## 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*

### Testing specifications:

- **Assay (GC)**: ≥ 99.0% (GC)
- **Characters / Description**: clear, colourless
- **Identification**: A / B / C (FT-IR) / B (GC)
- **Specific gravity**: $d_{20}^0 = 0.785-0.789$
- **Refractive index $n^0_D$$^\text{20}$**: 1.376 – 1.379
- **IR-Spectrum**: conforms Ph. Eur.*
- **Appearance**: clear, colourless
- **Clarity of solution**: –
- **Color**: –
- **Boiling point**: –
- **Distilling range**: 81 – 83°C
- **Acidity or alkalinity**: ≤ 0.6 ml 0.01 N-NaOH
- **Acidity**: ≤ 0.70 ml 0.02 N NaOH
- **Absorbance**: Steadily descending curve
- **Peroxides**: conforms Ph. Eur.*

### Test methods

- **Ph. Eur.* / USP* / JP**: LSM 070*
- **Ph. Eur.* / USP* / JP**:
- **Ph. Eur.* / USP* / JP**: Ph. Eur.*
- **Ph. Eur.* / USP* / JP**:
- **Ph. Eur.* / USP* / JP**: Ph. Eur.*
- **Ph. Eur.* / USP* / JP**:
- **Ph. Eur.* / USP* / JP**: ASTM D1209
- **Ph. Eur.* / USP* / JP**: Ph. Eur.*
- **Ph. Eur.* / USP* / JP**: ASTM D1078
- **Ph. Eur.* / USP* / JP**:
- **Ph. Eur.* / USP* / JP**: USP* / JP*
- **Ph. Eur.* / USP* / JP**: ASTM D1613
- **Ph. Eur.* / USP* / JP**: Ph. Eur.*

*meets excipient level
*current version

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

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### Table: Testing specifications

<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>Non-volatile substances</td>
<td>≤ 20 ppm = 0.002% m/m</td>
<td>–</td>
<td>–</td>
<td>≤ 10 ppm = 0.001% m/m</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td>Limit of nonvolatile residue</td>
<td>–</td>
<td>≤ 0.005% m/V</td>
<td>–</td>
<td>≤ 10 ppm = 0.001% m/m</td>
<td>USP*</td>
</tr>
<tr>
<td>Residue on evaporation</td>
<td>–</td>
<td>–</td>
<td>≤ 1.0 mg / 20.0 ml</td>
<td>≤ 10 ppm = 0.001% m/m</td>
<td>JP*</td>
</tr>
<tr>
<td>Water</td>
<td>≤ 0.5%</td>
<td>≤ 0.5%</td>
<td>≤ 0.75% m/V</td>
<td>≤ 0.10% m/m</td>
<td>Ph. Eur.* / USP* / JP*</td>
</tr>
<tr>
<td>Related substances:</td>
<td>GC, Σ ≤ 0.3% V/V</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Ph. Eur.* / LSO 070*</td>
</tr>
<tr>
<td>Benzene</td>
<td>≤ 2 ppm V/V</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Ph. Eur.* / LSO 070*</td>
</tr>
<tr>
<td>Limits of volatile impurities:</td>
<td>–</td>
<td>Each individual:</td>
<td>Sum: ≤ 0.3%</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>

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

**Shelf life:** Based on stability data the product may be stored as follows:
- bulk: 24 months from date of release
- drums: 24 months from date of release
- IBCs: 12 months from date of release
- Small containers ≤ 20l: 48 months from date of release

**Merchant 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.

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*current version

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**Compiled by:** 18.02.2020
**Approved by:** 03.03.2020
**Released by:** 04.03.2020
**Effective:** 15.03.2020
**Supersedes:** 05.12.2018

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Shell IPA-GMPx

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Product code: 070

BSE / TSE / GMO / Aflatoxins:
The material has no BSE / TSE risk, is not derived from GMO and complies with the German Aflatoxinverbots-Verordnung.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):
No solvents of class 1 are used during manufacturing of Shell IPA-GMPx. 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.

Elemental Impurities (Ph. Eur.* 5.20 / 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 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, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

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<tbody>
<tr>
<td>Dr. Katja Teufel</td>
<td>Dr. Anne Reiff</td>
<td>Dr. Frank Milek</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QC-Manager</td>
<td>QA-Manager</td>
<td>Qualified Person (GMP)</td>
<td></td>
<td></td>
</tr>
</tbody>
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