



# Membrane-based production of WFI



MWFI

## Cold WFI production

In order to meet the high requirements for WFI, we rely on consistent hygienic design in all areas of plant construction, which fulfills all EMA requirements as well as all other guidelines.

In addition, our biofilm control strategy includes an intelligent control, alarm, and sanitization concept as well as comprehensive and seamless monitoring.

In addition, our biofilm control strategy includes an intelligent control, alarm, and sanitization concept as well as comprehensive and seamless monitoring.

The process technology for feed water conditioning is based on the available drinking water quality.

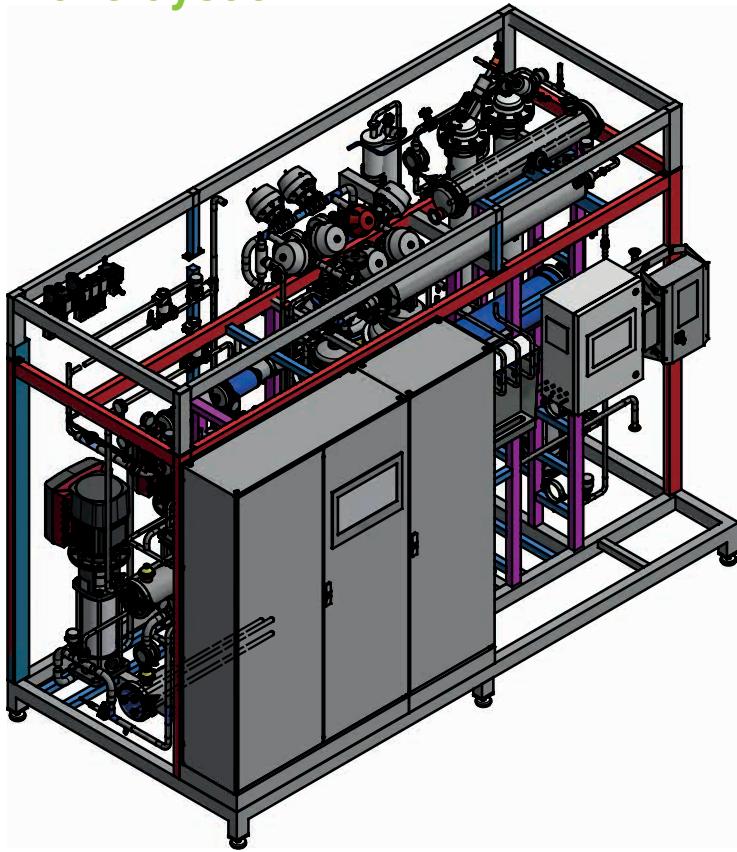
The subsequent core treatment stages in cold WFI production consist of a reverse osmosis stage with downstream electrodeionization and ultrafiltration as the final safety barrier.



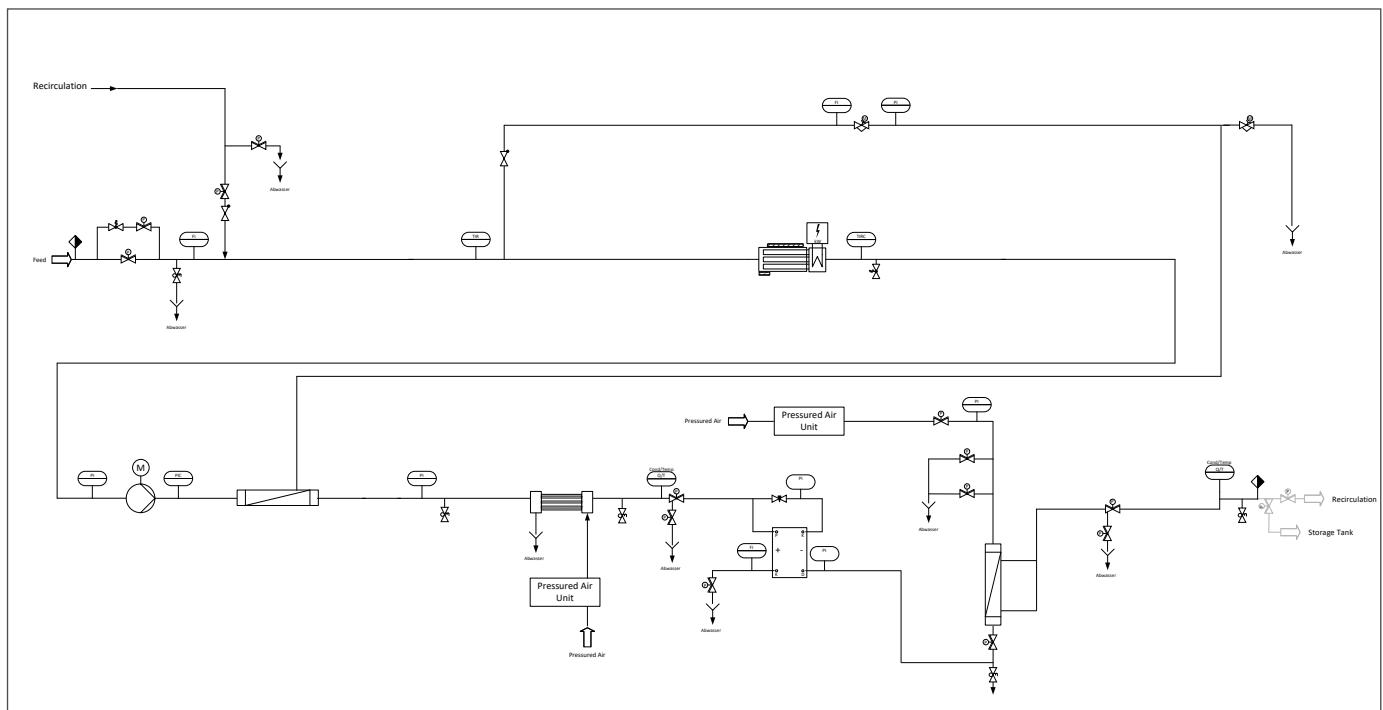
### Technical data:

<b>Material</b>	Stainless steel 1.4404 or 1.4435, Ra <0.8 µm, optionally < 0.6 µm, electropolished
<b>Process engineering</b>	Pre-treatment, 1- or 2-stage reverse osmosis, EDI, UF
<b>Available power levels</b>	200 - 20.000 l/h
<b>Total yield</b>	Approximately 70–75% with a concentrate level of up to >85%
<b>Module type ultrafiltration</b>	hollow fiber
<b>Cut-Off Ultrafiltration</b>	6,000 Daltons
<b>Ultrafiltration</b>	Optional fully automatic and logged verification of the integrity of the UF modules during operation
<b>Sanitization of the entire system</b>	Hot water > 80 °C
<b>Connections</b>	Aseptic clamp in accordance with DIN 11864-3 A
<b>Valves</b>	Diaphragm valves (optional T-valves)
<b>Inline/online process monitoring</b>	TOC and conductivity, flow rate, temperature, and pressure (optional bacterial count determination)
<b>Control and visualization</b>	System control via Simatic S7-1500 PLC, Operation and visualization via Siemens TIA Portal
<b>Computer validation</b>	in accordance with GAMP 5

## Plant layout



## Process representation



Produktflyer\_Kalte-WFI\_110226\_00\_final Technische Änderungen und Irrtümer vorbehalten.

**Wasser intelligent nutzen.**

EnviroFALK PharmaWaterSystems GmbH | Maybachstraße 29 | 51381 Leverkusen | +49 2171 76750 | info@envirofalk-pharma.com | [envirofalk-pharma.com](http://envirofalk-pharma.com)