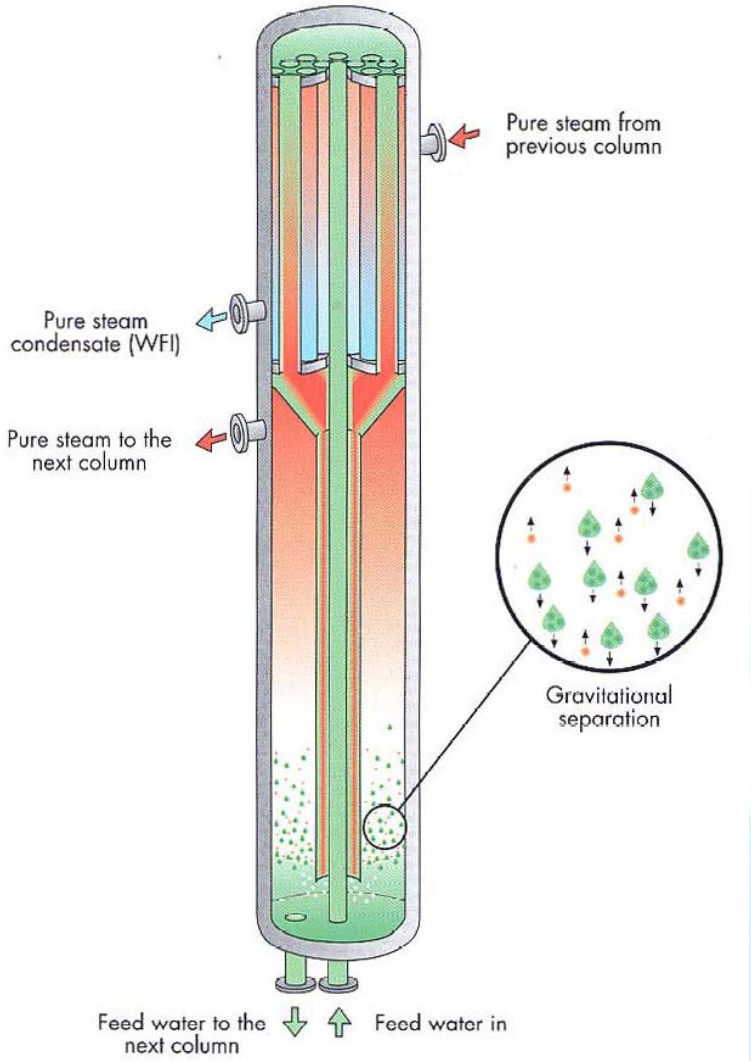
Validation Master Plan: DQ, FAT, IQ, OQ and PQ

- VMP protocols are submited to customer
- DQ is recommended to assure all user requirements have been covered before manufacturing
- FAT is carried our at our facilities to demonstrate full achievement of the main critical issues involved in the project
- IQ and OQ is performed at customer facilities, sepatated fron start up and training activities
- PQ protocols are issued to facilitate customer's validation

Competitive analysis - Stilmas



Competitive analysis - Stilmas



Thank you for your kind attention