

# Stilmas Purified Water Systems

## 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 the production of both purified and highly purified (endotoxin controlled) water for the Pharmaceutical, cosmetic and food industries.

Stilmas' standard plants can cover a range of production from 300 to over 30,000 liters per hour. All plants are in strict compliance with the relevant Pharmacopoeias.

## Stilmas Purification Optimisation

Stilmas have always understood that large quantities of PW cannot be produced by a simple packaged unit. Variations in feedwater, customer's own standards and the specific use of the purified product *require* a dedicated design. Whether there is a preference is for dual stage RO or RO & EDI, chemical or hot water sanitisation, preferred instrumentation or a particularly high feedwater characteristic, the best systems will always be designed according to these known requirements. Stilmas have the largest configurable range to suit these requirements.



As well as the chosen process technology, a key characteristic of Stilmas plants is that they are properly dimensioned to minimise non-productive time. By designing the system for proper regeneration and full use of each resin bed the systems can maximise their true production time whilst minimising replacement costs.

## Comparison of Purification Techniques

Stilmas are equally able to provide all the variations of PW generation summarised in the table which enables us to advise our customers on the most appropriate technology for their application without prejudice.

	Ion Exchange	RO double	RO / EDI	Distillation by VC
<b>Lifecycle costs</b>				
Capital cost	▲	▲▲	▲▲	▲▲▲
Chemical handling	▲▲▲▲	▲	▲	▲
Energy consumption	▲	▲▲	▲▲	▲▲▲
Water consumption	▲	▲▲	▲▲	▲
Maintenance	▲▲+	▲	▲+	▲
<b>Purified Water Product</b>				
Conductivity $\mu\text{S}/\text{cm}$ @25°C	0.06 – 1.1	0.5 – 1.1	0.06 – 1.1	0.1 – 1.1
TOC (ppb)	>500	< 100	< 500	< 100
Bacterial performance	Low	< 5 CFU/ml	< 100 CFU/ml	< 0.1 CFU/ml
Endotoxin	N/A	< 0.25 EU/ml	N/A	< 0.25 EU/ml

In our judgement that the most reliable solution for PW production for the pharmaceutical industry is dual stage RO.

## Feedwater pre-treatment design

At the core of an optimally functioning system will be the pre-treatment design. Stilmas will, according to the feedwater analysis design the system, using proven components such as :

- Sand and multimedia filters
- Micro filtration systems
- Ultra-filtration systems
- Organic scavenging
- Chemical dosing systems
- Activated carbon filters
- Duplex Softeners
- De-aerators
- Break-tanks
- Chemical and thermal sanitisation
- UV destructors
- Recirculation loops

Inadequate components or sizing can result in reduced availability and reduced RO membrane / EDI module life. Stilmas manufacture and test the complete system in their Milanese factory.

# SteriTech

### Stilmas Equipment

Pre-treatment  
Purified Water  
Multi Effect Stills  
Vapour Compression Stills  
Pure Steam Generators  
PS & WFI Combinations  
Storage & Distribution Systems

### Fedegari Equipment

Saturated Steam Sterilisers  
Counterpressure Sterilisers  
UltraWashers  
Dry Heat Sterilisation  
Pathogen Sterilisers  
Combined Units  
Laboratory Sterilisers

### Fedegari non-thermal equipment

Low Temperature Surface Decontamination Stations  
Laminar Flow Carts  
Isolators and Cleanroom Contamination Controls

### Olsa Equipment

Solids: Filtering, mixing and drying  
Semi-Solids: Mixing and turnkey plants  
Liquids: Preparation vessels, fermenters and bio reactors

### Bano Equipment

Stainless Steel Cleanroom Furniture  
Specialist Cleanroom Equipment

### SteriTech Limited

Complete Turn-Key Projects

# Stilmas Purified Water Systems

## SteriTech Services

SteriTech, 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 local highly trained team offering

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

## After-Sales

Full life-time local support for equipment including

- Full Training Packages
- Technical & Process support
- Spare parts supply
- Preventative Maintenance
- Calibration
- Routine Validation
- Upgrades and revampings



The documentation package supplied by Stilmas for its plants is designed to allow complete validation of the system according to GDP and GMP rules. Full validation and calibration protocols are also available.

## Full Turn-Key Supply

A major reason for Stilmas success worldwide is their ability to provide a full turn-key package, including a comprehensive process guarantee covering the complete generation, storage and distribution where provided by them.

Items that can be included in the supply are:

- Pre-treatment
- Purified water generation
- Purified water storage and distribution
- Full controls / SCADA system for complete supply
- WFI generation
- WFI storage and distribution
- Pure Steam Generation

The supply includes feasibility/concept studies, project management, all engineering design, FAT, installation, start-up, SAT, Calibration, IQOQ and customer training.

The integrated approach not only saves money, but important time to operations and offers complete peace-of-mind to clients' engineers, validation and purchasing departments.

SteriTech and Stilmas have been partners for over 20 years building a good relationship allowing SteriTech to offer customers support, such as:

- Feasibility studies
- Advice and guidance on machine specifications
- Full project management
- DQ/HAZOP expertise
- Commissioning and validation
- Sitework/Preventative maintenance from fully qualified, experienced and trained local engineers

A *full* lifetime support.

## Design & Build Standards

Stilmas purification plants are entirely made from AISI316L with mechanically polished surfaces.

Pre-treatment skids are either FDA compliant plastic or AISI316L for hot sanitisable versions.

All the components, instrumentation included are from industry reference suppliers, fully sanitary where appropriate.

Fully automatic control with Siemens S7-300/TP177B as the default hardware. Software is by Stilmas according to GAMP guidelines and 21CFRpart11 where required.



## SteriTech Customer Support

# SteriTech