

# WFI Quality Water

## WATER FOR INJECTION

Water for Injection (WFI) Quality Water is high purity water used for the preparation of cell culture media, buffers, and aqueous reagents. ILC Dover's WFI Quality Water is produced in a cGMP-compliant USA facility and meets monographs for USP, PhEur, and JP.



### APPLICATIONS:

WFI Quality Water is commonly used for:

- preparation of cell culture and buffers
- reconstituting dry reagents
- manufacturing high purity aqueous reagents
- rinsing critical equipment

### CONTAINERS:

WFI Quality Water can be provided in standard and custom packaging up to 1,000 L or filled directly into specified packaging. Sterile WFI is available in up to 1 L packages.

### PRODUCTION METHOD:

WFI Quality Water is prepared using a distillation still combined with upstream purification and 0.1 µm filtration, which results in an intrinsically safe WFI with less risk than other production methods.

WFI Quality water is manufactured in Durham, North Carolina, USA, in a facility that includes:

- ISO 9001:2005
- ISO 13485:2016 Quality Management Systems (QMS)
- compliance to 21 CFR 820 cGMP standards and FDA registration
- ISO 7 Cleanrooms
- on-site analytical and microbiology testing

## Quality

Every WFI Water includes:

- Testing according to USP, PhEur and JP monographs
- Certificate of Analysis (CoA)

# WFI Quality Water

## SPECIFICATIONS:

Assay	Specification	Method
Sterility	Pass	USP<71>, 21CFR610, EP (2.6.1), JP<4.06>
Endotoxin	<0.25 EU/mL	USP<85>, EP (2.6.14), JP<4.01>
Conductivity	≤ 5 μS/cm	USP<645>, EP Sterilized WFI, JP<2.51>
Oxidizable Substances	Conforms	USP/EP Sterile WFI
TOC	≤ 8000 ppb	USP<643>
Acidity or Alkalinity	Conforms	EP Sterilized WFI
Chlorides	Conforms	EP (2.4.4)
Nitrates	NMT 0.2 ppm	EP Sterilized WFI
Sulfates	Conforms	EP Sterilized WFI
Ammonium	NMT 0.2 ppm	EP Sterilized WFI
Calcium and Magnesium	Conforms	EP Sterilized WFI
Heavy Metals	NMT 0.1 ppm	EP (2.4.27)
Particulate Matter	Conforms	USP<788>, EP (2.9.19), JP<6.07>
Residue on Evaporation	NMT 0.003%	EP Sterilized WFI
Purity	Conforms	JP Sterile WFI in Containers
Extractable Volume	Conforms	JP<6.05>
Foreign Insoluble Matter	Conforms	JP<6.05>

ILC Dover is a world-leader in the innovative design and production of engineered single-use sterile packaging for pharmaceutical, biopharmaceutical, and cell and gene therapy industries. We are also a leading provider of Water for Injection and other liquid chemicals to biopharmaceutical, cell and gene therapy, medical device, and tissue banking industries. Our customers will attest to our relentless dedication to high value products, advanced technology, and responsive service.



ILC Dover LP  
100 Discovery Blvd,  
Suite 1001  
Newark, DE 19713 USA  
+1.302.335.3911  
+1.800.631.9567  
customer\_service@ilcdover.com  
[www.ilcdover.com](http://www.ilcdover.com)

