



Puretech™
delivering purity

WFI

 **MADE IN
BRITAIN**®

The ultimate in water for injection generation

Puretech Genesys^{WFI} opens a new chapter in water for injection (WFI) delivery. Genesys^{WFI} thermal sanitisation purification units are designed and constructed to produce WFI in full compliance with cGMP guidelines as per FDA and EMEA, EP, JP and USP requirements for pharmaceutical, laboratory and medical applications. From softened water to point of use, Puretech Genesys^{WFI} offers a true single source, multi-technology validated unit, for producing WFI.



Water for injections

In April 2017 the European Pharmacopoeia's revised monograph for water for injections (0169) became effective. The new monograph has now moved closer to the US Pharmacopoeia (USP) and Japanese Pharmacopoeia and allow the use of other methods of production of WFI, no longer specifying distillation as the means of production. The change in the specification to allow other methodologies such as reverse osmosis (RO) and other supporting technologies such as ultrafiltration (UF) and continuous electrodeionisation (CEDI) had been discussed for many years but there was insufficient evidence on the reliability of these technologies to consistently produce WFI. With the introduction of the specification for pure water by the EP in 2005, effectively the same quality as WFI but produced by other methods this missing evidence has become available and so we move into a new era for water for

injections where the three major pharmacopoeias are essentially harmonised.

The new monograph also states that whatever method of production is used validated procedures and in process monitoring of conductivity, along with regular monitoring of total organic carbon and microbial contamination should be applied. So now users can select a method of production to suit the requirements of their production process. If you need to have the WFI hot, then production using a Puretech multi effect still (WFIS) may be your choice, if you can use the WFI cold, then a Genesys WFI system coupled with a WFI distribution system, using either regular hot water sanitisation or continuous ozone sanitisation system, will allow you the benefits of robust production of WFI along with reduced capital and operating costs.

Genesys^{WFI}

Puretech has produced the Genesys^{WFI} using the experience of operating the Genesys pure water (pw) systems over many years. Puretech PW systems were based on using reverse osmosis followed by continuous electrodeionisation and then a final filtration using a 6,000 NMWL ultrafilter. These systems have reliably been producing PW since 2004.

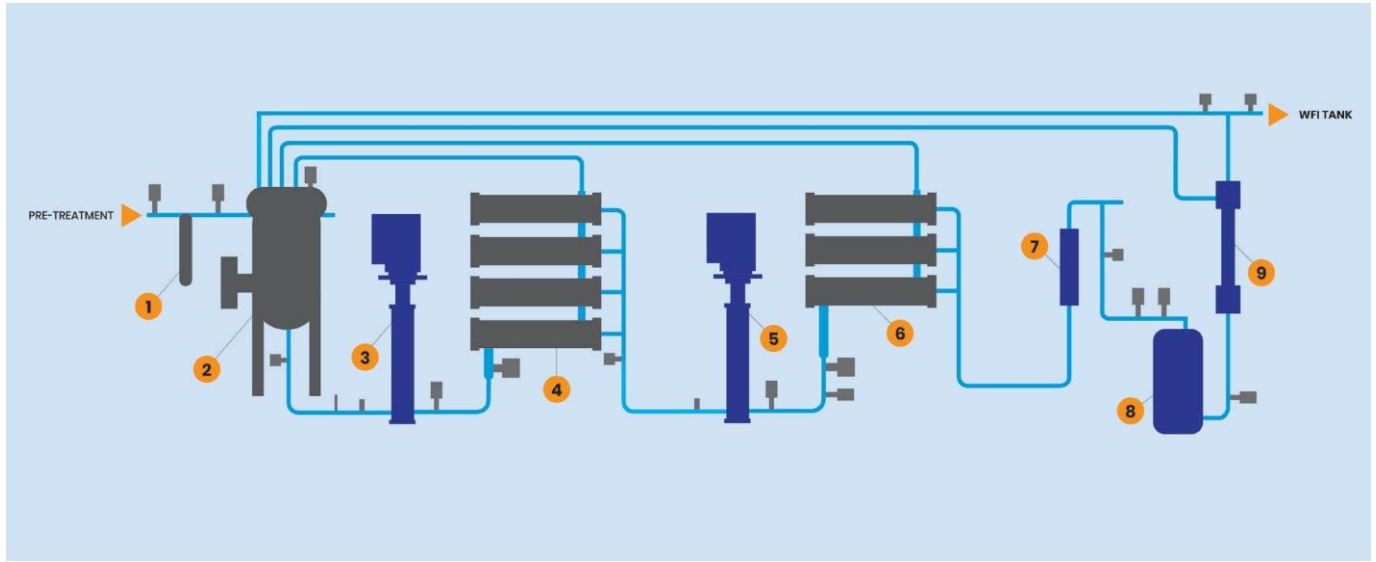
For Genesys^{WFI} Puretech worked on increasing the robustness of the system and final water quality further to give the user peace of mind. The Genesys^{WFI} has twin pass RO system with membrane degassing, continuous electrodeionisation, followed by ultrafiltration with 6,000 Daltons cut off membranes giving three membranes to ensure robust removal of bacteria and endotoxins (endotoxins are >10,000

Daltons). Four conductivity measurements are used to continuously give real time performance data for each RO stage and the CEDI. TOC and online bacterial monitoring can be added to give maximum real time monitoring of the main specification indices.

Control of bioburden is vital and so in addition to the fully automatic hot water sanitisation cycle, at up to 85 °C, the Genesys^{WFI} has a chemical sanitisation sequence to give further control. The Genesys^{WFI} is fed with pre-treated water from a tailored pre-treatment skid, designed to give optimum quality water from the site specific feed water.



Design & construction features



- | | | |
|----------------------|--------------------------|---------------------------|
| 1 Prefilter | 4 1st Stage RO membranes | 7 Membrane degasser |
| 2 Buffer tank | 5 High Pressure pump | 8 CEDI module |
| 3 High Pressure pump | 6 2nd Stage RO membranes | Ultrafiltration module(s) |
| | | 9 |

Trusted technology, safely implemented

Genesys^{WFI} is designed to generate water for Injections in accordance with the European, United States and Japanese Pharmacopieas. The system has been designed to meet the regulatory requirements and includes both hot water sanitisation and chemical sanitisation sequences to maintain low bioburden.

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 and 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, performance and quality.

The Genesys^{WFI} utilises the following major components to deliver product water exceeding the specification for WFI.

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

Two stages of reverse osmosis membranes in series are used to give optimal control of bioburden. 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 electrodeionisation

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

Ultrafiltration

The pure water exiting the CEDI passes through an ultrafilter which utilises 6,000 Dalton cut off hollow fibre membranes providing added security with a third membrane to guarantee robust production of WFI.

Key features

- Water for injections to USP, EP and JP
- Automatic hot water sanitisation
- Flexible outputs from 100 to 20,000 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
- Remote monitoring capability.

Softened water tank



Reverse osmosis



Continuous electro deionisation

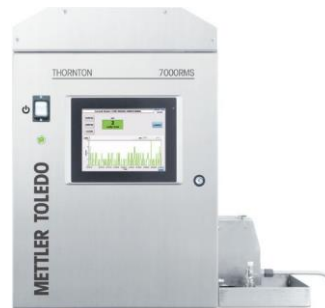


Ultrafiltration



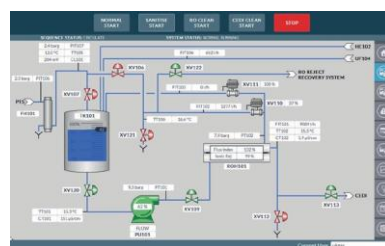
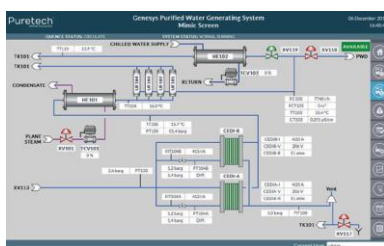
Online compliance monitoring

The Genesys^{WFI} includes continuous monitoring of conductivity at 4 points in the system and the unit can be supplied with online TOC and real time bacterial counting monitors to give maximum real time monitoring of the main specification indices.



Control system

The Genesys^{WFI} utilises the latest technology with touch screen HMI to allow ease of operation and monitoring. The Genesys^{WFI} allows control and monitoring from a single interface with data logging facilities and links to user systems e.g. BMS, DCS or SCADA. The Genesys^{WFI} 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^{WFI} control system ensures safe operation, protecting the system and the operator, giving you total confidence and peace of mind.



The Genesys^{WFI} is manufactured to suit client's individual site requirements. Puretech works with clients to ensure every system matches their needs.

Technical data

Model	Outlet Flowrate ⁽¹⁾	Width (mm)	Depth (mm)	Height (mm)
Genesys ^{WFI} 1A	300 l/hr	2,400	2,070	2,200
Genesys ^{WFI} 2A	500 l/hr	2,400	2,070	2,200
Genesys ^{WFI} 3A	750 l/hr	2,400	2,070	2,200
Genesys ^{WFI} 4A	1,000 l/hr	2,400	2,070	2,200
Genesys ^{WFI} 5B	1,500 l/hr	2,900	2,070	2,200
Genesys ^{WFI} 6B	2,500 l/hr	2,900	2,070	2,200
Genesys ^{WFI} 7B	4,000 l/hr	2,900	2,070	2,200
Genesys ^{WFI} 8B	6,000 l/hr	2,900	2,070	2,200
Genesys ^{WFI} 9C	7,500 l/hr	4,500	2,070	2,200
Genesys ^{WFI} 12C	10,000 l/hr	4,500	2,070	2,200

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

Other capacities are available upon request.

Material specifications

- Softened water tank 316L stainless steel vessel
- Reverse osmosis housings 316L stainless steel
- CEDI LX FDA approved materials
- Ultrafilters polysulfone/polyethersulfone
- Pipework 316L stainless steel, orbitally welded, internal surface finish <0.5 µm Ra
- Frame 304 stainless steel
- Control cabinet 304 stainless steel

Feed water requirements

- General Potable water free from organics, colloids and suspended matter: SDI<3
- Total hardness <5 ppm as CaCO₃
- Free chlorine <0.05 ppm
- Iron <0.1 ppm as Fe
- Temperature 5-35 °C
- Pressure 2-6 bar

Services: Electrical 380/415V; three-phase; 50Hz

Compressed air Oil free, instrument grade >6 bar

Attribute	Typical product water quality		
	Genesys ^{WFI}	US Pharmacopoeia	European Pharmacopoeia
Conductivity (µS/cm)	<0.1	<1.3 @ 25 C (Stage 1)	<1.1 @ 20 C
TOC (ppb)	<20	<500	<500
Nitrate	<0.01 ppm	N/A	<0.2 ppm
Bacteria (TVC CFU/100ml)	<1	<10	<10
Endotoxins (EU/ml)	<0.05 (UF option)	<0.25 EU/ml	<0.25 EU/ml

Puretech[™]
delivering purity

MicroGas
delivering purity

Medical Gases
delivering purity

Head Office

Aztec House
Perrywood Business Park
Salfords, Redhill
Surrey, England
RH1 5DZ

+44 (0) 1737 378 000
sales@puretech.uk.com
www.puretech.uk.com

Local Representative

Environment Products International Ltd
Unit 2/15 Olive Rd
Penrose 1061
Auckland
New Zealand

+64 9 579 6172
epil@epil.co.nz
www.epil.co.nz



ENVIRONMENT PRODUCTS INTERNATIONAL LTD