

SOLUTIONS FOR PURIFIED WATER, HIGHLY PURIFIED WATER AND WATER FOR INJECTION

Manufactured and preassembled by Ovivo

Constructed in pre-mounted, fully divided plant sections (Softening, RO-EDI-UF and distribution)

User and service friendly, compact construction

Tested and prequalified for connection

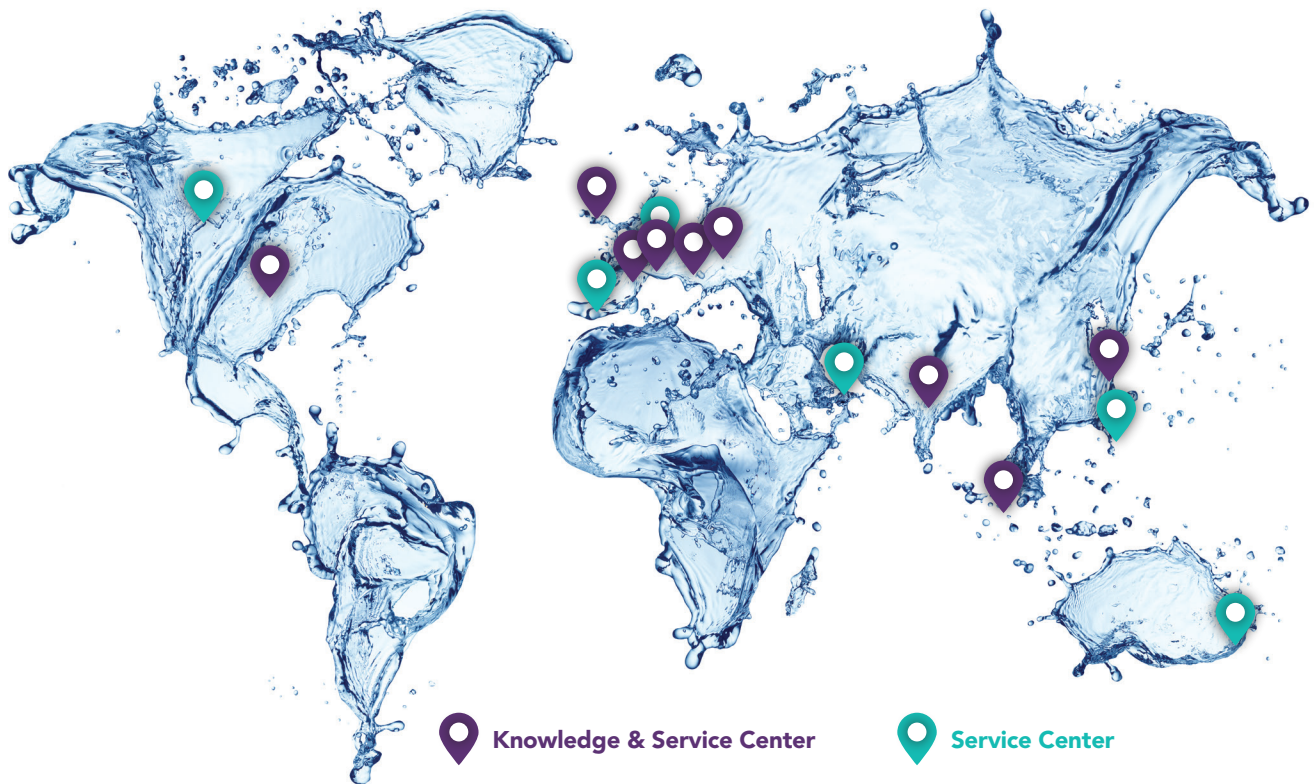
Equipped with high quality components that are available worldwide

Innovative Automation Concept



OVIVO PHARMACEUTICAL SOLUTIONS

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1. CORPORATE GROUP INFORMATION

Ovivo is a worldwide provider of equipment, systems and technology that produces some of the purest water on the planet, and treats some of the most challenging wastewater conditions in the industry.

Ovivo is a powerful global brand possessing more than 150 years of expertise in water treatment, with renowned trademarks supported by its proprietary products, advanced technologies, and extensive system integration knowhow.

Ovivo delivers conventional to highly technological water treatment solutions for the industrial and municipal markets, and leverages its large, installed base of equipment around the world to offer parts and services to its customers. Ovivo is dedicated to innovation in an industry that is in constant evolution, and offers water treatment solutions that are cost-effective, energy-efficient and environmentally sustainable.

Ovivo is owned by SKion Water International GmbH and Caisse de dépôt et placement du Québec. It operates an integrated global platform in over 15 countries, with 800 employees that are worldwide experts in water treatment.





2. INTRODUCTION

Ovivo is your contact partner for the design, development, production and maintenance of:

- Installations for the production of Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI) conform European Pharmacopoeia (EP) and United States Pharmacopoeia (USP)
- Storage and distribution systems for Purified Water (PW), Highly Purified Water (HPW) and Water for Injection (WFI)

Ovivo listens to your needs and advises you on the best water treatment solutions for your application. We thrive at delivering the process water quantity and quality required, guaranteeing a reliable, efficient and energy-optimized installation.

Most important features of the Ovivo PW/HPW/WFI and distribution installations:

- Manufactured and preassembled in our own Ovivo workshop
- Constructed in fully pre-mounted divided plant sections (Softening, RO-EDI-UF and distribution)
- User friendly, service friendly and compact construction
- Tested, prequalified and ready for connection
- Available in different capacities
- Sanitization through chemical and/or hot water for the PW/HPW and WFI production installations
- Sanitization through ozone, chemical, or hot water for the distribution systems
- Equipped with high quality (Grundfos, Gemü and E+H) components that are worldwide available
- Automation concept based on Siemens PLC or other brands

Working with Ovivo means:

- The best solution based on customer needs
- Own design and manufacturing accommodates customer requirements and specifications
- High quality installation and service



3. PHARMACEUTICAL WATERS



3.1 PURIFIED WATER (PW)

3.1.1 Purified Water in bulk

PW 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 pharmaceutical-grade pure steam. It is also used for rinsing purposes (cleaning of containers) and in the preparation of cleaning solutions.

3.1.2 Quality parameters Purified Water (PW)

Parameter	Unit	EP	USP
TOC (Total Organic Carbon)	ppb C	≤ 500	≤ 500
Conductivity (20 °C)	$\mu\text{S}/\text{cm}$	$\leq 4,3$	----
Conductivity (25 °C)	$\mu\text{S}/\text{cm}$	----	$\leq 1,3$
Nitrate (NO ₃)	ppm	$\leq 0,2$	----
Heavy metals	ppm as Pb	$\leq 0,1$	----
Bacteria	CFU/ml	≤ 100	≤ 100

3.2 HIGHLY PURIFIED WATER (HPW)

HPW is used in the preparation of medicinal products where bacterial endotoxins need to be controlled, except where water for injection is required. Current methods for the preparation include double-pass reverse osmosis, reverse osmosis combined with ultrafiltration and distillation.

3.2.1 Quality parameters Highly Purified Water (HPW)

Parameter	Unit	EP	USP
TOC (Total Organic Carbon)	ppb C	≤ 500	n.c.st.
Conductivity (20 °C)	$\mu\text{S}/\text{cm}$	$\leq 1,1$	n.c.st.
Nitrate (NO ₃)	ppm	$\leq 0,2$	n.c.st.
Heavy metals	ppm as Pb	$\leq 0,1$	n.c.st.
Bacteria	CFU/ml	≤ 10	n.c.st.
Bacterial endotoxins	I.U./ml	$\leq 0,25$	n.c.st.

n.c.st. = no comparable standard

3.3 WATER FOR INJECTION (WFI)

3.3.1 Sterilized Water for injection

WFI is used for dissolving or diluting substances or preparations for parenteral administration.

3.3.2 Water for injection in bulk

Bulk water injection is used in the manufacture of parenteral and ophthalmic products. It is also used for final rinsing of containers (e.g. primary packaging materials) and manufacture of these products.

It is produced in according to European Pharmacopoeia (EP) monograph (revised Monograph 169 effective from April 2017) either by:

- distillation in an apparatus of which the parts in contact with the water are of neutral glass, quartz or a suitable metal and which is fitted with an effective device to prevent the entrainment of droplets;
- a purification process that is equivalent to distillation. Reverse osmosis, which may be single-pass or double-pass, coupled with other appropriate techniques such as electro-deionisation (EDI), ultrafiltration (UF) or nanofiltration (NF), is suitable.

3.3.3 Quality parameters Water for Injection (WFI)

Parameter	Unit	EP	USP
TOC (Total Organic Carbon)	ppb C	≤ 500	≤ 500
Conductivity (20 °C)	$\mu\text{S}/\text{cm}$	$\leq 1,1$	----
Conductivity (25 °C)	$\mu\text{S}/\text{cm}$	----	$\leq 1,3$
Nitrate (NO ₃)	ppm	$\leq 0,2$	----
Bacteria	CFU/100 ml	≤ 10	≤ 10
Bacterial endotoxins	I.U./ml	$\leq 0,25$	----
Bacterial endotoxins	EU/ml	----	$\leq 0,25$
Heavy Metals	ppm as Pb	$\leq 0,1$	----



4. SYSTEMS AND TURNKEY SOLUTIONS

4.1 PRE-TREATMENT

Drinking water is mandatory and is used as the basis for the production of pharmaceutical water, but such water is not available everywhere in the necessary quality and quantity. The use of Ovivo ultrafiltration systems is a reliable method for the production of drinking water from raw water and as an optimal pre-treatment stage to protect downstream PW/HPW/WFI processes.

4.2 PURIFIED WATER, HIGHLY PURIFIED WATER AND WATER FOR INJECTION

PW, HPW and WFI is one of the most critical raw materials for pharmaceutical water production and related industries. As such the qualities present at the point of use are regulated by the different international pharmacopeia's such as USP, EP, JP etc.

To safely achieve the defined qualities and maintain appropriate safety, alarm and action levels, it is important to deliver highest qualities to the storage & distribution systems.

Ovivo pre-validated and tested PW/HPW/WFI generation products are an optimal choice and provide technology for any kind of PW/HPW/WFI generation need, project requirement and budget.

All Ovivo PW/HPW/WFI installations are available with chemical sanitization and/or with heat (hot water) sanitation.

4.3 OVIVO PROCESSES AND PRODUCTS

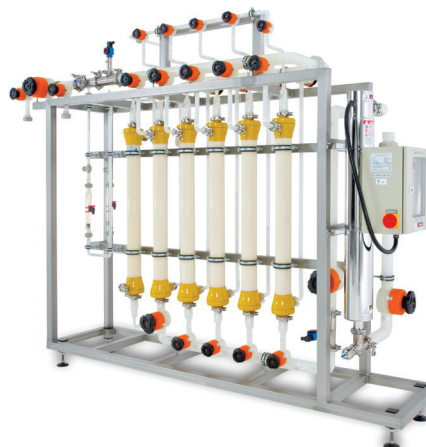
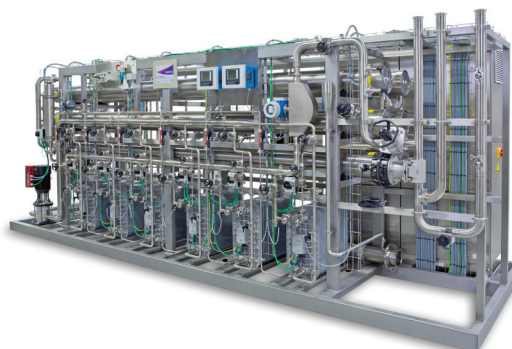
Ovivo will use the following processes and products for the

- Duplex water softeners in serial operation *
- Activated carbon
- Single and double stage reverse osmosis (RO) units *
- Electrodemineralisation (EDI) *
- Ultrafiltration (UF) *
- Storage and distribution systems, made of SS316L or PVDF
- UV units for disinfection and destruction of ozone
- Electrolytic ozone generation systems

** Standard with chemical sanitization and optional with hot water sanitization*

5. VALIDATION, QUALIFICATION & DOCUMENTATION

Validation and documentation engineers accompany each project through all steps of the V-model, starting with the URS and ending with FAT, SAT / IQ, OQ. Ovivo can also support the customer in the PQ phase.





6. AUTOMATION

The automation and control system is the brain and heart of every clean utility system. Executing projects according to cGAMP requirements is the basis for best performance and results.

Ovivo automation products are available for all systems and provide high quality process control with validated open source software and interface graphics. Everything is based on the internationally recognized premium control products of Siemens and other brands on request of the customer.

Based on the approved P&ID, control concept and electrical wiring diagrams a detailed functional logic (FL) document is developed. Describing all functions, controls, sequencers, set points, alarms, priorities etc., well-structured FL is the essential basis for the qualified programming and OQ testing. Transparent and documented PLC program descriptions will provide a logical and easy to understand program structure that is free of any dead code.

Ovivo offers many value added optional features to enhance system control and comfort.

Ovivo Data Export Ethernet connection with each of the individual systems and extract and monitor all available data.

The Ovivo Remote Operation allows for the complete replication of your HMI system to your office computer or remote tablet, and grants you comfortable access and information on the status of the system from any location.

Ovivo Remote Assistance allows skilled Ovivo engineers to support your operators via a safe VPN (Virtual Private Network) internet connection in case of emergency.

7. CUSTOMER SERVICES

Consistent performance in quality and quantity of the clean utility systems as well as maximum availability are critical to any pharmaceutical or related production process. To safely ensure the performance during the entire system life cycle regular and well documented maintenance as well as calibration of quality relevant process instrumentation is necessary.

7.1 CUSTOMER SERVICE PRODUCTS

Maximum flexibility, ranging from a scheduled preventive maintenance to a complete full service packages (including all wear and spare parts) allows you to configure your individual service demand.

Experienced and well trained field service engineers will provide cGMP conform service, maintenance of the complete installation and, with calibration, the routine calibration of all quality relevant instrumentation. Excellent documentation of all service activities and calibrations is provided.

7.2 24/7 SERVICE

Expertise combined with modern tools will provide support and service for your installation from anywhere around the globe. Our international team is available for you 365 days per year on a 24/7 basis and, with our Hotline, assisting you in all questions regarding your Ovivo installations.

Together with local critical spares Ovivo Parts department provides you with a central warehouse to supply validated high quality wear and spare parts for optimal system availability.

7.3 DOCUMENTATION

Ovivo keeps your system documentation up to date with all reports, calibration certificates, change controls, data sheets and manuals of updated parts and many more, for perfect inspections and audits.



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