

Turnkey Systems? We've got what you're looking for!

BWT - For You and Planet Blue.

LIPROLINE – Safe Liquid-processing Equipment

LIPROLINE is the product line for modern process technology in the Pharma & Biotech industry by BWT Pharma & Biotech. The product range consists of components and modules which can be assembled to form high-quality systems. In combination with the BWT water treatment components, it is thus possible to construct a complete, sterile production facility from a single source – perfect implementation of the turnkey philosophy from BWT Pharma & Biotech.

The LIPROLINE product line includes the following systems:

Cleaning systems for CIP/SIP

- LIPROLINE single-use and recirculation CIP/SIP system for all cleaning purposes
- Modular single and multitank package units
- Mobile and stationary systems
- cGMP and cGAMP in-house engineering and manufacturing

Decontamination and concentration of pharmaceutical waste water

- For treatment of pharmaceutical and biotechnological waste water
- Fully automatic batch or continuous processing
- Disposal of the inactivated waste water via normal factory sewage system
- Special evaporator technology for the inactivation of active substances and removal of water from the solutions to be treated

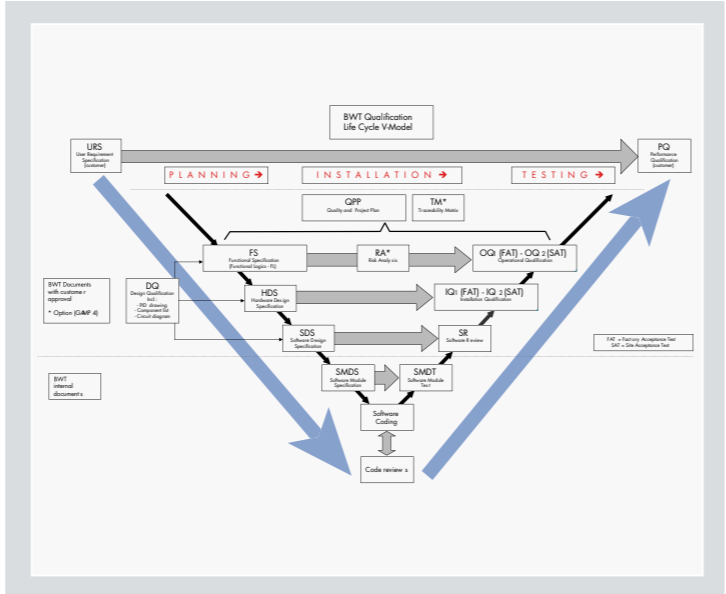


Successful Inspection Guaranteed – Validation, Quality Assurance and Documentation

BWT Pharma & Biotech systems are qualified in accordance with the requirements of FDA, cGMP, cGAMP, cUSP and cPh. Eur. The design and the documentation are based on the „ISPE Engineering Baselines for Water and Steam Systems“ and on „Commissioning and Qualification“. The systems carry the CE symbol in accordance with the regulations of PED, EMC, LV and the Machinery Directives.

During each project, a validation engineer accompanies all project activities in order to ensure optimal coordination of all steps, from the URS (User Requirement Specification) through all stages of the V model to the FAT/SAT. Our compact systems leave the factory only after they have passed a functional test (FAT) which checks the execution, functionality and quality of the system. This permits simple and fast installation and commissioning of the system on the customer's premises.

BWT Pharma & Biotech control systems are based on our many years of experience in the construction of pharmaceutical production systems. With the aid of our own validated software modules, our own cabinet production and a uniform user interface for all systems, we can produce flexible, easy-to-use and perfectly documented control and automation systems which are easy to understand.



Tailor-Made Control Concepts – For Easy Operation

Our control concept **AQU@VIEW Water Management** permits very easy operation of the systems and comprehensive outlet management. **AQU@VIEW Water Management** permits the control and documentation of all interventions and thus guarantees a complete audit trail. The current operating status of the water treatment system and the process systems can be displayed graphically at any time. The modular design permits linking of all system components and process systems.



AQU@VIEW Data Logger is the optimal supplement to our AQU@VIEW Water Management software and extends its scope with remote functions such as remote operation, remote monitoring and recording and archiving functions.

AQU@VIEW Data Logger offers the following possible functions:

21 CFR Part11 recorder function

- Long-term data archiving with graphical display
- Data export (for example to Excel or a database)
- Data backup on the customer's server
- Output of logs and reports

Remote data acquisition and evaluation

- Cyclical transfer of data to a central BWT server via modem or Internet (secure VPN connection)
- Data evaluation by BWT service personnel
- Assistance and recommendations in the case of a fault
- Production of reports and of documents required by the authorities

Remote operation of the system by BWT

- Event-triggered reporting on the system status
- Fault diagnosis by remote access by BWT
- 21 CFR Part11 compliant audit trail of all changes to parameters and/or configuration
- Final report after access by BWT, with risk analysis and change control
- Provision of consumable materials
- Remote support during maintenance work

The BWT Pharma & Biotech turnkey concept is rounded off by our worldwide and competent customer service. This ensures the maximum possible system availability, maintains the value of your investments and guarantees optimal life-cycle management.



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www.bwt-pharma.com

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ULTRASTIL TW – Raw-Water Ultrafiltration – in Many Cases Indispensable

Drinking water is mandatory 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 ULTRASTIL TW systems is a reliable method for the production of drinking water from raw water.

ULTRASTIL TW offers the following advantages:

Very economical operation

- High retention rate for particles, germs, bacteria and viruses
- Operation with membrane separation rates of 100 – 200 kD
- Requires far less space than comparable conventional flocculation and filtration processes
- Modular design
- Fully automatic operation means less work for the operating personnel

Constant top quality

The requirements of the drinking water laws with respect to the quality-relevant parameters such as turbidity and particles are continuously fulfilled.

Maximum production safety and simple operation

- Drinking water compliant components
- Fully automatic operation
- Operation is static or cross-flow mode, depending on the quality of the raw water

BWT Pharma & Biotech ULTRASTIL TW systems contribute decisively to the production and quality-assurance of drinking water.



OSMOTRON® PRO – The Original for the PW and HPW Production

OSMOTRON® PRO is the most widely used system for the production of Purified Water (PW) and Highly Purified Water (HPW) in accordance with Ph. Eur. and US Pharmacopoeia. These very compact production systems consist of the process stages:

- Pre-filtration
- Water softener
- Reverse osmosis
- Electro deionisation SEPTRON®
- Ultrafiltration stage for the production of HPW (OSMOTRON® PRO/SEPTRON - BIO-SAFE)

All of these stages are mounted in a frame, which means that each system can be prequalified before it leaves the factory. This includes a complete factory acceptance test in our production facility.

OSMOTRON® PRO is available in the following versions with outputs of 500 l/h to 20,000 l/h. With or without complete hot water sanitisation at temperature ≥ 80°C.

OSMOTRON® PRO – Different Types for Every Application:

	For production of	Compliant with		Process stages						Sanitization Softener		Sanitization RO/EDI	
		EP	USP	Softener	Microfiltration	Reverse Osmosis	Electrodeionisation	Ultrafiltration (integrated in the EDI module)	Chemical	SANISALP	Hot water	Chemical	Hot water
OSMOTRON® PRO PW	Purified Water	•	•	•	•	•	•	•	•	•	•	•	•
OSMOTRON® PRO PW-S		•	•	•	•	•	•	•	•	•	•	•	•
OSMOTRON® PRO PW-2S (double S)		•	•	•	•	•	•	•	•	•	•	•	•
OSMOTRON® PRO HPW	Highly Purified Water	•	•	•	•	•	•	•	•	•	•	•	•
OSMOTRON® PRO HPW-S		•	•	•	•	•	•	•	•	•	•	•	•
OSMOTRON® PRO HPW-2S (double S)		•	•	•	•	•	•	•	•	•	•	•	•



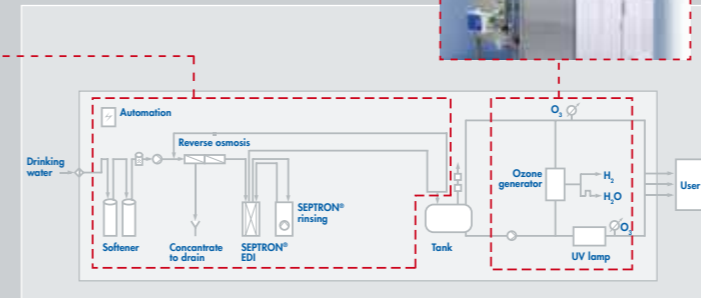
LOOPO – Compact Prequalified Distribution Package Units

With the compact system LOOPO pharmline, BWT Pharma & Biotech offers a solution for the distribution, sanitisation and quality monitoring of pure and ultrapure water. The rack-mounted system is a space-managing and reliable alternative to conventional stand-alone units and combines the following process components. This compact system is based on the OSMOTRON concept and is a space-saving alternative to individual components which can be installed quickly and safely.

- Speed-controlled feed pump for water distribution
- BWT STERITRON electrolysis ozone generator with single- and multi-point online ozone measurement (LOOPO C and CH)
- Bewades UV radiation unit for destroying ozone until it is below detection limit (LOOPO C and CH)
- Pressure, flow rate, temperature and conductivity measurement (optional online TOC measurement)
- For cooling the pure water during long circulation times, an additional double tube bundle heat exchanger can be integrated.
- Autonomous control with a dedicated CPU and validated software components for best operational safety

Options:

- Audit trail function for generation, storage and distribution
- Fully automatic operating-data logging for all process steps
- Evaluation of data & trends for preventive maintenance of the system
- Paperfree recorder for quality monitoring integrated in the PC panel
- FDA-compliant DTS heat exchanger for cooling the water during long recirculation periods
- Hot-water sanitisation (LOOPO S) which permits sanitisation of the entire loop system and the tanks with hot water at 80 °C to 85 °C



WFI and Pure Steam Production – For Highest Quality Requirements

MULTITRON systems are our reliable and energy-saving multi-effect-systems for the production of Water for Injections from 50 – 15,000 l/h, while the VAPOTRON systems are functional and durable pure steam generators from 50 – 5,000 kg/h.

The multi effect distillation system MULTITRON consists of up to eight columns. Permanent monitoring and documentation of the distillate guarantee production of water with the required quality. It is also possible to integrate an online TOC measuring system.

The pure steam generator VAPOTRON complies with the requirements for dry, pyrogen-free pure steam for:

- Sterilisation of systems (SIP)
- Sterilisation of pipes
- Heating of GMP sterilisers/ autoclaves
- Sealing of GMP floating-ring seals in fermenters in the biotechnology area
- Air moistening in clean rooms
- cGMP and cGAMP in-house engineering & manufacturing
- Optional parallel Pure Steam and WFI production with COMBITRON technology
- Integrated high-efficiency degassing technology according to EN 285



MULTITRON and VAPOTRON – for low-cost and safe production of WFI and pure steam

