High Purity Water, Buffers and Custom Solution Manufacturing Services
1. SOFTENING - Ion Exchange Filter
2. ACTIVATED CARBON - Chlorine Removal
3. REVERSE OSMOSIS - Applied Pressure Filter
4. OZONATION - Disinfection
5. MIXED BED DEIONIZATION - Ion Exchange Resin
6. 254 NANOMETER UV TREATMENT - Disinfection
7. 185 NANOMETER UV TREATMENT - TOC Removal
8. 0.2UM MICRON FILTRATION - Terminal Filter
9. TERMINAL MULTI-EFFECT DISTILLATION - Evaporation & Condensation Capture
Discover the RMBIO difference.

Addressing the need for a nimble, responsive and cGMP solution provider, RMBIO has expanded our market presence with the commissioning of our state-of-the-art Salt Lake City, Utah manufacturing facility. Focused on the entirety of your work flow needs, our core product offering and custom production services are designed to meet your quality, timing and cost objectives.

Our cGMP and ISO 13485:2003 certified facility was custom designed and built to exceed stringent regulatory and customer expectations. At the heart of the operation is a cutting edge, 9 step, water-for-injection (WFI) purification system. Capable of producing in excess of 20,000 Liters per day, RMBIO offers a highly competitive core portfolio of USP water and USP saline for manufacturing and processing applications. Additional product offerings include ASTM, Cell Culture and Molecular Biology waters with recent expansion into buffered salt solutions. RMBIO strives to leverage our technology, business leadership and logistics to ensure our customers receive their exact needs, when they need it, at a competitive price point.
RMBIO
High Purity Water For Every Use

Water is widely used as a raw material, ingredient, and solvent in the processing, formulation, and manufacture of pharmaceutical products, active pharmaceutical ingredients (APIs), and intermediates, compendial articles, and analytical reagents.

RMBIO’s cGMP production process and release testing deliver products of unparalleled quality. From start to finish, RMBIO’s WFI production process follows cGMP guidelines so we can be certain it meets our own discerning quality standards. Our team of experienced scientists tests each lot of WFI quality water in our state-of-the-art lab so our customers can rely on absolute purity and unparalleled scientific results. Additionally all of our water products are available in multiple packaging configurations. Our standard sizes include 200L drums, 20L cubitainers, and 1L bottles, but we also work with customers to meet custom packaging design needs.
**WATER FOR INJECTION, USP/EP:** Our Terminally Distilled Water for Injection, multi-compendial USP/EP Grade, is a sterile, non-pyrogenic preparation which contains no bacteriostat, antimicrobial agent or added buffer. It complies with both United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) monographs for water for injection packaged in bulk for commercial use elsewhere.

**WATER FOR INJECTION, USP:** Our Terminally Distilled Water for Injection, USP, is a sterile, non-pyrogenic preparation which contains no bacteriostat, antimicrobial agent or added buffer. It complies with both United States Pharmacopoeia (USP) monographs for water for injection packaged in bulk for commercial use elsewhere.

RMBIO’s water system is fully validated with defined water quality standards including sampling and system controls. Our form of Water for Injection is prepared and stored in a manner that limits microbial introduction and growth.

**WATER FOR IRRIGATION, USP:** Our Water for Irrigation, USP is a sterile, hypotonic, non-pyrogenic fluid or solvent. It is prepared by distillation and contains no antimicrobial or bacteriostatic agents or added buffers. The pH is 5.7 (5.0-7.0) It complies with the United States Pharmacopoeia (USP) monograph for water for irrigation.

**CELL & MOLECULAR ULTRA PURE:** A universal ultra pure water for your most sensitive research applications. For your cell culture applications, this product is sterile and extremely low in endotoxin. It is suitable for media and reagent preparation. For your molecular biology applications, this water has been analyzed for the absence of nucleases and proteases. It is suitable for research investigations of nucleic acid and protein systems.

**PURIFIED WATER, USP:** Used as an excipient in the production of non-parenteral preparations and in other pharmaceutical applications, such as cleaning of certain equipment and non-parenteral product-contact components. Available in sterile and non-sterile formats, RMBIO’s products comply with the United States Pharmacopoeia (USP) monograph for purified water.

**MOLECULAR CERTIFIED:** Our Molecular Grade water is carefully quality tested and certified RNase, DNase, and protease free. We ensure every lot sent to our customers represents zero traces of toxic agents such as DEPC, and is well-suited for use in diverse molecular biology applications.

**ASTM TYPE II:** Our Type II grade of reagent water is prepared by distillation using a still designed to produce a distillate having a conductivity of less than 1.0 µS/cm at 298 K (25°C). It is further subdivided into class B as bacteria levels and endotoxin limits are tested and controlled.
# RMBIO

High Purity Water Lineup, Buffers, & Saline

<table>
<thead>
<tr>
<th>Description</th>
<th>Water for Injection, USP/EP</th>
<th>Water for Injection, USP</th>
<th>Sterile Water for Irrigation, USP</th>
<th>Cell &amp; Molecular Ultra Pure</th>
<th>Purified Water, USP Sterile</th>
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<tbody>
<tr>
<td>Standard Size</td>
<td>1L 4L 20L 200L</td>
<td>500ml 1L 20L 200L</td>
<td>1L 20L 200L</td>
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<td>1L 200L</td>
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<td>0.2UM Filtration</td>
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<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>TOC &lt;500ppb</td>
<td>●</td>
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<td>Conductivity</td>
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<td>●</td>
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<tr>
<td>Sterility</td>
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<tr>
<td>EP</td>
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<td>●</td>
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<tr>
<td>RNase, DNase, Protease Free</td>
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<td>●</td>
<td></td>
<td>●</td>
</tr>
<tr>
<td>ASTM</td>
<td>●</td>
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<td></td>
<td>●</td>
</tr>
<tr>
<td>Description</td>
<td>Purified Water, USP Non-Sterile</td>
<td>Molecular Grade Water</td>
<td>ASTM Type II Reagent</td>
<td>Sodium Chloride 0.9%, USP</td>
<td>Phosphate Buffered Saline (PBS) 1x, w/o Ca/Mg</td>
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<tr>
<td>Standard Size</td>
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RMBIO utilizes our state-of-the-art production facility to manufacture cGMP custom media, purification and process solutions.

Driven by our exacting customer applications, the need for the utmost quality and responsiveness, RMBIO has become recognized as a leading provider of cGMP bulk liquid manufacturing services. Whether your needs are relatively simple, or incredibly complex, think of RMBIO as your one-stop shop for high quality custom media, purification and process solutions. Utilizing our WFI system, validated filling operations and stringent quality program, we can support your solution needs from pilot scale to full production. Our facility and capabilities include:

- **2 x 3000L & 2 x 250L Pharmaceutical Stainless Process Tanks** (10,000L expansion in progress)
- **Rigorous Quality Systems:**
  - cGMP to FDA 21 CFR 820
  - ISO 13485:2003 Certified
  - FDA Registered
- **Multi-Compendial Raw Materials**
- **Batch to Batch Consistency**
Non-Animal Derived Component Facility

12,000 WFI Tank (20,000L WFI Daily Output)

Full Spectrum of Packaging Options
- Bioprocess Containers (BPC’s) 1L to 500L
- Rigid Bottles from 30ml to 4L
- Cubitainers- 5L, 10L, 20L
- 55gal drums to 275gal totes

Industry Leading Manufacturing Times (4-6 Weeks Typical)

ISO Classified Fill Suites

Full COA, SDS, BSE/TSE Statements
Common Process Liquids:

- Classical & Serum Free Media
- Biological Buffers
- Sugars & Carbohydrates
- Inorganic Salts
- pH controls
- Antifoam agents
- Surfactants
- Trace metals, vitamins
- Reducing agents
- Chelators
- Amino Acids
- Detergents
- Protease inhibitors
- Benzyl Alcohol in WFI
- Cleaning/Storage solutions
Addressing the increasing demand for cGMP media and buffer preparation, RMBIO has emerged as an innovative, responsive and value driven outsourcing partner. Utilizing our state-of-the-art manufacturing facility and WFI system, we manufacture custom formulations in a wide variety of packaging and delivery options allowing ease of integration into today’s diverse manufacturing platforms.

Upstream Expression Systems:
Solutions for Mammalian, Yeast, Insect and Bacterial production platforms

Downstream Purification Processes:
Solutions for Protein, Antibody and Cell/Gene Therapy workflows

Cell and Tissue Processing Solutions

Molecular Biology and Diagnostic Reagents

Medical Device Manufacturing/Processing Solutions