



**GENESYS™**

*Purified Water Systems*





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## *A choice of quality*

Telstar-Puretech introduce the Genesys, opening a new chapter in pure water delivery. Telstar-Puretech Genesys Purified water systems are designed and constructed to produce Purified and Highly purified water in full compliance with cGMP guidelines as per FDA and EMEA, EP, JP and USP 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, 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 of performance and quality.



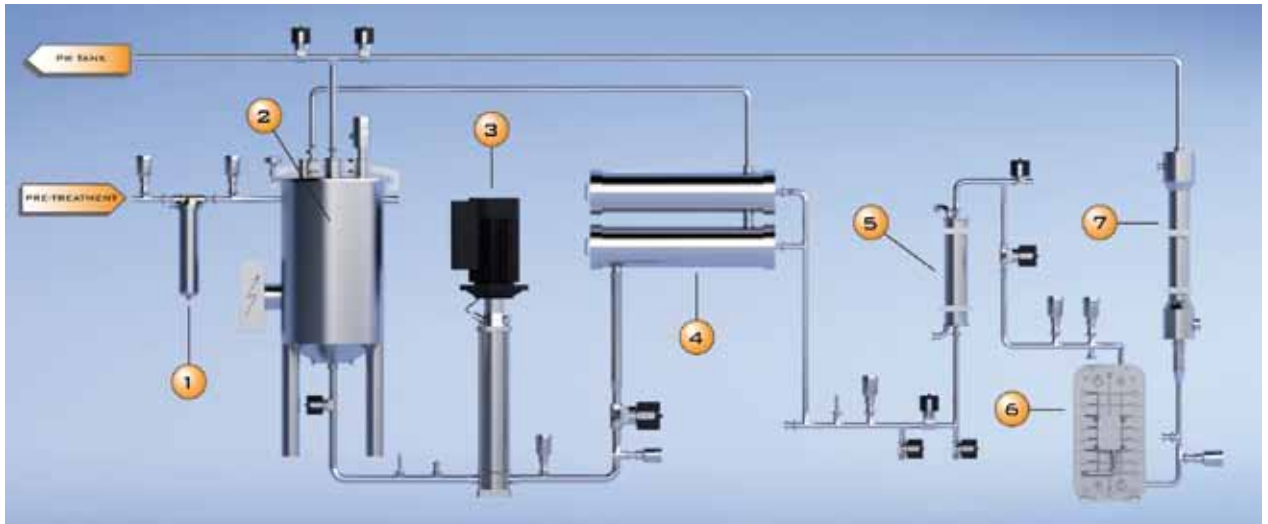
## *Purified & Highly purified water applications*

Purified water is used as an excipient in the preparation of non-sterile products and as a starting material in the preparation of water for injection and pure steam. It's also used for rinsing purposes and in the preparation of cleaning solutions.

Highly Purified water is used in the preparation of medicinal products where bacterial endotoxins need to be controlled, except where water for injection is required.



# Operating principle



The pretreated (softened) water is passed through a filter housing (typically 5 µm) and analysed for free Chlorine prior to entering the RO feed tank. The filtered water then enters the stainless storage tank, if the tank is full the softened water is returned to the raw water tank to ensure constant movement to minimize the risk of bacterial proliferation.

The softened water is then pumped at high pressure using a stainless steel multistage centrifugal pump, through the RO membranes. The RO permeate is then fed through a membrane degasser to remove dissolved Carbon Dioxide, followed by a CEDI unit in order to remove ionic contaminants.

The purified water is then passed through a UV irradiator unit before being fed to the storage vessel.

- 1 **PRE-FILTER**
- 2 **STORAGE TANK**
- 3 **SANITARY HIGH PRESSURE PUMP**
- 4 **RO MEMBRANES**
- 5 **MEMBRANE DEGASSER**
- 6 **CEDI MODULE**
- 7 **UV/UF UNIT**

# Control system

The Genesys utilises the latest technology with touch screen HMI to allow ease of operation and monitoring.

The Genesys allows control and monitoring from a single interface with data logging facilities and links to user systems eg, BMS, DCS or SCADA.

The Genesys control system has the flexibility to operate complete turnkey packages allowing customers to reduce costs and simplify operation using a single access interface for pre-treatment, purification, storage and distribution.

The Genesys control system ensures safe operation, protecting the system and the operator, giving you confidence and peace of mind.



*Design & construction features*



*Softened water tank*

*Reverse osmosis*

*Ultrafiltration*





## *Trusted technology, safely implemented*

The Genesys Purified Water System is designed to generate Purified water in accordance with the International Pharmacopoeial specifications for Purified or Highly Purified water. The system has been designed to allow automatic hot water sanitisation of the complete unit including the pipework feeding the Purified water into the storage vessel.

The Genesys units utilizes the following major components within a fully protected skid so that the system can be kept clean and prevent any injuries to operators during sanitisation.

### *Key components*

#### **Softened water tank**

This 316L stainless vessel is used as a reservoir for sanitisation and can be used for the automatic CIP cycles.

#### **Reverse osmosis**

RO technology involves using a variable speed pressure pump to force a portion of the feed water through semi-permeable membranes. The permeate flow is kept constant, independent of variables such as the feed water temperature.

#### **Continuous electro deionisation**

The water passing through the CEDI is deionised to Purified Water using an electric current. The concentrate water exiting the CEDI unit is reused and mixed with the RO feed water.

#### **Ultraviolet irradiation/ultrafiltration**

The pure water exiting the CEDI passes to a UV unit or a 6,000 NMWL Ultrafilter to give added security in achieving the Purified and Highly Purified water specifications.

*Continuous electro deionisation*



## *Unique selling points*

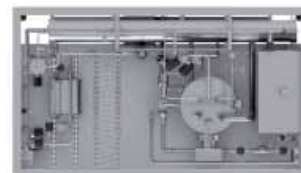
- Purified and Highly Purified water to USP, EP and JP
- Automatic hot water sanitisation
- Fully lockable protective panels and doors for secure and safe operation
- Flexible outputs from 100 to 10,000 l/hr
- Designed for simple upgrading of production rate
- Provides constant monitoring of RO status and gives warning of requirement for cleaning
- Constructed from 316L stainless steel, orbitally welded, internal surface finish 0.5 Ra. Designed to ASME BPE
- Choice of sophisticated control systems with inbuilt data logging and paperless chart recorder
- GAMP and 21 CFR part 11 compliant
- Validation to regulatory and client standards
- Minimises waste water
- Flexible system integration with proven technologies.

## Technical data

Model flowrate <sup>(1)</sup>	Outlet conversion (l/h)	System	Width (mm)	Depth (mm)	Height (mm)
Genesys 1A	300	75%	2,400 <sup>(2)</sup>	1,600	2,200
Genesys 2A	500	75%	2,400 <sup>(2)</sup>	1,600	2,200
Genesys 3A	800	75%	2,400 <sup>(2)</sup>	1,600	2,200
Genesys 4A	1,100	75%	2,400 <sup>(2)</sup>	1,600	2,200
Genesys 5B	1,600	75%	2,900	1,600	2,200
Genesys 6B	3,000	75%	2,900	1,600	2,200
Genesys 7B	5,000	75%	2,900	1,600	2,200
Genesys 8B	6,500	75%	2,900	1,600	2,200

<sup>(1)</sup> Actual flowrate dependent on feedwater temperature and site feed water quality. Each system is designed on client exact requirements

<sup>(2)</sup> Units can be delivered in larger frame to allow future flowrate increase



## Material specifications

- **Softened water tank** 316L Stainless Steel vessel
- **Reverse osmosis** 316L Stainless Steel
- **CEDI LX** FDA approved materials
- **Pipework** 316L Stainless Steel, orbital welded, Internal surface finish <0.5 µm Ra
- **Frame** 304 Stainless Steel
- **Control cabinet** 304 Stainless Steel.

**Services:** Electrical 380/415V; 3 Phase; 50Hz.

## Feed water requirements

- **General** potable water free from organics, colloids and suspended matter: SDI<3
- **Total hardness** < 5 ppm as CaCO<sub>3</sub>
- **Free chlorine** < 0.05 ppm
- **Iron** < 0.1 ppm as Fe
- **Temperature** 5 – 30°C
- **Pressure** 2 - 6 bar.

**Compressed Air** Oil free, instrument grade >6 bar.

Typical product water quality			
Attribute	Genesys	US Pharmacopoeia PW	European Pharmacopoeia
Conductivity (µS/cm)	<0.1	<1.3 @ 25 C (Stage 1)	PW=<4.3, HPW=<1.1 @ 20 C
TOC (ppb)	<100	<500	<500
Bacteria (TVC CFU/ml)	<10	<100(3)	<100
Endotoxins (EU/ml)	<0.05 (UF option)	N/A	HPW=<0.25 EU/ml

HPW = Highly Purified water; PW = Purified water; (3) FDA recommended action limit



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