Water for Injection

Bulk Packaged WFI-Quality Water

Product Information

Bulk packaged for commercial use elsewhere, not for parenteral administration

Our WFI-Quality Water is aseptically processed from a validated Water For Injection System that meets current USP and EP specifications in the loop. Our WFI-Quality Water is not to be confused with Sterile Water for Injection which is intended for use in extemporaneous prescription compounding, and as a diluent for injectable parenteral products. We manufacture and test our Water For Injection (WFI)-quality products to strict industry standards. Prepared through a process of ultrafiltration, reverse osmosis, deionization, distillation and sterile filtration, we meet or exceed USP and EP requirements.

Benefits

- Highest quality standards: WFI-Quality Water is manufactured according to 21CFR820 guidelines
- Fast implementation: Flexsafe® bags can be used at every stage of the process for all applications
- Regulatory compliant: WFI-Quality Water is released based on EP and USP specifications
Derisking Media & Buffer Preparation by Outsourcing WFI-Quality Water

<table>
<thead>
<tr>
<th>Release Criteria</th>
<th>Specifications (at 25°C)</th>
<th>Test Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterility</td>
<td>Sterile</td>
<td>&lt;USP71&gt;</td>
</tr>
<tr>
<td>Conductivity</td>
<td>≤ 5.0 µS/cm</td>
<td>&lt;USP645&gt;</td>
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<tr>
<td>pH</td>
<td>5 to 7</td>
<td>&lt;USP791&gt;</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>&lt; 0.25 EU/ml</td>
<td>&lt;USP85&gt;</td>
</tr>
<tr>
<td>TOC*</td>
<td>&lt; 500 ppb in the loop**</td>
<td>&lt;USP643&gt;</td>
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* TOC: Total Organic Carbon
** 500 ppb is the requirement for water in the recirculating loop as specified in the European and US pharmacopeias

<table>
<thead>
<tr>
<th>Feature</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Packaged in Flexsafe® bags</td>
<td>Ready-to-use</td>
</tr>
<tr>
<td>Manufactured and released according to both EP</td>
<td>USP</td>
</tr>
<tr>
<td>Off-the-shelf 20L and 200L bags</td>
<td>Instant capacity increase</td>
</tr>
<tr>
<td>Standard and customized bag sizes and designs</td>
<td>Avoid CAPEX for installing onsite WFI loop and associated maintenance costs</td>
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</tbody>
</table>

Our dedicated team of Project Managers will help you select the best solution for the supply of your products and minimize the burden of transport logistics associated with large volumes of liquids.

**WFI and Buffers in Biologics Manufacturing**

All our liquid formulations are manufactured in ISO certified facilities following the strict guidelines and are packaged in our robust Flexsafe® bags. The complete range of scalable Flexsafe® bags enables you to implement single-use bioprocessing throughout all steps of drug manufacture, from process development to production – all using just one film.

- WFI Quality water
- Acids, Bases & Alcohols (HCl, NaOH, EtOH)
- Organic Solvents (Glycine, HEPES)
- Phosphate- and Amine-based (PBS, Tris)

**Your Customized Formulations**

Our buffer & media specialists will support you to create a solution that perfectly matches your expectations. For critical raw materials you can either request specific suppliers or rely upon our established global network of qualified suppliers. Customized primary and secondary packaging and release assays are also available upon request to our Media Project Managers.

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