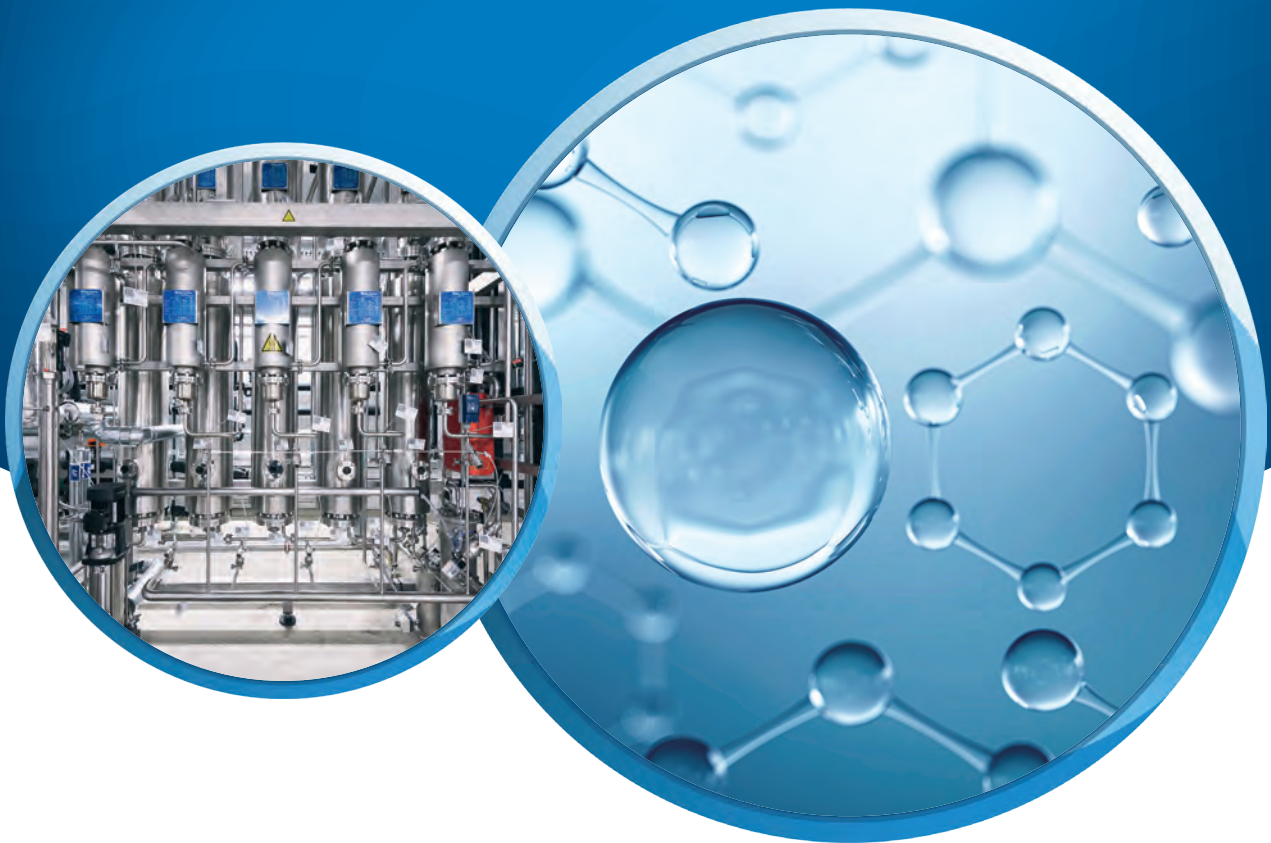


# WATER FOR INJECTION (WFI) PURIFIED WATER (AP)

Suitable for further processing  
in biopharmaceutical production



## HIGHLIGHTS

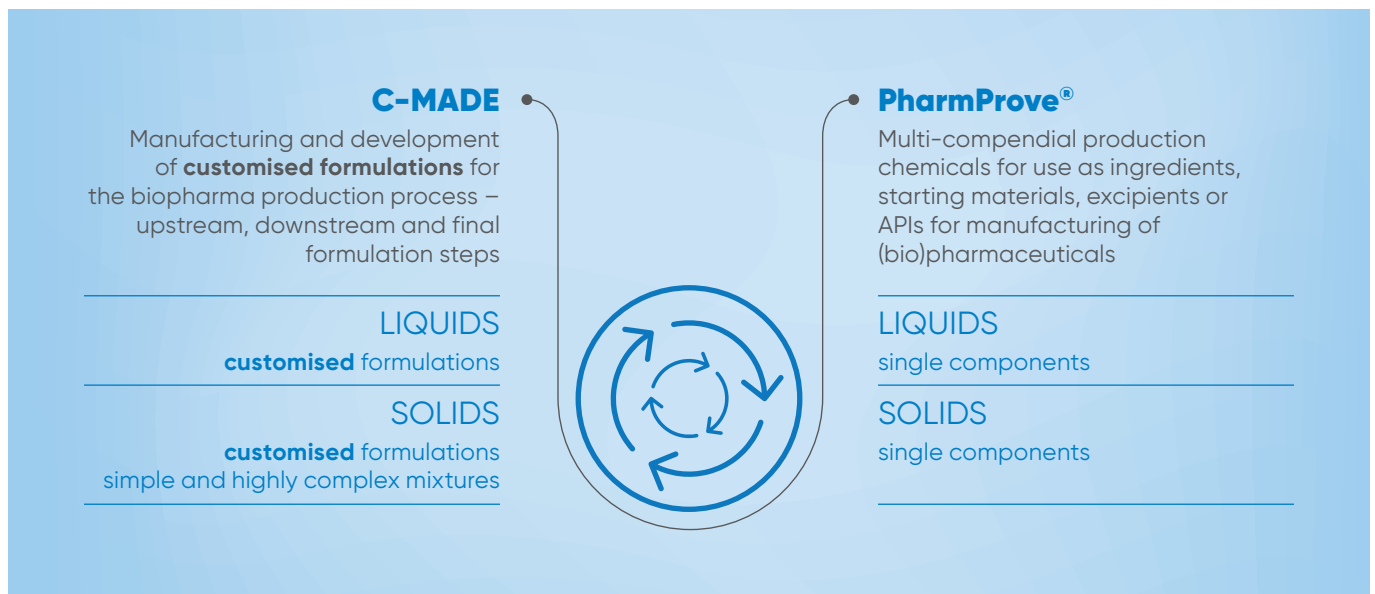
Audited partner of global pharma and biopharma companies	2D and 3D single-use bags ranging from 5 L - 1,000 L volume for water for injection (Wfi)
EU GMP-certified production facility	Storage and transport packaging for 2D and 3D single-use bags
Manufacturing authorisation according to §13 German Medicinal Products Act; cleanroom production according to ISO 7/8	Short-term availability
Various packaging for purified water ranging from 10 L - 1000 L	In-house GDP logistics and fleet
	"Made in Germany"

Your challenge - Our solution

# CG PHARMA & BIOTECH

We support your bio-manufacturing journey

As a leading developer, manufacturer and supplier of critical raw materials for biopharmaceutical manufacturers, CG Pharma & Biotech understands the complex challenges our partners face. We are your dedicated partner, providing reliable support from the start of development through to clinical phases and commercial production. Our commitment to the highest quality is reflected in our customised services and products, which are designed to seamlessly adapt to each client's individual requirements. Thanks to our modular approach, you have the flexibility to select and combine the solutions that perfectly fit your needs.



## UTILISING WATER FOR INJECTION (WFI) IN SINGLE-USE BAGS: ENSURING QUALITY AND CONVENIENCE IN BIOPHARMACEUTICAL APPLICATIONS



Using water for injection (Wfi) supplied in single-use bags offers several advantages compared to in-house Wfi generation. Firstly, it eliminates the need for complex and costly water purification systems, saving on capital investment and maintenance expenses. Additionally, using pre-packaged Wfi in single-use bags reduces the risk of contamination and human error associated with onsite generation, enhancing product safety.

The convenience of ready-to-use Wfi minimises downtime and speeds up production processes. This approach also allows for flexible scalability, as you can adjust the quantity of Wfi required without adjusting in-house equipment. Overall, utilising single-use bags for Wfi streamlines operations, ensures consistent quality and optimises resource utilisation.

# PREMIUM WATER

Meeting the highest quality standards in biopharmaceutical manufacturing

**At CG Pharma & Biotech, there are no compromises when it comes to quality. Highly pure water is an essential component of our portfolio, serving as an internal raw material source for the production of our GMP-compliant buffer and process solutions as well as a pure element itself.**

It is used for the cleaning of production equipment, in the manufacturing of cell culture media and in many other applications within the biopharmaceutical manufacturing process, both upstream and downstream. We have in-house production of **purified water (PW)** as well as **water for injection (Wfi)**. Our PW and Wfi quality meet the highest regulatory requirements and industry standards outlined in the European and United States pharmacopoeias (EP/USP).

Compliance with the specification limits from these pharmacopoeias is continuously monitored and ensured through in-process controls and the oversight of the quality unit. Our water qualities are manufactured at our GMP-certified

production facility in Germany. Moreover, this facility holds manufacturing authorisation according to AMG §13. Each produced batch is released for the market by our qualified person. We understand the critical importance of maintaining a steady supply of high-quality purified water (PW) and water for injection (Wfi) in biopharmaceutical processes. To ensure seamless production and flexibility for our clients, we offer substantial storage capacities for both PW and Wfi.

Our state-of-the-art storage facilities are designed to accommodate the specific needs of biopharmaceutical manufacturing. With advanced temperature control and monitoring systems, as well as adherence to stringent regulatory guidelines, we provide a secure environment for your water storage needs. Whether you require a reliable reserve of purified water for various stages of production or a readily available stock of water for injection, our storage capacities are tailored to your demands. This allows you to optimise your manufacturing processes and respond effectively to changes in demand.

## WE OFFER OUR WATER QUALITIES IN A FLEXIBLE RANGE OF PACKAGING OPTIONS

### PACKAGING OPTIONS FOR PURIFIED WATER (PW)

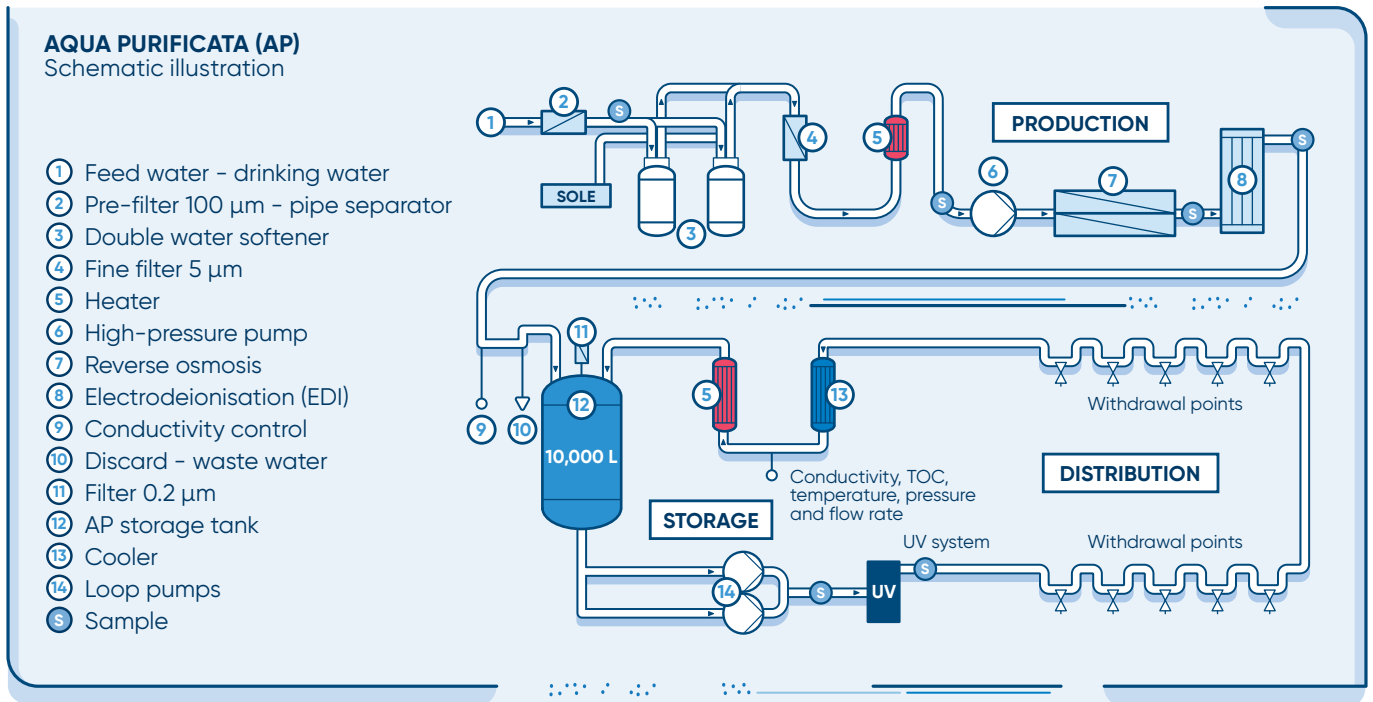
HDPE canisters: 10 L	HDPE canisters: 25 L	HDPE drums: 200 L	HDPE IBC (intermediate bulk container): 1,000 L
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### PACKAGING OPTIONS FOR WATER FOR INJECTION (WFI)

2D and 3D single-use bags ranging from 5 L - 1,000 L volume	Connector for main bag: MPC/MPX male
Customised bag design in collaboration with business partners	Connector for sample bag: Luer Female + Clave Connector
Preconfigured standard design available for fast-track development	Sterile filtration with 0.2 µm filter
Bag film material: multi-layered film (including ULDEP, LLDPE, EVOH, PE)	Storage and transport packaging for 2D and 3D single-use bags
Bag sterilisation: gamma irradiation (up to 25 kGy)	In-house development of the returnable plastic transport container: CG Tainer for bags ranging from 100 L - 1,000 L
Tubing material: TPE	

# PURIFIED WATER (AP)

Efficient production processes



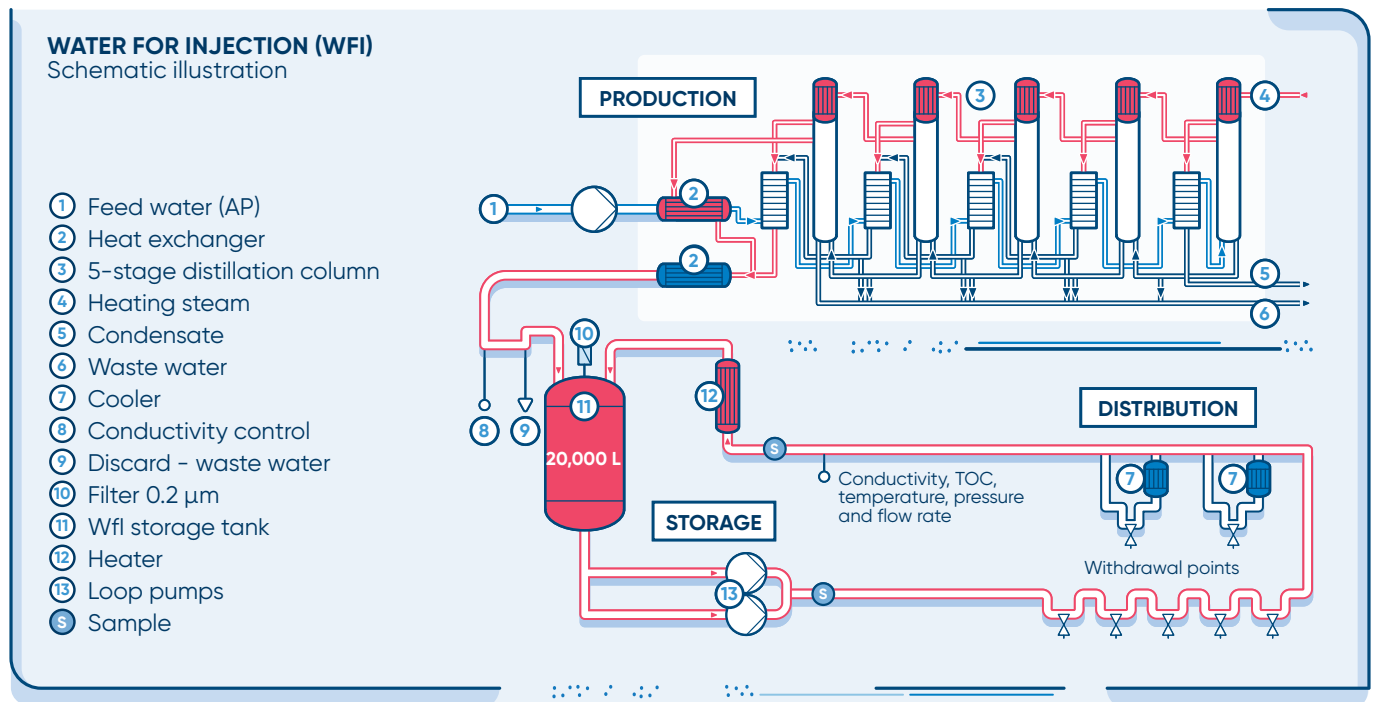
Our purified water, which is generated from drinking water through a process involving water softening, reverse osmosis and various filtration steps, serves as the source for the subsequent water for injection (Wfi) production.

PURIFIED WATER (AP)	
PARAMETER	ACCEPTANCE CRITERIA
Appearance	clear, colourless liquid
Conductivity (25 °C)	≤ 1.3 µS/cm
Nitrate	≤ 0.2 ppm
TOC	≤ 500 ppb
TAMC	≤ 100 CFU/mL
Bacterial endotoxins	< 0.25 I.E./mL
Acidic or alkaline reacting substances	passes
Oxidisable substances	passes
Chloride	passes
Sulphate	passes
Ammonia	≤ 0.2 ppm
Calcium, magnesium	passes
Residue of evaporation	≤ 0.001 %

PERFORMANCE
Production: 4,000 L/h
Storage tank: 10,000 L
Withdrawal volume: max. 7,000 L/h
Specification: (EP/USP)

# WATER FOR INJECTION (WFI)

Rigorous production processes



Our Wfi is generated from purified water (AP) through a 5-stage distillation column and a 0.2 µm filter. Throughout the entire process, the equipment used must be made of materials that are compatible with pharmaceutical-grade water and designed to minimise the risk of contamination. The production process is subject to rigorous validation and monitoring to ensure compliance with regulatory standards, such as those outlined in the European Pharmacopoeia (EP) or other relevant guidelines.

PERFORMANCE
Production: 500 L/h
Storage tank: 20,000 L
Withdrawal volume: max. 7,000 L/h
Specification: (EP/USP)

WATER FOR INJECTION (Wfi)	
PARAMETER	ACCEPTANCE CRITERIA
Appearance	clear, colourless liquid
Osmolality	0 - 1 mOsmol/kg
Conductivity (25 °C)	≤ 1.3 µS/cm
Bacterial endotoxins	< 0.25 I.E./mL
TOC	≤ 500 ppb
Nitrates	≤ 0.2 ppm
Sterility	sterile

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