

# AMBIENT PWWFI GENERATION

## PHARMACEUTICAL WATER SOLUTIONS

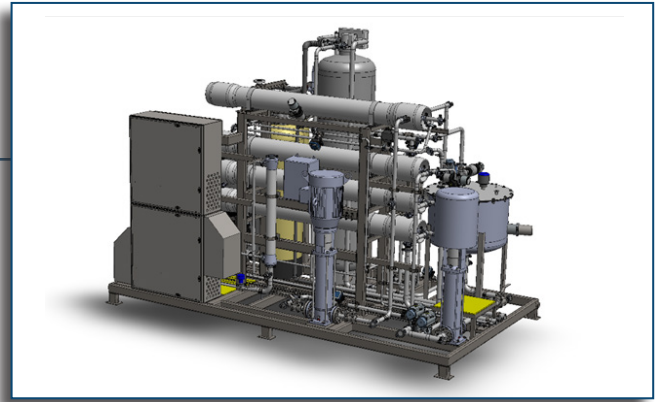
### SUPERIOR STANDARD FEATURES

Our smart design focus integrates many upgrades that combine sustainable operation and ergonomic sampling and maintenance in order to enhance the ownership experience of your Aqua-Chem system.

- Modular “plug-and-play” design
- 304/316L SST frame and piping with  $\leq 25.0 \mu\text{m}$  Ra wetted components
- Stainless steel enclosures with large 15” HMI
- Energy and water saving optimizations
- Operator-focused sampling and maintenance
- Fully automated operation with 21 CFR Part 11 and GAMP 5 compliant control system
- Active feedwater disinfection
- Insulated process break tank with spray ball
- All-electric Hot Water Sanitization (HWS)
- Continuous product demineralization
- Complete Factory Acceptance Test (wet FAT)
- Remote diagnostics & 24/7 post-sales support
- Made in and serviced from the USA

### FLEXIBLE OPTIONS & UPGRADES

- Hot or ambient storage and distribution
- 1 or 2 Pass reverse osmosis in FRP or SST
- Loop disinfection and 6.0 kDa ultrafiltration
- Chart recorder and optional Chlorine, Hardness, TOC, and Bioburden monitoring
- Highly regarded SAT or IQ/OQ/PQ protocols
- Engineer-led Commissioning and Validation
- Extended warranty, service, and spare parts



### WATER FOR INJECTION & PURIFIED WATER SYSTEMS

The Aqua-Chem pharmaceutical water system has been developed to generate validated, compendial water for USP, PhEur, and JP compliant pharmaceutical applications. Standard models supply loops between 2.0-50.0 gpm and are fully factory tested for fast install and start-up. Systems are engineered with industry leading components including Mettler-Toledo® instruments, Bürkert® fluid controls, and IonPure® CDI-LX™ modules for maximum performance and reliability.

**When compared to competitor systems or technologies like distillation, our key innovations:**

- **Reduce Risk**
- **Reduce Total Cost of Ownership**
- **Improve Uptime**
- **Improve the Owner Experience**



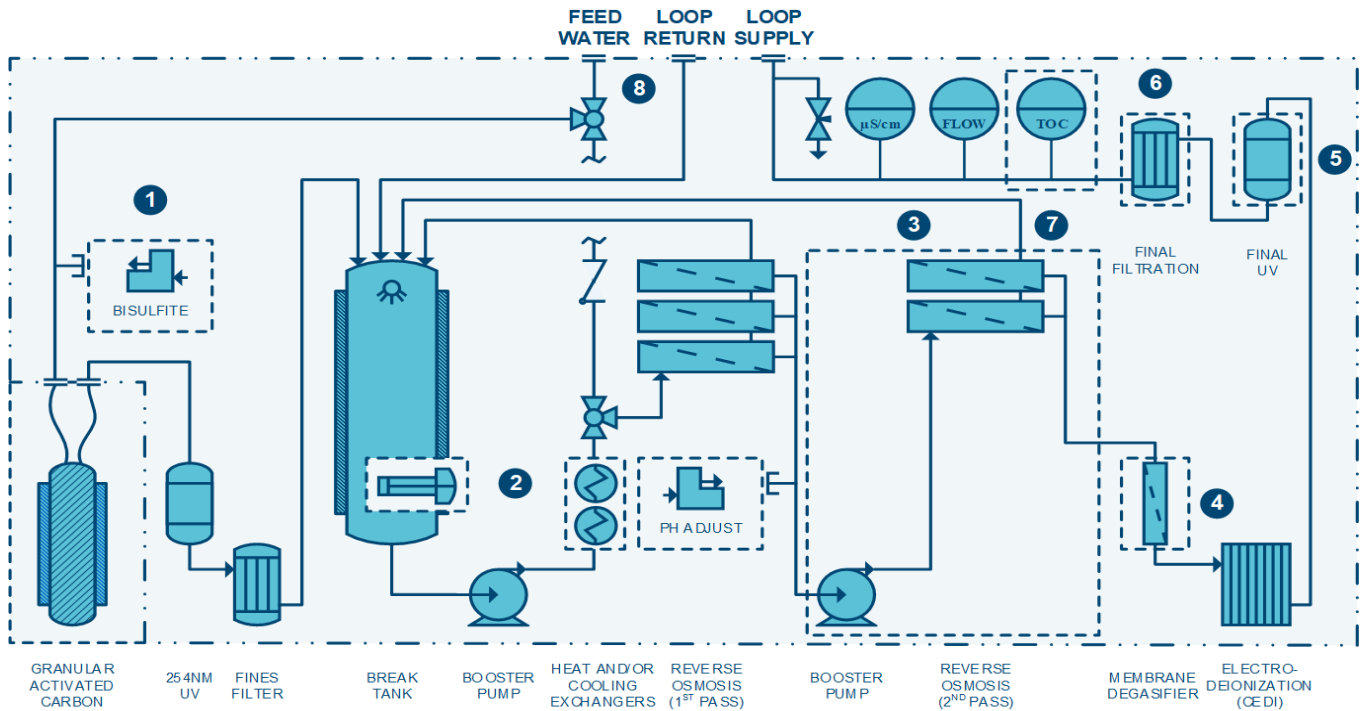
## GENERAL SPECIFICATIONS

Standard Models <sup>1</sup>	03	05	10	25	45
<b>Loop Supply Rate<sup>2</sup></b>	2.0-4.0 gpm	4.0-6.0 gpm	8.0-12.0 gpm	20.0-30.0 gpm	40.0-50.0 gpm
	0.5-1.1 m <sup>3</sup> /h	1.1-1.6 m <sup>3</sup> /h	2.2-3.3 m <sup>3</sup> /h	5.5-8.2 m <sup>3</sup> /h	10.9-13.6 m <sup>3</sup> /h
<b>Makeup Rate<sup>2</sup></b>	0.5-1.5 gpm	1.0-2.5 gpm	2.0-5.0 gpm	5.0-15.0 gpm	1.0-25.0 gpm
	0.1-0.4 m <sup>3</sup> /h	0.3-0.7 m <sup>3</sup> /h	0.5-1.4 m <sup>3</sup> /h	1.4-4.1 m <sup>3</sup> /h	2.7-6.8 m <sup>3</sup> /h
<b>Designed to Exceed</b>	FDA cGMP Guidelines and USP, PhEur (EP), and JP Requirements for PW and WFI				
<b>Purified Water (PW) Base Configuration</b>	Activated Carbon, Disinfection UV, Fines Filter, Break Tank + Electric HWS, Single-Pass Reverse Osmosis, Continuous Electrodeionization				
<b>Water for Injection (WFI) Base Configuration</b>	Activated Carbon, Disinfection UV, Fines Filter, Break Tank + Electric HWS, Two-Pass Reverse Osmosis, Continuous Electrodeionization, 6.0 kDa MWCO Ultrafiltration				
<b>Nominal Recovery</b>	75.0-85.0%				
<b>Conservation Mode</b>	Up to 100.0%				
<b>Feedwater Source</b>	Filtered and Softened EPA Potable Water				
<b>Feedwater Temperature</b>	40.0 °F - 77.0 °F (4.5 °C - 25.0 °C)				
<b>Frame Construction</b>	304 Stainless Steel				
<b>Piping Materials</b>	304 & 316L Stainless Steel				
<b>Enclosures</b>	Stainless Steel NEMA 4X w/ large 15" HMI (Allen Bradley Standard)				

<sup>1</sup>Alternate configurations, including higher flows, are available via our dedicated project engineering and management team.

<sup>2</sup>Feedwater conditions may affect system performance. Given ranges assume specified water source and operation at 77.0 °F (25.0 °C)

## PROCESS FLOW DIAGRAM



### PROCESS OPTIONS AND UPGRADES

- |   |  |  |
|---|--|--|
| <b>1</b> CARBON OR CHEMICAL DECHLORINATION      | <b>3</b> 1 OR 2 PASS REVERSE OSMOSIS + FRP OR SST      | <b>6</b> LOOP ULTRAFILTRATION                              |
| <b>2</b> ELECTRIC OR STEAM HEATING & COOLING HX | <b>4</b> MEMBRANE OR CHEMICAL CO <sub>2</sub> REM OVAL | <b>7</b> TOC + CL <sub>2</sub> ANALYTICAL & CHART RECORDER |
|   | <b>5</b> LOOP DISINFECTION                             | <b>8</b> UTILITY PRETREATMENT & DRAIN QUENCHING            |