

Energy-saving WFI Systems.

INNOVATIVE AND EXPERTLY DESIGNED SOLUTIONS FOR WFI GENERATION AND STORAGE

A NEW SERIES OF GENERATOR UNITS DEVELOPED SPECIFICALLY FOR WFI. BASED ON THE "COLD" MEMBRANE PROCESS OF REVERSE OSMOSIS COMBINED WITH ELECTRODEIONIZATION AND ULTRAFILTRATION.

ULTRAFILTRATION PROCESS

- ❑ Important finishing step for the final removal of endotoxins
- ❑ Utilizing only the most robust modules (e.g. hollow fiber, 6K Dalton) with a long service life (2-3 years)
- ❑ Suitable for both hot and chemical sanitization
- ❑ Integrated filter integrity monitoring (bubble point, differential pressure conductivity)

Features

- ❑ WFI quality using only "cold" processes with higher energy efficiency
- ❑ Modular design to meet customer-specific requirements
- ❑ Meets all applicable compendial (e.g. USP, EP) as well as regulatory (e.g. DIN, ASME, GMP, and FDA/EMA) pharmaceutical manufacturing guidelines
- ❑ Significant operating costs and CO2 emissions reduction potential due to less energy intensive processes
- ❑ Skidded, compact system for drop-in installation
- ❑ Excellent accessibility for easy maintenance
- ❑ Standard configuration output of 300 to 13,300 l/h

CO2 savings potential:
500-3,500 t CO2/year
 depending on output
 (5-70 million liter/year)

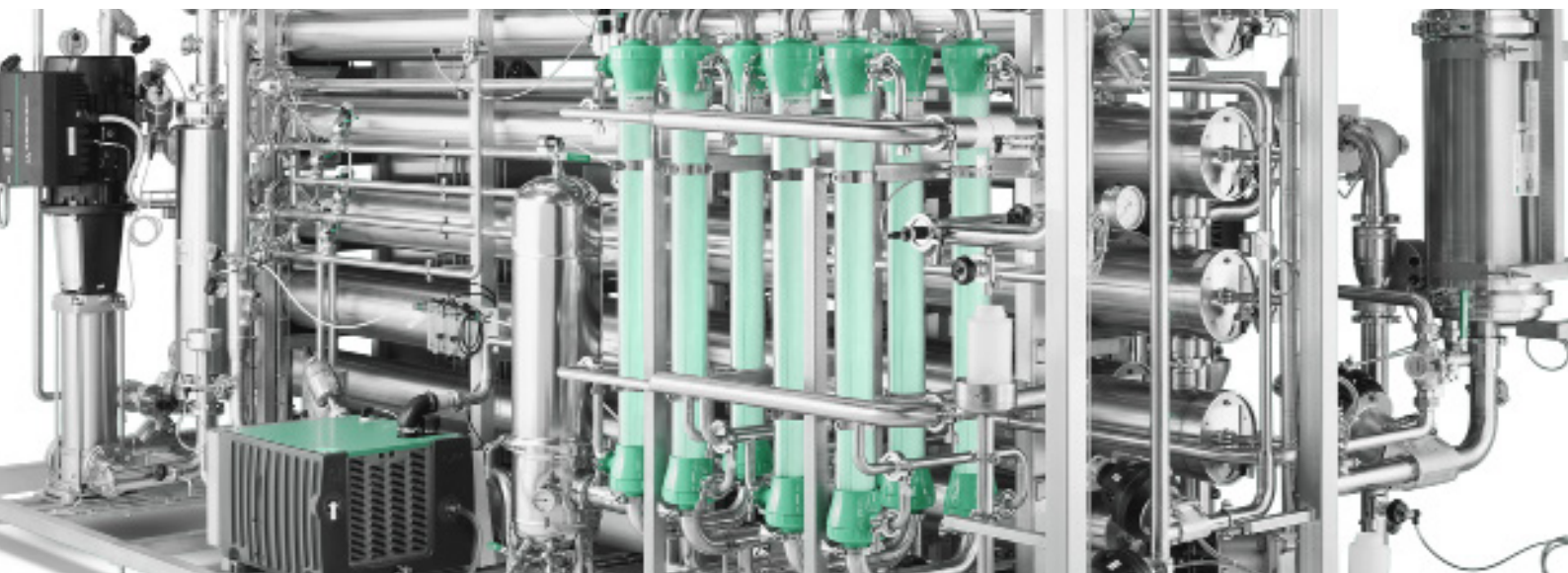
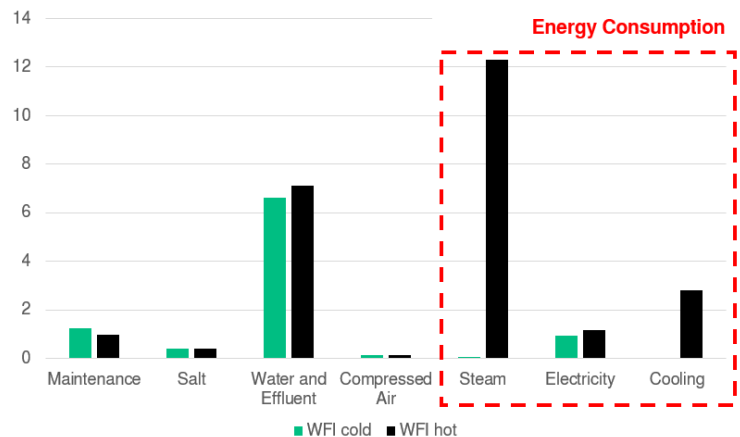


HOT VS. COLD WFI GENERATION

OPEX: Membrane-based WFI units have a ~50% lower total operating cost than hot WFI units at 5m liters and ~40% lower at 40m liters. The total cost savings include maintenance and materials in addition to utilities consumption.

Sustainability: Only ~10% of the total operating cost of cold WFI units is energy consumption, whereas for hot WFI units it is >50%. CO2 emissions are correspondingly 90-95% lower.

Total Operating Cost (EUR/m3) by Type



STORAGE AND DISTRIBUTION SYSTEMS

THE STORAGE AND DISTRIBUTION OF COLD AND HOT WFI ARE AMONG THE MOST CRITICAL PROCESSES IN PHARMACEUTICAL PRODUCTION. A WELL-DESIGNED SYSTEM CONCEPT MAKES SURE IT IS DONE RIGHT!

SUSTAINABILITY

Our advanced technology and modular design features best-in-class energy efficiency throughout. Our fully integrated solutions substantially reduce both operating costs and the carbon footprint.

HOT VS. COLD WFI STORAGE

Storage can be either hot (with thermal sanitization) or cold (with chemical sanitization) to prevent microbial growth and preserve the media quality. The specific use case determines which storage type is the better option for the particular application.

Benefits

- Comprehensive storage and distribution systems for PW, HPW and WFI
- Well-designed solutions for cold and hot storage
- Continuous monitoring of all quality-relevant attributes
- Sanitization method flexibility according to requirements
- Easy expansion thanks to a modular design

Cold storage solution	Hot storage solution
<ul style="list-style-type: none">Introduces ozone into the holding tanks and modular distribution skids to protect against microbial contaminationUses a UV system to ensure that the dissolved ozone is depleted during productionHas a lower risk of rouging (build-up of ferric oxide)Operating costs are substantially lower	<ul style="list-style-type: none">Recirculates WFI continuously to protect against microbial contaminationCold taps are provided via subloops with integrated cooling modulesAvoids the use of ozone, which is can be problematic to handle and difficult to measure accurately in solutionAlso an option in conjunction with cold generation

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REGULATIONS

- US, EU, and JP Pharmacopoeias
- EMA: Guideline on the Quality of Water for Pharmaceutical use
- EU Eudralex Volume 4: Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use
- EU GMP Annex 1: Manufacture of Sterile Medicinal Products

Energy efficiency

Syntegon uses the highly energy-efficient “cold” membrane process of reverse osmosis, along with electro-deionization and ultrafiltration, in a modular, full-featured design. Storage can still be either hot or cold. This approach substantially reduces the initial capital investment, required footprint, energy consumption, as well as the ongoing qualification and maintenance costs when compared to traditional distillation-based systems.

