

MULTITRON – VAPOTRON – COMBITRON



WFI & Pure Steam Production

MULTITRON – multiple-effect distillation units

VAPOTRON – pure steam generators for the pharmaceutical industry

COMBITRON – combined pure steam and WFI production

For You and Planet Blue.

 **BWT**
BEST WATER TECHNOLOGY

BWT Pharma & Biotech offers reliable and the most energy-efficient, multi-effect equipment for the production of Water for Injection (WFI) and Pure Steam. Each system complies with the latest cGMP requirements and includes features that enable integration into an overall system. The state-of-the-art control package complies with GAMP requirements (optional) and can be operated intuitively via a touch-screen panel. Each system is fully equipped to be able to be hooked up to an overall building management or 21 CFR Part 11 data storage system.

MULTITRON – Multi-Effect Distillation Units

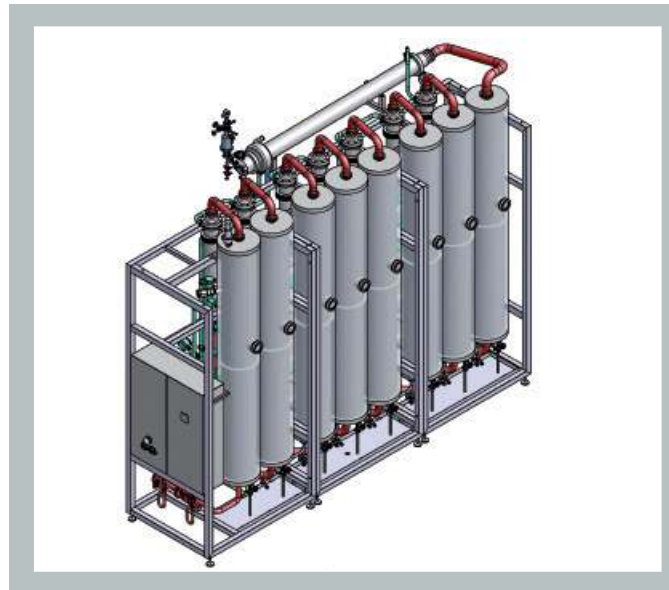
WFI from the pharmaceutical water specialist

MULTITRON is a uniquely designed, multi-effect distillation unit with a superior energy efficiency and an extremely reliable WFI water quality. You are guaranteed the best technologies in multiple-effect distillation, an energy-saving design with from 1 to 8 columns, plus years of experience and specialist know-how.

BWT Pharma & Biotech has designed a unique double-tube-sheet evaporator, which is integrated into each of the columns without any fixed points. The entire heat exchanger is submerged below the preheated feed water, thus eliminating the risk of scaling or rouging, and uses all the energy that is fed into the shell side of the evaporator.



The MULTITRON distillation units meet all special pharmacopoeia specifications, such as European and the USP regulations.



Economic and efficient

Latest control techniques, coupled with proven BWT engineering, provides decisive advantages:

- Maximum efficiency through optimised cGMP-compliant design
- Total reliability through proven distillation technique
- Lowest consumption of heating steam and cooling water guaranteed
- High-quality manufacture via orbital welding and smooth surface polishing
- Optimum operational reliability and easy operation using PLC control with touch-screen operator interface
- Plant steam, hot water or electrically heated systems available
- Performance can be set between 20 and 100 % as an option for optimised energy-efficient operation

High standards with optional features

MULTITRON distillation units consist of 1 to 8 columns. Continuous monitoring and documentation of the distillate via the control system guarantees automatic rejection of, for example, distillate with excessively high conductivity or an unacceptable temperature.



MULTITRON distillation units are characterised by customer-oriented performance features:

- Compact design. All parts mounted in a stainless steel frame
- No moving parts, hence minimal maintenance
- All parts in acid-resistant stainless steel
- Feed water pump and feed water pre-heater integrated in the frame
- Low steam velocity
- Pure steam can be taken from the first column either when producing WFI or independently (COMBITRON version)
- Unique three-phase droplet separation system
- Optional automatic sterilisation available
- Standard control components
- Standard fittings, metering and control engineering
- User-friendly control panel with easy-to-read display and continuous indication of the process status. Standard in all BWT units and skid-mounted systems

All parts in contact with the product are made of high-quality stainless steel (AISI 316 L) 1.4404/1.4435 and all joints have an aseptic TC connection. Calculation, design and production of the pressure vessels are based on PED manufacturing and inspection guidelines of PED or ASME rules.

VAPOTRON – for Efficient Pure Steam Production



BWT Pharma & Biotech offers both separate pure steam generators (VAPOTRON) for the production of sterile, pyrogen-free steam and combined systems (COMBITRON) for pure steam and WFI in a single unit.

VAPOTRON meets the strict requirements for dry, pyrogen-free pure steam for the following applications:

- Equipment Sterilisation-in-Place (SIP)
- Sterilisation of piping systems
- Operational heating source for GMP sterilisers
- Sealing of GMP gaskets, such as Biotech fermenters
- Air humidification of clean rooms

To meet these needs, BWT Pharma & Biotech offers the fully cGMP-compliant VAPOTRON pure steam generators. For pure steam requirements complying with EN 285 for sterilisation in an autoclave, the plants can be equipped with a degasifier mounted in the same skid.

Higher capacity – fully automatic

The basic principle of a VAPOTRON pure steam generator is the same as the first column of a multiple-effect distillation unit. It uses identical technology to provide the best possible level of production efficiency and the most reliable pure steam pressure to feed into the pure steam network.



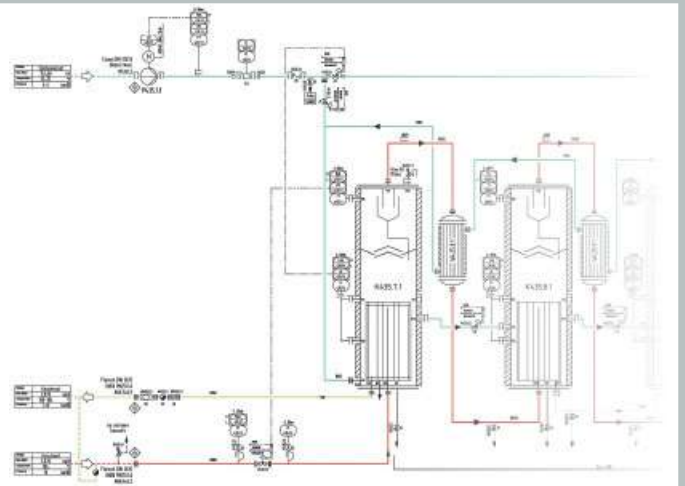
COMBITRON – The Perfect Combination

A combined pure steam and distillation unit simplifies the provision of ultrapure media: pure steam and Water for Injection (WFI) can be generated with COMBITRON in a single instead of two units. This is made possible by the use of a specially designed first column that has a bigger diameter and uses the natural circulation principle.

The media can be produced simultaneously or separately with an output of about 1,000 kg of pure steam and up to 4,000 litres of WFI per hour. The ratio of pure steam to WFI can be adjusted in the range 2:1 to 1:4 to match individual project requirements. Customer-specific versions with higher outputs and with individual configurations are available.

Reduced investment costs – smaller footprint

Since the COMBITRON produces two ultrapure media from a single unit, the investment costs for the system and its periphery are reduced by up to 30 per cent, and the combined unit requires considerably less space than two separate units.



The Right Solution for Every Need

User-friendly and Individually Programmable

MULTITRON distillation units, VAPOTRON pure steam generators and COMBITRON skids, equipped with a Siemens or similar control, can be individually programmed for specific requirements. An additional touch-screen panel enables simultaneous operation and process monitoring of the whole distillation unit. Production and process data can be scanned, documented and updated at any time.

As recommended by the FDA, fully automatic production of the distillate guarantees rejection of the first product after restart-up.

Quality control is then performed at every stage of the project

- Design review
- Inspection of incoming goods
- Software review
- Pre-inspections of control cabinet
- Manufacturing inspections as per ISO 9001 procedures
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)

Validation, quality control and documentation

At the beginning of each project a Quality & Project Plan is created to show the quality control elements, together with scope, responsibilities etc. It is given to the customer for approval. This process ensures that the project will run smoothly.

MULTITRON, VAPOTRON and COMBITRON are validated in compliance with FDA, cGMP, GAMP, USP and Ph. Eur. requirements. BWT Pharma & Biotech also follows the ISPE Engineering Baselines for Water and Steam Systems, and Commissioning and Qualification. The systems are CE-marked according to the relevant directives, such as PED, EMC, LV and the Machinery Directive.

The validation engineers remain with each project through all steps of the V-model, starting with the URS and ending with FAT/SAT prior to handing the unit over.

Our skid-mounted distillation units and pure steam generators leave the manufacturing site after a successfully executed FAT with test-run checking capacities. The units can be commissioned quickly and easily and are finally validated on site to start producing WFI and/or pure steam.



Highest Level of Reliability

BWT Heat Exchanger Designs – technical advantages that have proved themselves time and time again

Stress-free heat exchangers

The heat exchangers are immersed completely in feed water and the heating steam, that is at a constant temperature through the entire column, allows free and uniform expansion heat exchanger tubes and of the outer jacket. The advantage of this is minimal stress within the heat exchanger and weldings. The risk of corrosion is also reduced to a minimum, considerably extending the life of the product. Optimal process engineering ensures that vibrations and thermal stress for heat exchangers and installed equipment are avoided.

Thorough testing

- Dye penetration testing of tube/tube end plate welds
- Hydrostatic testing and final inspection in compliance with PED
- Radiography of the main welds in compliance with German regulations

Reduced risk of scaling

Scaling is kept to an ideal minimum, particularly in the case of feed water containing silicates, as the heat exchangers are immersed completely in feed water and the tubes are always wet.

Drainability

BWT's design allows full drainability of each column and all heat exchangers.

Large expansion area for the steam

Half the column height is available for expansion of the steam and for droplets to form in the upper column area.

FDA-approved double-plate tubular heat exchangers with seamless tubes

The double-plate tubular heat exchangers are supplied with seamless tubes. The FDA recommends their use where a less pure medium is available at a higher pressure than the purer medium. For example, the first column, condenser, cooler and pre-heater in our distillation units.

The heat exchanger tubes are then rolled into the inner tube plate and welded into the outer tube plate. Our heat exchanger design is characterised by longer service intervals and fewer spare parts (no gaskets), considerably extending the life of the equipment.

BWT Pharma & Biotech – Your Partner for Sterile Technologies

Skilled employees

All BWT Pharma & Biotech systems are manufactured by highly qualified fitters and welders. Development, production and pressure tests take place in accordance with the strictest regulations and under official supervision. Before being commissioned the plants are fully tested and pre-validated during the FAT (Factory Acceptance Test). This means that all BWT Pharma & Biotech employees comply with ISO 9001 and 14001 and guarantee the highest quality for our customers. Every BWT system is delivered with a declaration of conformity and the CE mark.

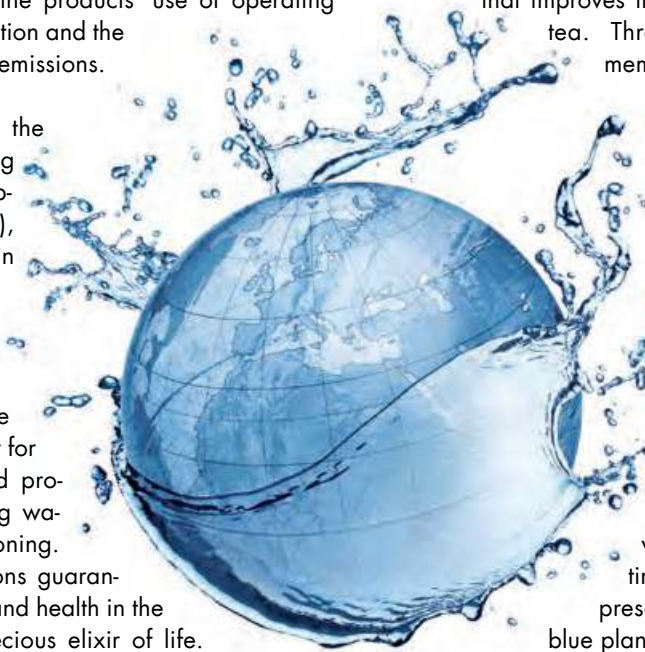


BWT – the Company

Best Water Technology Group (BWT) is Europe's leading water technology company. Our water partner network comprises the group's 3,300 employees and thousands of plumbers, planners, architects and hygiene experts. Our Research & Development teams, using state-of-the-art methods, work on new processes and materials to create products that are both ecological and economical. Looking ahead, a key development issue is a reduction in the products' use of operating resources and energy consumption and the resulting minimisation of CO₂ emissions.

Whether at the place where the water pipe enters the building ('point of entry') or at the tapping point ('point of use'), BWT's trend-setting 'Made in Europe' products have proved their quality millions of times over in the treatment of: drinking water, mineral water and ultrapure water for the pharmaceutical industry; water for swimming pools; heating and process water; boiler and cooling water; and water for air-conditioning. BWT's wide-ranging innovations guarantee maximum safety, hygiene and health in the daily use of water – that precious elixir of life.

These innovations, among others, include: SEPTRON®, the world's first electrodeionisation module (EDI) with spiral wrap; manganese oxide activation (MDA) – a method for effective manganese removal; AQA total bipolar technology for chemical-free limescale protection; SANISAL – the world's first regeneration salt for softening water systems, which also works as a disinfectant; and the new, revolutionary Mg²⁺ technology that improves the taste of filtered water, coffee and tea. Through its unique, high efficiency membranes for fuel cells and batteries, BWT is creating a cleaner, more sustainable energy supply for the 21st century.



BWT – For You and Planet Blue signifies that our mission is to take ecological, economical and social responsibility, to provide our customers and partners with the best products, systems, technologies and services in all areas of water treatment and, at the same time, to make a valuable contribution to preserving the global resources of our blue planet.



For You and Planet Blue.

Find us on www.bwt-pharma.com

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