

# Multi-Effect Still

## Multiple Effect Distillation Unit

Multiple Effect Still produces Water for Injection(WFI) that meets the latest requirements of the international pharmacopeias including USP, EP and JP. Standard models range from 50 ~10,000 l/hr production with smaller units available as electrically heated.

### Main Features

LD(S) range has been designed to maximise thermal efficiency and reduce wastage, the principle features are as follows:

- ◆ Guarantee of WFI quality due to low velocity separation, reduction in endotoxin.
- ◆ Rapid production due to thin-falling film technology.
- ◆ Low maintenance, long life due to simple mechanical construction no complex welded structures, or components within components.
- ◆ Lowest utility consumptions due to high thermodynamic balance and optimal design of each component, no corners are cut.
- ◆ High inspectability and validatability due to separation of all components.
- ◆ High reliability due to unstressed design.
- ◆ Low wastage as blowdown is only taken from the last column as opposed to a high percentage from each column.
- ◆ Degassing from the last column is the most efficient method.



WATER FOR INJECTION GENERATION PLANT



### Pharmaceutical Water System

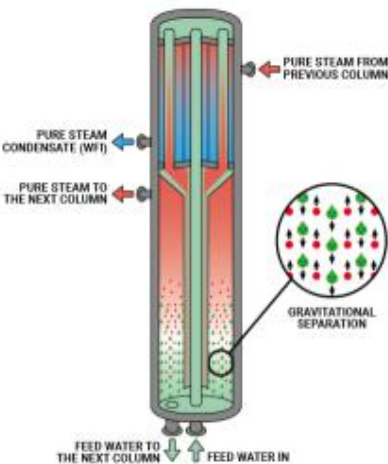
- ◆ Pre-treatment
- ◆ PW–Purified Water System
- ◆ WFI–Multi-Effect Still
- ◆ WFI–Electrically Heated Multi-Effect Still
- ◆ PS– Pure Steam Generator
- ◆ PS– Electrically Heated Pure Steam Generator
- ◆ PS & WFI Combination
- ◆ PS/WFI–Storage & Distribution System
- ◆ HPW–EDI Skid
- ◆ Cold WFI –Integrated Membrane System For WFI
- ◆ CIP& SIP
- ◆ Mixing Vessel
- ◆ Double Tube Sheet (DTS) Shell & Tube Heat Exchanger

### Purified & Highly Purified System

- ◆ Pre-Treatment System
- ◆ Reverse Osmosis Plant (RO)
- ◆ Nanofiltration Plant (NF)
- ◆ Ultra Filtration Plant (UF)
- ◆ Electro Dionization (EDI)
- ◆ Electrodialyzer (ED)
- ◆ Ion Exchanger (IX)
- ◆ Mixed Bed Plant (MB)

### Laboratory Ultrapure Water Machine & Sewage Treatment Machine

- ◆ Plus-E2 UP Water Machine
- ◆ Plus-E3 UP Water Machine
- ◆ Fast-X3 UP Water Machine
- ◆ Integrated Sewage Treatment Equipment



### Endotoxin Reduction:

The detailed design of the decontamination chamber allows to guarantee the highest standards of endotoxin reduction. The gravitational separation system is simple and extremely effective. Feedwater spiked to artificially high endotoxins levels has been used to demonstrate its capability of reducing endotoxins from 2500 Eu/ml to 0.25.

### Multiple Effect Design:

Each effect consists of a demountable tube heat exchanger on top, feeding pressurized, evaporated feedwater to a separation chamber below. Pure dry steam rises to the outlet at the top of this chamber; entrained impurities fall back to the bottom, feedwater for the next column and ultimately, reject blowdown. A flanged connection allows the column sections to expand without restraint.

### Build Standards

All product contact surfaces are AISI 316L stainless steel, pickled and passivated. For GMP applications contact surfaces are mirror polished to 0.6µRa and optionally electropolished.

Supporting frame is AISI 304 as standard (epoxy-coated carbon steel option)

Heat exchanger and condenser are shell and tube type, double tube sheet wherever distillate is involved.

### \*NOTE :

The pipes are totally hygienic execution, and a better resistance against dilatation stress. An addition benefit of this solution is the compact and the high efficiency heat exchanger.



# Biocell

### Qirui Water Treatment

Complete Turn-Key Project

# Multi-Effect Stills

## Services

Biocell, like our suppliers are solely dedicated to the regulated pharmaceutical sector. This enables us to fully understand not only the quality of performance required, but the documented evidence of all activities.

## Project Management

A dedicated Project Manager follows each sale through to OQ handover. Liaison with customers, suppliers and field operations team to ensure effective project delivery.

## Project Sitework

From our highly trained team offering:

- ◆ Installation Assistance
- ◆ Start-up & Commissioning
- ◆ SAT, IQ/OQ
- ◆ Calibration
- ◆ Thermal Mapping
- ◆ Cycle & Process Development

## After-Sales

Full life-time support for equipment including:

- ◆ Full Training Packages
- ◆ Technical & Process Support
- ◆ Spare Parts Supply
- ◆ Preventative Maintenance
- ◆ Calibration
- ◆ Routine Validation
- ◆ Upgrade and Revamping



## LD(S) Combi

All conventional multi-effect stills can be equipped to supply around a third of their rated output as pure steam from the first stage, simultaneous WFI production is not realistically practical. Without extensive pre-heating systems, instant boilers operate properly only close to their rated capacity so are only useful for steady state steam demands. Additionally, inner pipe wetting is only achieved while WFI is produced.

The innovative LD(S) Combi combines into one system a pure steam generator with its output flexibility and instantaneous response, with the columns of a multi-effect still. This achieves uninterrupted WFI supply and simultaneously, pure steam for a typical fluctuating demand load. By applying the optimum technology for each service need the LD(S) Combi pure steam generator/multiple effect still is the most flexible unit available.

## Electrically Heated MES



Industrial steam is the most cost-effective source of heating for multiple effect still. Where Industrial steam is not available, options exist to electrically heat the first stage.

## Storage & Distribution

The WFI storage and distribution SKID features professional modular design, which is characterized with reasonable and compact structure, pleasant appearance, convenient daily maintenance and operator-friendliness. According to the actual requirements of clients and the operation mode of different dosage forms,

the system can be designed for various operation modes, such as high temperature storage and high temperature circulation, high temperature storage and low temperature circulation, low temperature storage and low temperature circulation, with the purpose to conserve energy and reduce emissions. The system can be designed with multiple sterilization modes, such as pure steam sterilization or 121°C superheated water sterilization. The pump, heat exchanger, valve, pipe, instruments and other main components selected for the equipment are all well-known brands around the world, which can ensure the stable operation of the system in a long term. The program is optimized in accordance with GAMP5, which improves the stability of the program and complete documentation system to ensure the traceability of the system. To check whether the WFI system can stably produce WFI that meets the quality requirements in various circumstances in the future, the system will be subjected to the main verification and testing activities including Risk Assessment (RA)/Design Qualification (DQ)/Installation Qualification (IQ)/Operation Qualification (OQ). The system can fully meet the requirements of FDA cGMP, EU GMP, WHO GMP and SFDA GMP.

## Customised Solution

Stills are all built to the same uncompromising standards. Further than that, Biocell have decades of experience customising each unit to the specific project needs of customers such as:

- ◆ Elevation of final condenser to elevate WFI output
- ◆ Feeding and collection tank
- ◆ Fully automated production rate
- ◆ Customer specific instrumentation supplier
- ◆ WFI Pressurisation set



WFI TANK



WFI SKID

A full lifetime support.

# Biocell