



H+E Pharma

**From drinking water to
pharmaceutical water**

| PRE-TREATMENT | GENERATION | STORAGE | DISTRIBUTION |





Highest quality of system design and water quality while minimizing investment and operating costs

This has been going on for more than 80 years



Water is of exceptional importance in pharmaceutical production. It is an essential raw material for pharmaceutical products, and an important tool for cleaning the systems used to produce these products.

The quality specifications in the pharmacopoeia's monographs, qualification requirements as well as specific design demands for the water treatment system are accordingly high. Specifically, highest demands on design, implementation and operation are made so that the microbiological purity is guaranteed.

Whether with membrane processes, chemical and thermal procedures or intelligent sanitation concepts - we have been supporting our customers who operate all over the world for more than 80 years with turnkey and standard solutions which meet the highest international quality, documentation and validation criteria.

Our actions and our uncompromising understanding of plant engineering and qualification have always been motivated by ideas and innovations. From research and development to our own analytical laboratory, we cover the whole manufacturing range from plant design and engineering up to our own software and hardware production.

We focus on what we do best, and for complete solutions we look for strategic expert partners, like for example STERIS FINN-AQUA®. So we still honour what our founder Willy Hager once demanded:

"If we want to achieve market leadership, the quality and added value of our plants for our customers must be double the price difference to our competitors taken as a percent."

This is why top system quality and maximum system availability remain our primary objective also for the future.

"Water is one of the essential elements of our being. Here at H+E we have always invested a lot of energy into considering its condition..."

The late founding director during an opening in the USA. As one of the first companies worldwide, H+E Pharma were supplying systems as early as 1971 which worked according to the principle of reverse osmosis...





300 kg/h pure steam? 6,000 l/h water for injection? Package unit or turnkey system?

Pharmaceutical water is precious. Pharmaceutical and cosmetic production relies on purified water - and the more efficient a processing plant, the larger the benefit for the operator. Furthermore, water is one of the few raw materials which is produced directly on site.

In addition to customer requirements, highest safety standards and strict laws specify the production method of water qualities like PW and WFI.

But the water processing plants themselves are fundamental in further improvements in the operation and economics of producing, storing and distributing pharmaceutical water in the future.

Apart from the water quality in a system, energy and water efficiency should be mentioned here.

Whether package unit or turnkey system, extra small or extra large system, our experience means we are prepared for all developments worldwide. And that for more than the past 80 years.



Sanitisable as a complete system, the ROCEDIS®. DIRECT PW-TS supplies the points of delivery directly via the ring main without a storage tank. This saves investment costs for the PW storage tank and the pump, sanitisation equipment and instrumentation.



Turnkey system with hot water sanitisable PW and WFI generation incl. storage and distribution system as well as pure steam generation at a well-known Swiss pharmaceutical manufacturer.

Process plants

H+E Pharma is the expert partner of the pharmaceutical industry worldwide when it comes to processes related to the production of sterile liquids.

We provide preparation and storage systems for parenterals, suspensions and other solutions, CIP/SIP systems individually tailored to the process, process trains for individual requirements, from design and qualification to the turnkey installation with after sales warranty.

In compliance with international standards we implement almost all conceivable requirements of efficient processes and cleaning.



Package units, as stand-alone solutions or a part of a process train

Raw water pre-treatment

We offer our customers a broad range of safe and economical processes for the pre-treatment of raw water and thus ensure optimum protection against water contaminants which might seriously affect the operation of a downstream equipment.



Reduction of bacteria, endotoxins and nutrients (TOC) and a modular structure with our ultrafiltration system ULTRALIS, undissolved colloidal impurities are removed effectively.

Softening

Softening plants are a crucial integral part of the pre-treatment for generating pharmaceutical-grade water in compliance with USP/EP. With PHARMASOFT® and PHARMASOFT®.E we offer two volume controlled softening plants with direct or countercurrent regeneration.



PHARMASOFT®.TS with residual hardness measurement TESTOMAT® 2000 is integrated on skit.

Generation of PW and WFI

Purified water (PW) is obtained from softened water via the process reverse osmosis, if applicable membrane degassing, and electrodeionisation. For the production of water for injection (WFI), ultrafiltration is installed downstream from the ROCEOIS®, which results in excellent microbiological water quality.



The ROCEDIS® PW/WFI-TS is used for the reliable and replicable production of purified water (PW) or water for injection (WFI). The system is completely assembled in stainless steel 316L and is thermally sanitisable.

Generation of WFI

Energy efficiency and complete reliability - since 1971, the STERIS FINN-AQUA® water stills have been equipped with the patented falling film technology and have more than 3,000 installations worldwide. The efficient phase separation ensures excellent WFI quality, free from endotoxins and pyrogens.



The water distribution in the column of the MWS increases performance and ensures less consumption of plant steam.

Pure steam generation

Sterilisation processes in the pharmaceutical industry require high-quality pure steam with accurate pressure control and quick response time. With the pure steam generator by STERIS FINN-AQUA®, not only do we meet this requirement, but we also ensure the removal of non-condensable gases.



Fast response to changing requirements – the PSG is supplied with PW from our ROCEDIS® system. The pure steam generator with proportional capacity control is based on a new patented procedure.

Distribution and storage systems

Our compact system SANICIRCLE® was designed for the distribution of PW and WFI. The pharmaceutical-grade water is stored in a storage tank to cover the usual consumption peaks. The system is sanitisable with ozone/UV or hot water, pre-installed ready for connection and supplied pre-wired.



SANICIRCLE® prevents microbial growth in ambient temperature loop systems with an ozone/UV sanitisation. For periodic hot water sanitisation we provide the SANICIRCLE®.TS version.



Our systems meet the standards and regulations of all nations of this world

So does our project team...

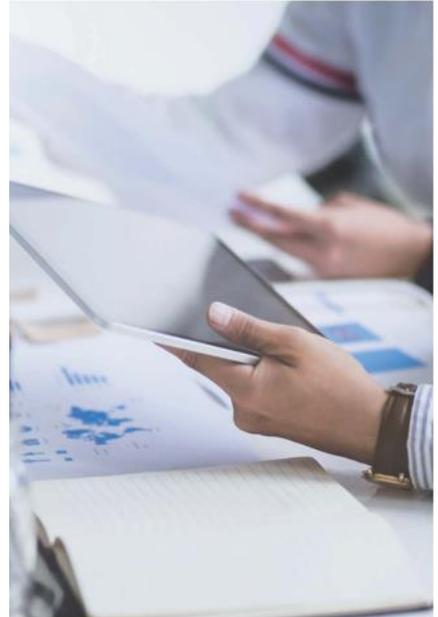
If the water system fails, production stops. For this reason, water treatment is an extremely sensitive area, which requires proper handling from the planning through to monitoring. As these are also complex systems from the generation, storage and distribution up to operation, expert knowledge is key.

To have such knowledge is one thing; to apply this knowledge to every production site in the world and build reliable equipment is quite another. A qualification and documentation service which can be easily implemented for our customers in accordance with the applicable authorities is necessary.

It is thus the combination of international market experience, long-standing knowledge of the customer requirements and the collaborative dealing with authorities and auditors which characterizes our project team as competent and reliable.

H+E Pharma systems are FDA- and GMP-compliant systems and provide reliable solutions worldwide for the production of all water qualities. From planning through to construction and operation, they guarantee compliance with international as well as national guidelines at the system site, and are documented and certified in accordance with the guidelines of our quality management system ISO 9001:2015 from the first design study up to the turnkey.

To ensure a reproducible quality of the pharmaceutical water across the entire lifecycle of our systems, we offer a series of tailor-made maintenance, repair and service measures, which ensure a high degree of safety and availability.



Tim L. postpones his date in Stuttgart to 9:30 pm. Because Tim L. still has an important appointment abroad At 9:30 pm.



Based on proven PLC control technology from SIEMENS, the automation concept of our systems is created and qualified in compliance with the GAMP and EG-GMP guideline. The data exchange between assemblies and chained modules occurs via a system-internal Ethernet.

When it comes to the total cost of ownership, capital expenditure is always considered in addition to the total operating costs and also the "non-operational" costs: the highest costs occur when a system is not running.

H+E Pharma systems are renowned for their absolute reliability and their long service life. In addition, we provide our customers with the straightforward service needed to keep their water plant running reliably. Whether in Singapore or anywhere else, each of our customers has their personal service contact person known to them by name, who can be contacted at any time via an on call service.

This enables unbureaucratic system inspection, remote system maintenance and monitoring independent of the timezone of the operator. Shortest response times are enabled via Internet, and a solution is usually provided quickly via remote control.

And in the worst case? We can fall back on a service network with well trained engineers who help you avoid downtimes. Furthermore - depending on the maintenance contract and service agreement - SAFETYSTOCK ensures fast supply of spare parts and thus highest possible system availability for our customers.

At any time. Anywhere. And with competent service staff like Tim L. for any eventuality...



Why do so many worldwide technology leaders originate in Stuttgart?

Because we leave nothing to chance

Stuttgart: Our home stands for the global times of glory for automotive manufacturing worldwide and world-renowned sports cars - but hardly anybody knows that this is home to the most hidden champions in Germany: family-run businesses.

Superlatives do not come naturally to us, even though our region is one of the strongest in research within the EU - the most patent applications in Germany are made here.

We are lucky to have a multitude of people and employees full of ideas, inventiveness and diligence, creativity and accomplishments. They also say about us that we tend to be overly precise sometimes and can do anything, except speak without an accent. But we are working on that as well. And we will not leave anything to chance...



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