High-Quality Gx® Glass Tubing for Pharmaceutical Packaging

www.gerresheimer.com
Gerresheimer is a leading global partner to the pharma and healthcare industry. With our specialty glass and plastic products, we contribute to health and well-being. We have worldwide operations and our 11,000 employees manufacture our products in local markets, close to our customers. With over 40 plants in Europe, North America, South America and Asia, we generate revenues of more than EUR 1.2 billion. Our comprehensive product portfolio includes pharmaceutical packaging and products for the safe, simple administration of medicines: Insulin pens, inhalers, prefillable syringes, injection vials, ampoules, bottles and containers for liquid and solid medicines with closure and safety systems as well as packaging for the cosmetics industry.
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As a vertically integrated manufacturer Gerresheimer focuses on the one hand on the production of high-quality glass tubes as primary products. On the other hand, syringe systems, cartridges, ampoules and vials are produced as primary packaging containers for the pharma and biotech industries.

- Extensive experience in both tubing and converting
- Borosilicate glass of the hydrolytic class I
- Risk mitigation addressed by multiple production sites around the world
- Production and packaging in accordance with cGMP requirements
In its two tubing production sites in Pisa (Italy) and Vineland, NJ (USA), Gerresheimer produces clear and amber borosilicate glass tubing of best hydrolytic quality. To meet our customers’ growing demand for highest quality performance we use state-of-the-art furnace technologies guaranteeing a homogeneous melting process which is checked by modern control systems and regular chemical analysis.

- Two tubing production sites
- 6 furnaces
- Clear and amber glass tubing
- Glass type I USP/EP/JP
- Expansion coefficient 33 and 51
- Diameters: 4 – 150 mm
- Wall weights: 0.18 – 8.00 mm
- Lengths: 1,050 – 3,500 mm
Glass composition and chemical resistance classification

### Glass Composition (approximate oxide weight [%])

<table>
<thead>
<tr>
<th>Oxide Component</th>
<th>Symbol</th>
<th>Gx®51-V</th>
<th>Gx®51-D</th>
<th>Gx®51-L (Amber)</th>
<th>Gx®33</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicon Dioxide</td>
<td>SiO₂</td>
<td>72.0</td>
<td>73.0</td>
<td>69.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Boron Oxide</td>
<td>B₂O₃</td>
<td>11.5</td>
<td>11.2</td>
<td>10.0</td>
<td>12.7</td>
</tr>
<tr>
<td>Aluminium Oxide</td>
<td>Al₂O₃</td>
<td>6.8</td>
<td>6.8</td>
<td>6.0</td>
<td>2.6</td>
</tr>
<tr>
<td>Calcium &amp; Magnesium Oxide</td>
<td>CaO + MgO</td>
<td>0.7</td>
<td>1.0</td>
<td>1.0</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Sodium Oxide</td>
<td>Na₂O</td>
<td>6.5</td>
<td>6.8</td>
<td>6.0</td>
<td>4.3</td>
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<tr>
<td>Potassium Oxide</td>
<td>K₂O</td>
<td>2.4</td>
<td>1.2</td>
<td>2.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Chlorine</td>
<td>Cl⁻</td>
<td>0.1</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Iron Oxide</td>
<td>Fe₂O₃</td>
<td>&lt;600 ppm(*)</td>
<td>&lt;400 ppm(*)</td>
<td>1.0</td>
<td>&lt;500 ppm(*)</td>
</tr>
<tr>
<td>Barium Oxide</td>
<td>BaO</td>
<td>&lt;400 ppm(*)</td>
<td>&lt;400 ppm(*)</td>
<td>1.5</td>
<td>&lt;400 ppm(*)</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>TiO₂</td>
<td>&lt;400 ppm(*)</td>
<td>&lt;300 ppm(*)</td>
<td>3.0</td>
<td>&lt;400 ppm(*)</td>
</tr>
</tbody>
</table>

(*) Not introduced in the batch composition

### Chemical Resistance Classification

<table>
<thead>
<tr>
<th>Resistance Class</th>
<th>Specification</th>
<th>Gx®51-V</th>
<th>Gx®51-D</th>
<th>Gx®51-L</th>
<th>Gx®33</th>
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<tr>
<td>Acid Resistance Class</td>
<td>DIN 12116</td>
<td>Class S1</td>
<td>Class S1</td>
<td>Class S1</td>
<td>Class S1</td>
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<tr>
<td>Alkali Resistance Class</td>
<td>ISO 695</td>
<td>Class A2</td>
<td>Class A2</td>
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<tr>
<td>ASTM Laboratory Glass Class</td>
<td>ASTM E 438</td>
<td>Class B</td>
<td>Class B</td>
<td>–</td>
<td>Class A</td>
</tr>
</tbody>
</table>
Vello and Danner –
two production technologies

Our range of technologies enables us to offer the best solution for each specific tubular glass product.
**Fully controlled and automated production process**

From raw material preparation up to the final packaging the Gerresheimer glass tubing production process is seamlessly integrated. An innovative process control monitors the entire production flow through built-in feedback loops and dedicated in-line and in-process inspections.

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**Traceability to a single bundle**

The Gerresheimer Bundle Label allows total traceability down to a single bundle.
In-line quality inspection

1. Cosmetic inspection system
   - 100% cosmetic inspection on all lines with automated reject
   - Camera and laser inspection
   - Circular coverage: 100%
   - Defect types: airlines, knots & stones

2. Dimensional inspection for OD/ID
   - 100% inspection on all lines with automated reject
   - Laser inspection for OD
   - Camera inspection for ID

3. Dimensional inspection for WT
   - 100% inspection with automated reject
   - One to four axes thickness measurement
   - Wall-siding measurement
   - More than 40 points measured per tube

4. SPC
   - IPC by shift quality inspectors
   - Final acceptance by QC
   - Cp/Cpk monitoring
Finishing and packaging

1. Gx Tekion System – Active particle prevention and removal

Tekion is a Gerresheimer patented system for the removal/reduction of glass particles
- Sharper and cleaner cut by H₂ burners
- Antistatic blow with ionized air
- Optimization of blow nozzle shape and parameters by CFD analysis

2. Tubing end finishing inspection
- Defect types: end cracks, cosmetic defects
- Inspection also for square cut and glaze ID
- Circular coverage: 100%

3. Fully automated packaging station
- Tubes are automatically stacked in single packs
- Compact bundles are formed using plastic shrink film
- Bundle labelling assures traceability
- Staggered bundle configuration reduces scratches
Converted glass products

Gx® Syringes

We supply a comprehensive range of prefilled syringe systems both as bulk products and in a ready-to-use format. These syringes under our leading trademark RTF® (Ready-to-Fill) are washed, siliconized, preassembled and sterilized (Ethyleneoxide). System components and accessories complete the range and ensure ease of use and end-user safety.

- Type I glass (compliant with Pharm. Eur./USP/JP)
- Wide range of pre-assembled needles

Gx® Cartridges

We are an approved supplier of cartridges for various pharmaceutical applications and we produce them in clear and amber (glass type I). All our cartridge lines are equipped with visual inspection systems for dimensional, cosmetic and glazed-end control. Final packaging is performed under controlled environmental conditions.

- Cartridges for pen systems, auto-injectors and needle-free injectors
- Insulin and dental cartridges

Gx® Ampoules

We make our many years of expertise in the field of pharmaceutical ampoules available to you as a highly competitive global supplier and partner. Even our standard range offers you a wide variety of high-quality ampoules. Several options complete this range and enable us to match the type and properties of our ampoules to your special requirements and needs beyond the ISO norms.

- Type I glass (Pharm. Eur./USP/JP compliant)
- Clear and amber glass ampoules

Gx® Vials

We offer a comprehensive range of vials in different designs, with or without blowback (European and American version) according to industry standards or to your individual specifications. State-of-the-art production processes and in-line camera inspection systems ensure high-performance in filling lines and lyophilization processes. Production and packaging are performed under cGMP conditions.

- Type I, II or III glass (Pharm. Eur./USP/JP/FEUM compliant)
- Pharmaceutical vials, diagnostic vials and special vials
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