Pharmatec GmbH
Units for the Production, Storage and Distribution of High-purity Media
High-purity Media Systems

Contact Pharmatec for the planning, development and production of:
- High-purity steam generators
- Distillation units
- HPW generation
- Storage and distribution systems for high-purity water and high-purity steam

Pharmaceutical products have a constant need for high-purity media such as purified water, water for injection and high-purity steam. Quality fluctuations or supply bottlenecks for these sensitive pharmaceutical raw materials are unacceptable for producers. In other words, high-purity systems are central supply systems which, if they fail or if the quality drops, can lead to far-reaching consequences in the production units.

Overview
- Planning support to help decisions about the most efficient solution (feasibility study on request)
- Basic and detailed engineering services going as far as qualification (including full-loop calibration)
- Complete FAT in realistic operating conditions (on request: including endotoxin challenge test)
- Customized sizes and functions
- Connections to process control systems (PCS)
- Individualized software applications
- User ID password protection to 21 CFR Part 11
- Systems integration, e.g. feed water header and WFI tank
- Support with on-site installation
- Remote maintenance using modem

High-purity media units from Pharmatec

High-purity steam generators from Pharmatec can be used to produce from small to very large quantities of sterile, high-purity pyrogen-free steam. This high-purity steam is suited for:
- Sterilizing fittings (tanks, preparation vessels, piping systems, filling machines, filters, etc.)
- Humidification of air in clean rooms with WFI quality steam

Example of a PSG 500 high-purity steam generator

Pharmatec is your partner for the development, construction and manufacturing of individual high-purity steam generators. To meet fast deadlines or budget limitations, Pharmatec can provide standard solutions with no reduction in quality.

High-purity steam generators from Pharmatec

<table>
<thead>
<tr>
<th>Type</th>
<th>High-purity steam pressure</th>
<th>High-purity steam quantity for pressurized heating steam</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 bar (g)</td>
<td>58 psig</td>
</tr>
<tr>
<td>PSG 50 E*</td>
<td>20 kg/hr</td>
<td>45 lb/hr</td>
</tr>
<tr>
<td></td>
<td>30 kg/hr</td>
<td>66 lb/hr</td>
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</tbody>
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Performance features (*electrically heated)

If a customer has a special request or requirements for the removal of inert gases within the high-purity steam, in accordance with EN285 and HTM2010, with proportions < 3.5 by volume, Pharmatec can deliver degassing systems to pre-treat the feedwater. We have membrane or thermal degassing for this application.

Optional: Membrane gas removal

A compact vacuum gas removal unit basically consists of a membrane pipe module and a vacuum pump. It works on the basis of gas permeation through a semi-permeable membrane, by applying a vacuum to a filtration module through which the feed water flows. The unit is constructed so that there is no drop in high-purity steam production when the feed water degasifier is switched on or operated.

Optional: Thermal gas removal

Thermal non-condensable gas removal can be used in special cases and with ozone sanitized systems. It is based on extracting the finely atomized feed water vapor in a degasifying tank. In this process, the feed water is conducted via a heat exchanger, where it is heated to a gas removal temperature, then nebulised using a spray nozzle into a tank which is surrounded by a vacuum.
High-purity media generators are constructed following the principle of the natural circulation evaporator. Here, special shell-and-tube heat exchangers are used. The distillation process is based on an energy-saving multi-stage principle. Driven by the density gradient, the power of the natural circulation process is used to create a circulating flow without any additional energy. Our engineers and energy experts are constantly improving the energy-efficient methods for the benefit of our customers.

Multi-stage pressure column distillation units from Pharmatec

These units consist of three to eight columns. The first is heated with steam (optionally: electricity). The proceeding columns are heated using the high-purity steam produced by the previous columns. The continuous monitoring of the distillate by the control system means that distillate of insufficient quality is rejected. This includes too high conductivity or a non-permissible temperature.

Pharmatec multi-stage distillation units are designed for the production of sterile, non-pyrogenic water for injection (WFI). Only the first column of the distillation unit needs to be heated with plant steam. In the case of units with seven to eight columns with the use of pre-heaters, the WFI product cooler is not required, as an external cooling medium is not needed.

Optional: Triple mode still

As well as the generation of WFI, there is often a need in pharmaceutical processing units for fairly small quantities of high-purity steam, e.g. to sterilize sampling devices, lab equipment or short pipe sections. The first column can optionally be used as an independent high-purity steam generator. Small quantities of high-purity steam can also be removed at the same time, i.e. simultaneously, during the distillation process.

Pharmatec multi-stage distillation units' unique process for eliminating pyrogens is based on the complete separation of the feed water and generated steam, with low steam rates. A specially developed baffle/reversing system is designed to almost entirely remove water drops from the steam produced in accordance with pharmaceutical laws.
Successful projects start with project management
- Efficient, transparent project management: we constantly inform you about the project’s progress
- Pharmatec is certified in accordance with DIN EN ISO 9001:2000
- Shorter delivery times for fast-track projects available on request

Successful projects need qualified staff
- Process engineers and software engineers with many years’ processing expertise in planning, construction and automation
- Practice-oriented mechanics, orbit welders and flexible fitters in production and final assembly
- Experienced service technicians can take on various tasks on our customers’ sites
- Specialists and experienced qualified staff fulfill our customers’ individual requirements and wishes

Successful projects can be proven
- Manufacturing traceability
- Documentation – in all main languages – from the first R & I draft until handover
- cGAMP documentation

Successful projects end with a high-quality product which meets your demands
- Compact construction with minimum floor space required
- Parts which come into contact with products come completely in premium steel 1.4404/1.4435 (AISI 316L)
- Frame profile, insulating sheath and switch cabinet in premium steel (AISI 304)
- Control components from Siemens, Allen-Bradley, Schneider Telemecanique
- Manufactured in accordance with the European Pressure Equipment Directive 97/23/EC, ASME, SVTI, CODAP
- Exceeds all requirements in the United States Pharmacopeia (USP), European Pharmacopeia
- Effective separation of pyrogens at low steam speeds
- Suited for low or changing pressure of heating steam or feed water
- Improved setup for high efficiency

On request:
- Ra < 0,5 µm surface qualities and electropolishing
- Delta-ferrite content of 0.5 % to 1 %
- Specially manufactured fittings and meters

In pharmaceutical production, high-purity media systems are used to supply the most important processes. High-purity media such as WFI and PW are generated, stored, distributed and used. So that enough medium of sufficient quality is available for every recipient at all times, the storage and distribution system is customized to precisely suit the requirements of the production or lab area.

Requirements for the material, the selection of the components themselves and the fulfillment of legal regulations for pharmaceutical construction play a decisive role in fulfilling the high quality requirements for WFI and PW storage systems.