



**GeminiBio**  
Empowering cell culture  
and process liquid workflows

# High Purity Waters to Empower Your Workflow

**GeminiBio** enables the **life science** and **biotechnology industries** to improve productivity and speed.

**We Get You** - We understand that life science and biotechnology researchers, developers, and manufacturers require specialty waters to successfully complete their work. Our range of high purity waters are ready to tackle your most demanding manufacturing workflows.

## The Right Water for Your Workflow

GeminiBio offers a wide range of high purity water products to meet the requirements of your workflow. Our waters are manufactured in our 25,000 square foot ISO 13485:2016 certified and animal origin-free (AOF) liquid manufacturing facility and are available in multiple packaging configurations based on common industry standards. For customers with unique needs, GeminiBio offers custom manufacturing to meet unique packaging, testing, and/or lot size requirements.

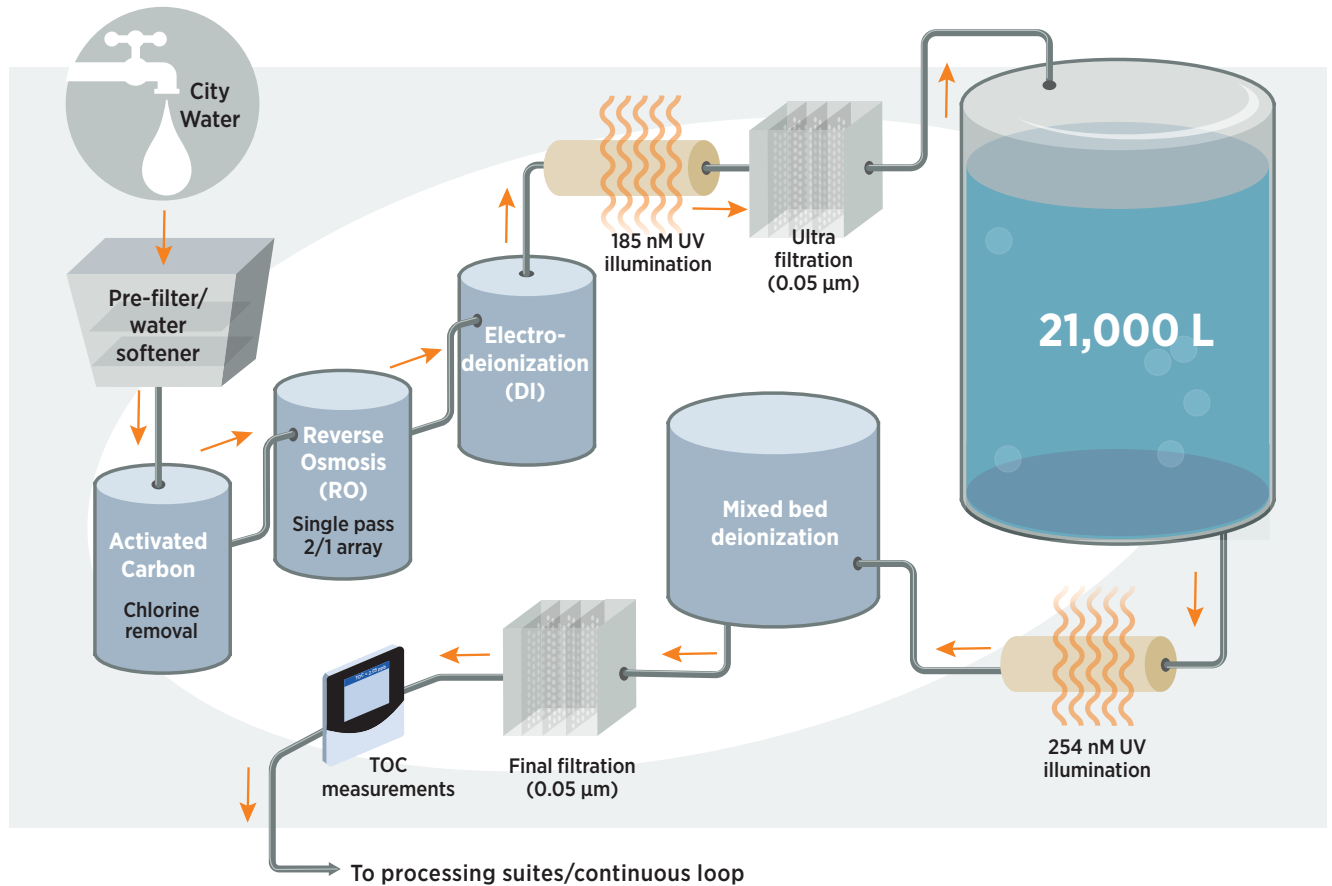


## GeminiBio High Purity Waters

- 💧 GemPure™ Plus Water For Injection (WFI) Quality Water (USP/EP/JP Grade)
- 💧 GemPure™ Select Water For Injection (WFI) Quality Water (USP Grade)
- 💧 GemPure™ Select Water For Irrigation (WFir) Quality Water (USP Grade)
- 💧 GemPure™ Select Purified Water, Sterile (USP Grade)
- 💧 GemPure™ Select Purified Water, Non-Sterile (USP Grade)
- 💧 GemPure™ Cell and Molecular Grade Water

# High Technology for High Quality

GeminiBio’s water system is a state-of-the-art reverse osmosis - water system producing  $\geq 18$  M $\Omega$ -cm water compliant with ASTM Type 1A\* water. GeminiBio’s ultrapure process water system generates water that exceeds Water For Injection (WFI) specifications and requirements, and meets USP, EP, and JP specifications for WFI quality water.\*\* Our WFI quality water manufacturing capacity exceeds 60,000 liters per day.



## Ultrapure water exceeds Water For Injection (WFI) requirements\*\*

Inline testing of GeminiBio’s Type 1A water demonstrates ultrapure quality compared to the requirements for Water For Injection (WFI) prior to packaging:

Analysis	GeminiBio	WFI
M $\Omega$ -cm	$\geq 18$	6
TOC (before packaging)	< 20 ppb	< 500 ppb

\* In-line Testing

\*\* Per USP <1231> Water for Pharmaceutical Purposes

# Waters for Life Sciences and Biotechnology

GeminiBio's GemPure™ waters are available in a wide range of packaging and testing options to support your research, development, or manufacturing workflows

Description	Water For Injection (WFI) Quality Water (USP/EP/JP Grade)	Water For Injection (WFI) Quality Water (USP Grade)	Water For Irrigation (WFIr) Quality Water (USP Grade)	Purified Water, Sterile (USP Grade)	Purified Water, Non-Sterile (USP Grade)	Cell and Molecular Grade Water
Grade	GemPure™ Plus	GemPure™ Select	GemPure™ Select	GemPure™ Select	GemPure™ Select	GemPure™
GeminiBio Product Code	901-002	901-001	901-003	901-005	901-006	901-004
TOC	●	●	●	●	●	●
Conductivity	●	●	●	●	●	●
Endotoxin	●	●	●			●
Sterility	●	●	●	●		●
Particulate Matter	●	●				
RNase DNase & Protease						●
Oxidizable Substances	●					
Ammonia	●					
Residue on Evaporation	●					
Acidity or Alkalinity	●					
Chlorides	●					
Nitrates	●					
Sulfates	●					
Calcium and Magnesium	●					
Heavy Metals	●					
Purity	●					
Extractable Volume	●					
Foreign Insoluble Matter	●					

WFI quality water that meets the needs of upstream and downstream bioprocessing and manufacturing.



# Water For Injection (WFI) Quality Water

**GeminiBio's ultrapure water is available in USP or multicompendial USP/EP/JP Grades for Water For Injection (WFI) Quality Water** packaged in bulk for commercial use. Our WFI quality water meets the needs of upstream and downstream bioprocessing and manufacturing applications and complies with the United States Pharmacopeia (USP), European Pharmacopeia (EP), and Japanese Pharmacopeia (JP) as indicated.

## GemPure™ Plus Water For Injection (WFI) Quality Water (USP/EP/JP Grade)

Meets the USP/EP/JP monograph for Water For Injection quality water packaged in bulk for commercial use.

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W484	901-002-4X4	GemPure™ Plus Water For Injection (WFI) Quality Water (USP/EP/JP Grade)	4L	HDPE Bottle	4/Case
CHM03W485	901-002-021		20L	Bioprocess Container (BPC)	1/Each
CHM03W486	901-002-203		200L	Bioprocess Container (BPC)	1/Each

## GemPure™ Select Water For Injection (WFI) Quality Water (USP Grade)

Meets the USP monograph for Water For Injection quality water packaged in bulk for commercial use.

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W487	901-001-5X6	GemPure™ Plus Water For Injection (WFI) Quality Water (USP/EP/JP Grade)	500mL	PET Bottle	6/Case
CHM03W488	901-001-1X6		1L	PET Bottle	6/Case
CHM03W489	901-001-011		10L	Bioprocess Container (BPC)	1/Each
CHM03W490	901-001-021		20L	Bioprocess Container (BPC)	1/Each
CHM03W491	901-001-103		100L	Bioprocess Container (BPC)	1/Each
CHM03W492	901-001-203		200L	Bioprocess Container (BPC)	1/Each

# Water For Irrigation (WFIr) Quality Water (USP Grade)

GeminiBio's Water For Irrigation (WFIr) Quality Water (USP Grade) is a sterile non-pyrogenic water produced by our proprietary water purification system. Manufactured and tested in compliance with the USP monograph for bulk packaged water for irrigation, **GemPure™ Select Water For Irrigation (WFIr) Quality Water (USP Grade)** is ideal for use in the manufacture and testing of medical devices, and applications where Water For Injection may not be appropriate.

## GemPure™ Select Water For Irrigation (WFIr) Quality Water (USP Grade)

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W493	901-003-5X6	<b>GemPure™ Select Water For Irrigation (WFIr) Quality Water (USP Grade)</b>	500mL	PET Bottle	6/Case
CHM03W494	901-003-1X6		1L	PET Bottle	6/Case
CHM03W495	901-003-021		20L	Bioprocess Container (BPC)	1/Each
CHM03W496	901-003-203		200L	Bioprocess Container (BPC)	1/Each

## Purified Water (USP Grade)

GeminiBio's **Purified Water (USP) Grade** is available in both Sterile and Non-Sterile presentations. GemPure™ Select Purified Water is manufactured and tested in accordance with USP monograph for Sterile Purified Water. Purified water is suitable in various non-parenteral applications including oral and topical products, non-active medical device manufacture and cleaning applications.

### GemPure™ Select Purified Water, Sterile (USP Grade)

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W497	901-005-1X6	GemPure™ Select Purified Water, Sterile (USP Grade)	1L	PET Bottle	6/Case
CHM03W498	901-005-021		20L	Bioprocess Container (BPC)	1/Each
CHM03W499	901-005-203		200L	Bioprocess Container (BPC)	1/Each

### GemPure™ Select Purified Water, Non-Sterile (USP Grade)

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W497	901-006-1X6	GemPure™ Select Purified Water, Non-Sterile (USP Grade)	1L	PET Bottle	6/Case
CHM03W498	901-006-C23		20L	Poly Cube	1/Each
CHM03W499	901-006-PD2		200L	Poly Drum	1/Each



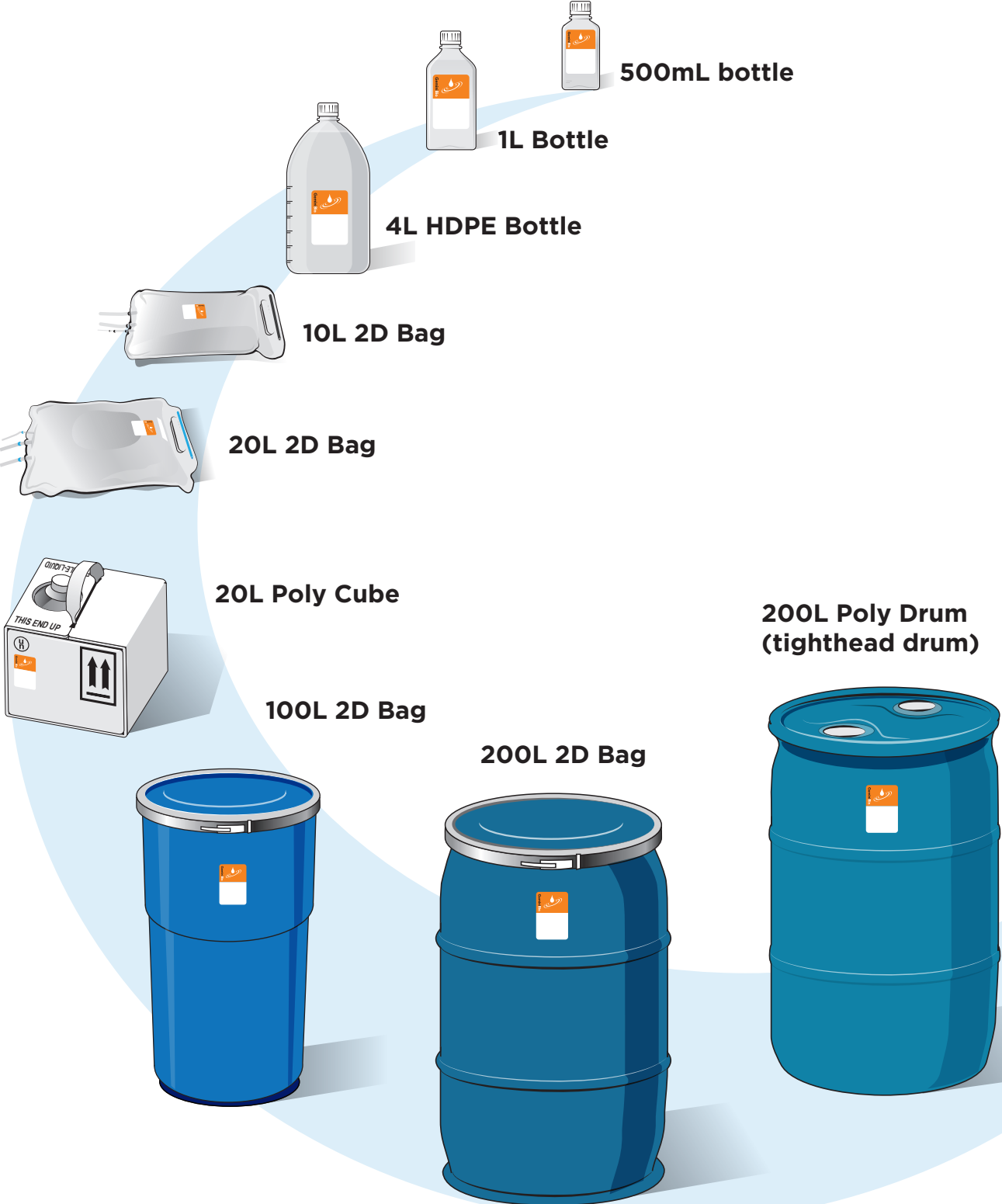
# Cell and Molecular Grade Water

GeminiBio's **Cell and Molecular Grade Water** is manufactured specifically for your most stringent research applications. GemPure™ Cell and Molecular Grade Water is sterile and low endotoxin for your cell culture processes. Protease and nuclease free, it is perfect for any of your molecular biology needs as well saving valuable lab space and simplifying your purchasing process.

## GemPure™ Cell and Molecular Grade Water

Thomas No.	Mfr. No.	Product	Size	Container Type	Pack Size
CHM03W503	901-004-1X6	GemPure™ Cell and Molecular Grade Water	1L	PET Bottle	6/Case











# GemPure™ Water Product Packaging Options Include:



# Integrated Quality Approach

Whether for research, development, or commercial production, our products are designed and manufactured to meet the stringent quality requirements of our customers.

To achieve our quality objectives, GeminiBio has developed and implemented a three tier **integrated quality approach** that includes: Certifications, Registrations & Compliance, Manufacturing Design, and Risk Management.

CERTIFICATIONS, REGISTRATIONS & COMPLIANCE	
 <p><b>ISO 13485:2016</b> The International Standard for a Quality Management System for Medical Devices. GeminiBio is a <b>Class 1 Medical Device Manufacturer</b></p>	 <p><b>21 CFR 820</b> FDA current Good Manufacturing Practice (cGMP) quality system regulation for medical devices.</p>
 <p><b>FDA Registered Facilities</b> Registration Number: 3006236690 / Owner Operator Number: 10058502</p>	 <p><b>USDA Registered Facility</b> Approved to export to the EU. Approval #: CA-TEC-0032</p>
MANUFACTURING DESIGN	
 <p><b>Animal Origin Free (AOF) Manufacturing Facility</b> AOF liquid manufacturing facility 0.25 miles from AO manufacturing facility</p>	 <p><b>Animal Origin (AO) Manufacturing Facility</b> Segregated human serum and animal component serum/media manufacturing suites</p>
 <p><b>Closed System Filling</b> Large volume liquid suites use closed system manifold filling for all bioprocess containers</p>	 <p><b>ISO 5 Aseptic Filling</b> Small volume liquid and AO suites use ISO 5 aseptic filling for bottles and bioprocess containers</p>
RISK MANAGEMENT	
 <p><b>Supplier Qualification Program</b> Focused program to qualify and manage supplier quality performance</p>	 <p><b>Change Management Program</b> Focused program to provide all stakeholders change notification</p>

Our quality system and processes are applied consistently across our product portfolio – spanning products used in research applications to products used in the manufacturing process for commercial biologic therapies.

# High Purity Waters to Empower Your Workflow

**GeminiBio** enables the life science and biotechnology industries to improve productivity and speed.



- 💧 **GemPure™ Plus Water For Injection (WFI) Quality Water**  
(USP/EP/JP Grade)
- 💧 **GemPure™ Select Water For Injection (WFI) Quality Water**  
(USP Grade)
- 💧 **GemPure™ Select Water For Irrigation (WFIr) Quality Water**  
(USP Grade)
- 💧 **GemPure™ Select Purified Water, Sterile**  
(USP Grade)
- 💧 **GemPure™ Select Purified Water, Non-Sterile**  
(USP Grade)
- 💧 **GemPure™ Cell and Molecular Grade Water**



**GeminiBio.**  
Empowering cell culture  
and process liquid workflows

**Thomas**  
Scientific



ThomasSci.com  
833.544.SHIP (7447)  
CustomerService@thomassci.com

Connect With Us:

