Isopropyl Alcohol GMP Ph. Eur.* / USP* / JP*

Shell IPA-GMP®

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 070*
The material meets all requirements of Ph. Eur.*, USP* and JP*

Product code: 070

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**Parameter** | **Ph. Eur.*** | **USP*** | **JP*** | **Additional Specification** | **Test methods**
--- | --- | --- | --- | --- | ---
Assay (GC) | – | ≥ 99.0% (GC) | – | ≥ 99.80% | LSM 070*
Characters / Description | clear, colourless | – | conforms JP* | – | Ph. Eur.* / JP*
Identification | A / B / C | A (FT-IR) / B (GC) | conforms JP* | – | Ph. Eur.* / USP* / JP*
Specific gravity | d_{20}^{20} = 0.785-0.789 | d_{25}^{25} = 0.783-0.787 | d_{20}^{20} = 0.785-0.788 | – | Ph. Eur.* / USP* / JP*
Refractive index n_{20}^{20} | 1.376 – 1.379 | 1.376 – 1.378 | – | – | Ph. Eur.* / USP*
IR-Spectrum | conforms Ph. Eur.* | conforms USP* | – | – | Ph. Eur.* / USP*
Appearance | clear, colourless | clear solution | – | – | JP* (2.2.1/2.2.2)
Clarity of solution | – | – | – | – | APHA ≤ 5 | ASTM D1209
Color | – | – | – | – | ASTM D1078
Boiling point | – | – | 81 – 83 °C | ≥ 94% | Ph. Eur.* (2.2.12)
Distilling range | – | – | 81 – 83 °C | ≥ 94% | Ph. Eur.*
Acidity or alkalinity | ≤ 0.6 ml 0.01 N-NaOH | – | – | – | USP* / JP*
Acidity | – | ≤ 0.70 ml 0.02 N NaOH | conforms JP* | – | ASTM D1613
Acidity (Acetic acid) | – | – | – | ≤ 0.001% m/m | Ph. Eur.*
Absorbance | conforms Ph. Eur.* | – | – | – | ASTM D1078
Peroxides | conforms Ph. Eur.* | – | – | – | USP*
Non-volatile substances | ≤ 20 ppm =0.002% m/m | – | – | – | ASTM D1078
Limit of nonvolatile residue | – | ≤ 0.005% m/V | – | – | ASTM D1078
Residue on evaporation | – | ≤ 1.0 mg / 20.0 ml | – | – | ASTM D1078
Water | ≤ 0.5% | ≤ 0.5% | ≤ 0.75% m/V | ≤ 0.10% m/m | Ph. Eur.* / USP* / JP*

*meets excipient level
*current version

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Compiled by: 04.01.2017
Approved by: 04.01.2017
Released by: 09.01.2017
Effective: 09.01.2017
Supersedes: 23.11.2015

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<table>
<thead>
<tr>
<th>Parameter</th>
<th>Ph. Eur.*</th>
<th>USP*</th>
<th>JP*</th>
<th>Additional Specification</th>
<th>Test methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related substances:</td>
<td>GC, Σ ≤ 0.3 % V/V</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Ph. Eur.* / LSM 070*</td>
</tr>
<tr>
<td>Benzene</td>
<td>≤ 2 ppm V/V</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Ph. Eur.* / LSM 070*</td>
</tr>
<tr>
<td>Limits of volatile impurities:</td>
<td>-</td>
<td>Each individual: ≤ 0.1% Sum: ≤ 1.0 %</td>
<td>-</td>
<td>Sum: ≤ 0.3 %</td>
<td>LSM 070*</td>
</tr>
<tr>
<td>Acetone</td>
<td>-</td>
<td>≤ 0.1%</td>
<td>-</td>
<td>-</td>
<td>LSM 070*</td>
</tr>
<tr>
<td>2-Butanol</td>
<td>-</td>
<td>≤ 0.1%</td>
<td>-</td>
<td>-</td>
<td>LSM 070*</td>
</tr>
<tr>
<td>Diisopropyl ether</td>
<td>-</td>
<td>≤ 0.1%</td>
<td>-</td>
<td>-</td>
<td>LSM 070*</td>
</tr>
<tr>
<td>Diethyl ether</td>
<td>-</td>
<td>≤ 0.1%</td>
<td>-</td>
<td>-</td>
<td>LSM 070*</td>
</tr>
<tr>
<td>n-Propyl alcohol</td>
<td>-</td>
<td>≤ 0.1%</td>
<td>-</td>
<td>≤ 750 ppm (m/m)</td>
<td>LSM 070*</td>
</tr>
</tbody>
</table>

Packaging and storage: Preserve in tight containers and prevent exposure to excessive heat. Protect from light.

Shelf life: Analysis date plus 2 years

Manufacturer and manufacturing site: Shell Chemicals Europe B.V., NL-Rotterdam/Pernis

GMP compliance: The material is manufactured, filtered, transported, stored, repacked, tested and released according to IPEC-GMP Standard.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / CPMP/ICH/82 260/06):
No solvents of class 1 are used during manufacturing of Shell IPA-GMP®. Within the manufacturing process out of class 1 only benzene can occur in a concentration lower than 1 ppm. Solvents of class 2 and 3 can occur as by-products, but only in concentrations far below from the stipulated limits.

Every batch is analysed according to all parameters of this specification (except Description / Characters and Identification JP*). The Certificate of Analysis (CoA) provides all results above including analysis date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

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