# SPECIFICATION

**Acetic Acid, Glacial Ph. Eur.* / USP* / JP**

product code: 288

**Testing specifications:** Ph. Eur.* / USP* / JP* / LSM 288*

The material meets all requirements of Ph. Eur.*, USP* and JP*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Ph. Eur.*</th>
<th>USP*</th>
<th>JP*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specification</strong></td>
<td><strong>Specification</strong></td>
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</tr>
<tr>
<td>Assay</td>
<td>99.0 – 100.5%</td>
<td>99.5 – 100.5%</td>
<td>≥ 99.0%</td>
</tr>
<tr>
<td>Identification</td>
<td>A / B</td>
<td>conforms Acetate test</td>
<td>Acidity and Acetate</td>
</tr>
<tr>
<td>Appearance</td>
<td>clear / colourless</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Freezing point Ph. Eur.* / Congealing point JP* / Congealing temperature USP*</td>
<td>≥ 14.8°C</td>
<td>≥ 15.6°C</td>
<td>≥ 14.5°C</td>
</tr>
<tr>
<td>Reducing substances Ph. Eur./ Potassium permanganate reducing substances JP*</td>
<td>conforms</td>
<td>-</td>
<td>conforms</td>
</tr>
<tr>
<td>Readily oxidizable substances</td>
<td>-</td>
<td>conforms</td>
<td>-</td>
</tr>
<tr>
<td>Chloride(s)</td>
<td>≤ 25 mg/l</td>
<td>conforms</td>
<td>conforms</td>
</tr>
<tr>
<td>Sulfate(s)</td>
<td>≤ 50 mg/l</td>
<td>conforms</td>
<td>conforms</td>
</tr>
<tr>
<td>Iron</td>
<td>≤ 5 ppm</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Heavy metals</td>
<td>-</td>
<td>-</td>
<td>≤ 10 ppm</td>
</tr>
<tr>
<td>Residue on evaporation Ph. Eur.<em>/ Limit of non-volatile residue USP</em>/ Non-volatile residue JP*</td>
<td>≤ 0.01%</td>
<td>≤ 0.005% (m/V)</td>
<td>≤ 0.01% (m/V)</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>-</td>
<td>-</td>
<td>$d_{20}^2 \approx 1.049$</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Additional Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Specification</strong></td>
<td><strong>Method</strong></td>
</tr>
<tr>
<td>Assay (Freezing point / Congealing temperature)</td>
<td>≥ 99.9%</td>
</tr>
<tr>
<td>Aluminium</td>
<td>≤ 0.5 ppm</td>
</tr>
</tbody>
</table>

**Shelf life:** 36 months

**Manufacturer:** BP Chemicals Ltd.

**Manufacturing site:** Saltend, Hull (UK)

**Storage:** Store in air tight containers

*current version

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*Compiled by: 02.12.2019*

Dr. Anne Reiff
QA/QC-Manager

*Approved by:*

Dr. Philipp Hoch
QA/QC-Manager

*Released by:*

Dr. Frank Milek
Qualified Person (GMP)

*Effective:*

06.12.2019

*Supersedes:*

15.08.2019

Aug. Hedinger GmbH & Co. KG, Heiligenwiesen 26, D-70327 Stuttgart, phone:+49(0)711-402050, fax: +49(0)711-4020535 Page 1 of 2
SPECIFICATION

Acetic Acid, Glacial Ph. Eur.* / USP* / JP*  
product code: 288

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 288*  
The material meets all requirements of Ph. Eur.*, USP* and JP*

No plant or animal derived raw materials are used for the manufacture (no BSE risk); the material is not derived from GMO. Aflatoxin content exceeding the limits of the German Aflatoxin Directive is not expected because of the manufacturing process.

Residual solvents (ICH Q3C*):
The product complies with the requirements of the ICH Q3C* Residual Solvents Guideline: The class 2 solvent methanol as starting material for the synthesis can occur in trace amounts, but far from the stipulated limit. The class 3 solvents (except from acetic acid) that can occur in trace amounts are below 0.02%.

Elemental Impurities (ICH Q3D*):
At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities were below the level of 30% of the permitted concentrations for parenteral application according to table A.2.2 of the guideline ICH Q3D. More detailed information is available upon request.

Every batch is analysed according to all Ph. Eur.*, USP*, JP* and Additional Parameters of this specification. The Certificate of Analysis (CoA) provides all results like above including batch release date and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

*current version

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