



Pure water production plants





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 water production plants

Stilmas' pure water generation plants are the result of many years of experience and constant technical development. They represent the simplest, safest and most reliable water purification method for:

- *Production of ultra pure water for Pharmaceutical, cosmetic and food industries.*
- *Production of deionized water for industrial use when high bacteriological and chemical quality is required.*

Stilmas' standard plants can cover a range of production from 300 liters per hour to 30.000 liters per hour. Larger sizes are available on request.

Stilmas' Pure water production plants are full compliance with the Standard request of Pharmacopoeias.

Produced Water Quality

Due to an innovated design and component selection, according to the specific application needs, Stilmas pure water plants grants the production of Purified water and Highly purified water in compliance with the latest editions of the International Pharmacopoeias.

A unique care in Manufacturing procedures as well as in process design, the Stilmas pure water plants ensures the absolute control of microbiological growth, reducing the minimum need of system sanitization.

Construction characteristics

Stilmas pure water production plants are designed and manufactured according to GMP requirements.

Plants are fully in AISI 316 L stainless steel with active surfaces mechanically polished ($<0.6\mu$ as standard) and piping system realized by orbital welding.

All the components, instrumentation included are selected in base to sanitary criteria.

Different sanitization methods are available according to the plant configuration.



Pretreatment system-softener. Hot water sanitization type

Look closely...

Pure water production plant by double stage reverse osmosis

STILMAS MODEL PHARMA-RO

Granting the best quality in terms of bacterial purity.

The Stilmas' double stage Reverse osmosis plants constitutes the most reliable solution for purified water production and the only solution for HIGHLY purified water production.

Stilmas' double stage RO plants are fully designed in compliance with the standards requested by the International Pharmacopoeias.

Operating principle

Softened feed water is pre-filtered into a break tank. Circulation pump and high pressure pump after a final filtration feeds the first stage of membranes, the number of which will determine the processing capacity.

The osmosed water produced through a further pump system enters the second stage of membranes while the concentrate is rejected.

The pure water produced is sent to the storage and the second stage concentrate is recovered to the break tank for consumption optimization.

Tank, pumps and filter of the first stage are also used for chemical washing and sanitizing the membranes.

The plant configuration of Stilmas' exclusive design, ensures the best performance and operation flexibility by permitting periodical recirculation during stand-by condition for bacterial contamination control.



Purified water storage and distribution with ozone generation

a unique and original design

Second stage Break Tank

The double stage RO configuration with a second break tank between the first and second rack of membranes is the most updated Stilmas design and allows to use the second stage RO as microbial polisher of the PW/HPW distribution loop.

When no consumption of PW/HPW water occurs, periodically according to a program defined, part of the water circulating in the PW/HPW loop is reprocessed by the second stage RO membranes.

The result is high performance with two advantages:

- recirculation of RO package during stand-by phases;
- to have always the best microbial quality without need of frequent loop sanitization by heating, by ozone or other systems.

Reverse osmosis membrane

The characteristics functioning of the membrane is able to separate 99% of all dissolved salts of raw water in each stage. It retains bacteria, pyrogens and organic substances.

Stilmas possesses years of experience in the use and selection of membranes on the market and will select those best suited to each application.



PHARMA-RO - Pure Water Production Plant

Pure water production reverse osmosis and electrodeionization

STILMAS MODEL PHARMADION

Granting extremely low conductivity, Stilmas' Reverse Osmosis + Electro Deionization (RO+EDI) plants constitutes a reliable and more adopted alternative to the traditional double stage Reverse Osmosis for purified water production. Stilmas RO+EDI plants are fully designed in compliance with the standards requested by International Pharmacopoeias

Operating Principle

Softened feed water is pre-filtered into a break tank. Circulation pump and high pressure pump after a final filtration feeds the first stage of membranes, the number of which will determine the processing capacity.

The osmosed water produced enters the EDI Package while the concentrate is rejected.

The pure water produced is sent to the storage and the EDI concentrate is recovered to the break tank for

consumption optimization. Tank, pumps and filter of the Reverse osmosis unit are also used for chemical washing and sanitizing the RO membranes and EDI modules.

The plant configuration of Stilmas' exclusive design, ensures the best performance and operation flexibility by permitting periodical recirculation during stand-by condition for bacterial contamination control.



PHARMADION - Pure Water Production Plant

Electrodeionization

CDI (Continuous Deionization) technology is adopted. The operating principle consists in the generation of an electrical field into the water stream, which is separating positive and negative ions, being then captured by ion exchange resins enclosed into the system. Captured salt ions are then released to a small stream of water (concentrate), recycled to the break tank of the PW system.

CDI technology also grant continuous regeneration of the resins, without the need of periodic regeneration by an external concentrate flow. In this way the contact of the CDI modules with external and potentially contaminated stream of water is avoided.

Sanitization processes

Stilmas pure water production plants PHARMARO and PHARMADION can be sanitized chemically (standard version) or by heating (on request).

The chemical sanitization is performed by circulation of low concentrate H_2O_2 solution which represents a non dangerous chemical, even extremely easy to be removed at the end of the process (H_2O_2 is naturally converted into H_2O).

On request the plants can be provided with a steam heated exchanger and membranes and EDI modules suitable for hot water circulation.

Quality of feed water

The feed water characteristics and Pre-Treatment are fundamental to the use of the membranes and the EDI modules. Pre-Treatment is necessary for:

- removing particles which could damage the membranes
- reducing the possibility of scale precipitation
- elimination of free chlorine

Stilmas is able to furnish the pre-treatment suited to every requirement. For sizing of plant it is necessary to know the complete raw water analysis.

Feed water Pre-Treatment systems

Stilmas can supply:

- potabilization plant
- oxidation processes for elimination of heavy metals
- sand and multimedia filters
- activated carbon filters simple or steam sterilizable
- zeolyte filters
- organic scavengers
- softeners
- chemical dosing system
- microfiltration systems
- UV lamp

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.



Viale delle Industrie, 14 • 20090 Settala (Milan), ITALY

Phone +39 02 9508061 • Fax +39 02 95770022

stilmas@stilmas.com

www.stilmas.com