



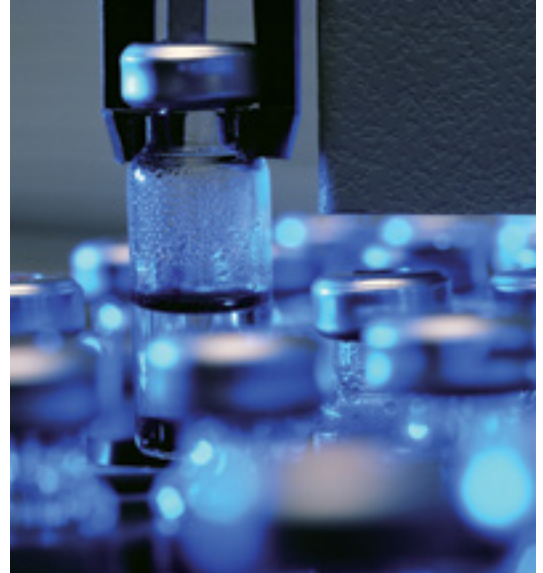
Puretech™  
delivering purity

# ASEPSYS

Purified Water Systems

## Purified water generation

Puretech Asepsys offers world-leading thermally sanitised pure water delivery. From softened water to point of use, the Asepsys offers a true single source, multi-technology validated unit, for producing purified water. Asepsys systems are designed and constructed to produce purified water in full compliance with cGMP guidelines as per FDA and EMEA, EP, JP and USP requirements for pharmaceutical, laboratory and medical applications.



## 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 is also used for rinsing purposes and in the preparation of cleaning solutions.

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



## A choice of quality

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.

## Key features

- Purified water to USP, EP and JP standards
- Automatic hot water sanitisation
- Flexible outputs from 200 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 for product water. Designed to ASME BPE
- Choice of control systems
- GAMP and 21 CFR part 11 compliant
- Validation to regulatory and client standards
- Minimises waste water
- Flexible system integration with proven technologies.

## Design & construction features



### Trusted technology, safely implemented

The Asepsys Purified Water System is designed to generate purified water in accordance with the International pharmacopoeial specifications for 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.



## 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 water specifications.

Softened water tank



Reverse osmosis



Continuous electro deionisation



Ultrafiltration (Option)



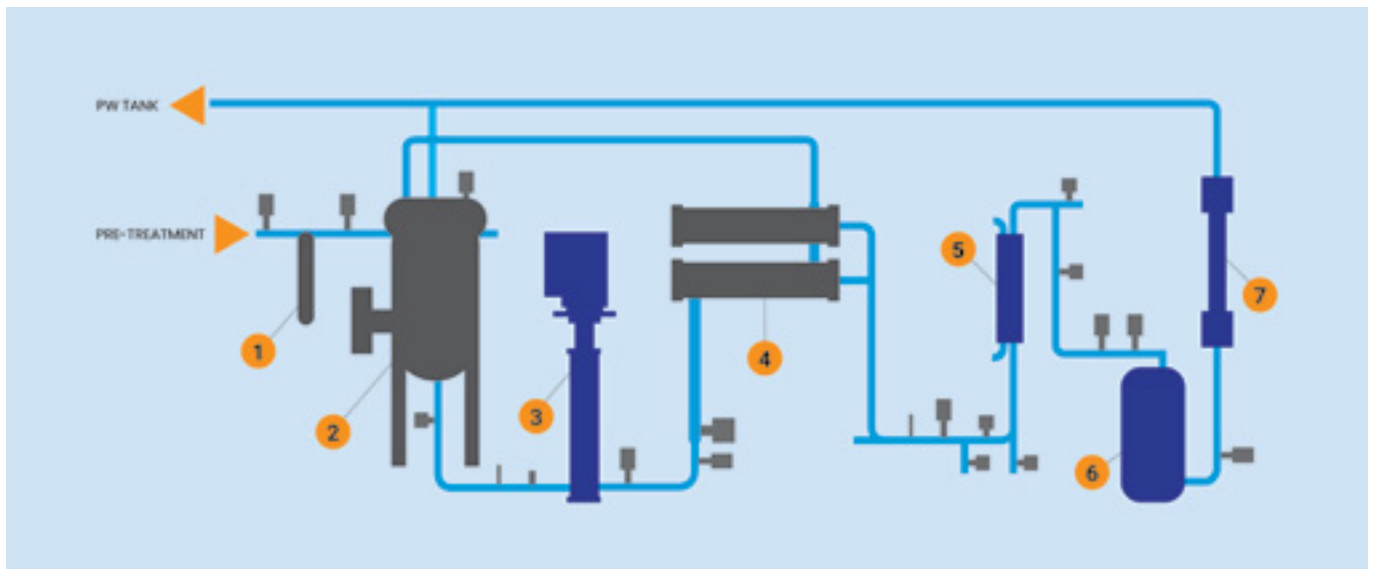
## The Asepsys control system

- Utilises the latest technology with touch screen HMI to allow ease of operation and monitoring.
- Offers control and monitoring from a single interface with data logging facilities and links to user systems e.g., BMS, DCS or SCADA.
- Provides 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.
- Ensures safe operation, protecting the system and the operator, giving you confidence and peace of mind.

## Operating principle

The pre-treated (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 minimise the risk of bacterial proliferation.

The softened water is then pumped at high pressure using a stainless steel multi-stage 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 Prefilter          | 4 RO membranes      | 6 CEDI module         |
| 2 Storage tank       | 5 Membrane degasser | 7 UV/UF unit (option) |
| 3 High pressure pump |                     |                       |

## Technical data

Model <sup>(1)</sup>	Outlet Flowrate	Production Rate	Width (mm)	Depth (mm)	Height (mm)
Asepsys 1A	300 l/hr	75% – 90%*	2,400 <sup>(2)</sup>	1,650	1,800
Asepsys 2A	500 l/hr	75% – 90%*	2,400 <sup>(2)</sup>	1,650	1,800
Asepsys 3A	800 l/hr	75% – 90%*	2,550 <sup>(2)</sup>	1,650	1,800
Asepsys 4A	1,100 l/hr	75% – 90%*	2,550 <sup>(2)</sup>	1,650	1,800
Asepsys 5B	1,600 l/hr	75% – 90%*	2,900	1,650	2,200
Asepsys 6B	3,000 l/hr	75% – 90%*	2,900	1,650	2,200
Asepsys 7B	5,000 l/hr	75% – 90%*	2,900	1,650	2,200
Asepsys 8B	6,000 l/hr	75% – 90%*	2,900	1,650	2,200
Asepsys 9C	7,500 l/hr	75% – 90%*	4,500	1,650	2,200
Asepsys 12C	10,000 l/hr	75% – 90%*	4,500	1,650	2,200

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

(2) Units can be delivered in larger frame to allow future flowrate increase

\* Dependent on incoming water quality and recovery RO option being specified

Other capacities are available upon request.

## Material specifications

- **Softened water tank** 316L stainless steel vessel
- **Reverse osmosis** 316L stainless steel
- **CEDI LX** FDA approved materials
- **Pipework** 316L stainless steel, orbitally welded, internal surface finish <0.5 µm Ra
- **Frame** 304 stainless steel
- **Control cabinet** painted mild steel

**Services:** Electrical 380/415V; three-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	Asepsys	US Pharmacopoeia	European Pharmacopoeia
Conductivity (µS/cm)	< 0.1	< 1.3 @ 25 C (Stage 1)	PW=<4.3
TOC (ppb)	< 100	<500	<500
Bacteria (TVC CFU/100ml)	<10	<100 <sup>(3)</sup>	<100
Endotoxins (EU/ml)	< 0.05 (UF option)	N/A	PW=< 0.25 EU/ml

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

**Puretech Asepsys is manufactured to suit client's individual site requirements. Puretech works with clients to ensure every system matches their needs.**

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