

An Ingersoll Rand Business



**ENGINEERED FOR PURITY**

# Water for Injection (WFI) Quality Water

ILC Dover's WFI Quality Water is a high-purity solution manufactured in a cGMP-compliant USA facility and designed for pharmaceutical and biopharmaceutical applications.

# Pure. Compliant. Reliable.

ILC Dover's WFI Quality Water is produced and filled in a state-of-the-art facility in Lillington, NC, featuring:

- **ISO 9001:2015** Certified Quality Management System
- **ISO 13485:2016** Medical Device Quality Management System
- Compliance with 21 **CFR 820** cGMP Standards & FDA Registration
- **ISO 7 Cleanrooms** for Controlled Production Environments
- On-Site Analytical & Microbiology Testing for **Quality Assurance**



## Applications

ILC Dover's WFI Quality Water is designed for pharmaceutical and biopharmaceutical applications, ensuring unmatched purity, consistency, and compliance. Ideal for cleaning surfaces and equipment, preparing cell culture media and buffers, manufacturing high-purity aqueous reagents, and facilitating buffer exchange, our WFI Quality Water meets the highest standards.

## Consistent Quality

Our WFI Quality Water is 0.2µm sterile filtered at the fill time, ensuring the highest purity for pharmaceutical, biopharmaceutical, and diagnostic applications. Each batch undergoes rigorous quality control testing to maintain consistency and compliance with industry standards. Every WFI Quality Water includes testing per USP and a Certificate of Analysis (CoA) for full transparency and traceability.

**Note:** WFI Quality Water is for research and further manufacturing use only. Not for direct injection, ingestion or inhalation in humans or animals.

# Specifications & Compliance

## Purification & Dispensing Process

Our WFI Quality Water undergoes a rigorous multi-step purification process to ensure the highest purity and compliance:



**Purification:** Produced through steam distillation following reverse osmosis and deionization, then filtered through a 0.2-micron filter at the point of use—with no added substances.



**Filling:** Filled under validated conditions from a water system that meets current USP specifications.



**Quality Monitoring:** Routinely tested for conductivity, Total Organic Carbon (TOC), endotoxins, and bioburden to ensure consistency and compliance.

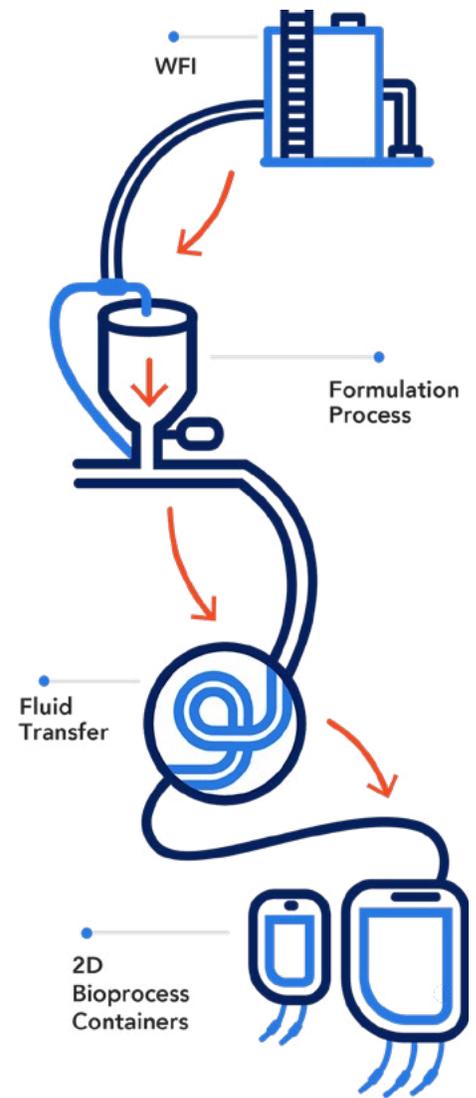
## Post-Production Details



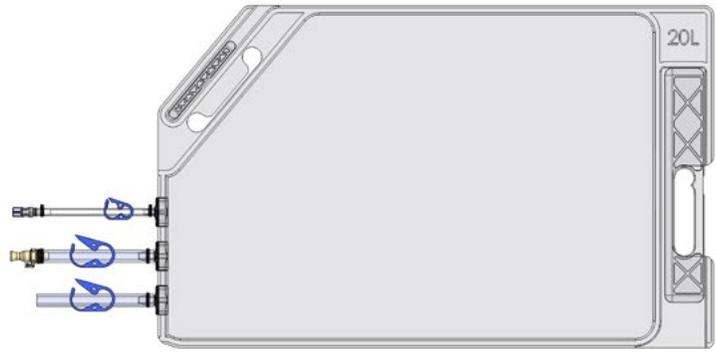
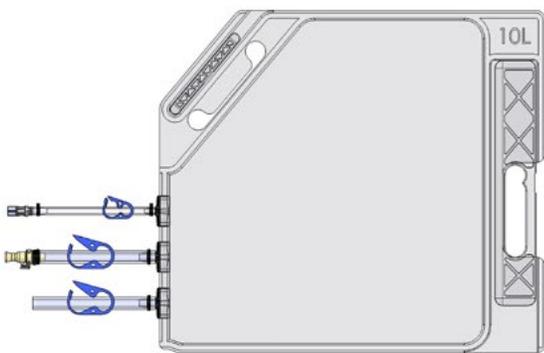
**Shelf Life:** 2 years from the date of manufacture, validated using IPEC Guideline principles for stability.



**Packaging Options:** Available in standard and custom packaging up to 1000 L or filled directly into specified containers.



Parameter	Limits	Units
<i>Batch Release Testing</i>		
TOC	≤500	Ppb
Conductivity	≤1.3	μS/cm
pH	5.0–7.0	—
Bioburden	≤10	CFU/100 mL
Endotoxin	<0.25	EU/mL



## Choose ILC Dover's WFI Quality Water

Trust ILC Dover for high-quality water that supports pharmaceutical and biopharmaceutical applications.



Scan the QR code to connect with ILC Dover for ordering details.

**Rapid turnaround available.**



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