### Glycerol Ph. Eur.* / USP* 99.7 % (synth.)

OPTIM™ Glycerine 99.7% USP/EP

Product code: 091

Testing specifications: Ph. Eur.* / USP* / LSM 091*

The material meets all requirements of Ph. Eur.*, USP*, FCC*, 21 CFR 182.1320, (EU) No 231/2012 (E422)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purity</td>
<td>≥ 99.7 % (m/m)</td>
<td>GC, LSM 091*</td>
</tr>
</tbody>
</table>

#### Characters
- Viscous, colourless, clear very hygroscopic

#### Assay
- 98.0 – 101.0 %

#### Identification
- A / B / C

#### Appearance of solution
- Clear, colourless

#### Color
- Conforms USP*

#### Acidity or alkalinity
- ≤ 0.2 ml 0.1N NaOH

#### Esters (Ph. Eur.)*
- Conforms Ph. Eur.*

#### Fatty acids and esters (USP*)
- Conforms USP*

#### Halogenated compounds (Ph. Eur.*) / Limit of chlorinated compounds (USP*)
- ≤ 35 ppm

#### Aldehydes
- ≤ 10 ppm

#### Sugars
- Conforms Ph. Eur.*

#### Chloride(s)
- ≤ 10 ppm

#### Sulfate
- ≤ 20 ppm

#### Relative density (Ph. Eur.)
- \( d_{20}^{1.258} – 1.268 \)

#### Specific gravity (USP)
- \( d_{20}^{20} \geq 1.249 \)

#### Refractive index \( n_{D}^{20} \)
- \( 1.470 – 1.475 \)

#### Residue on ignition
- ≤ 0.01 % m/m

#### Sulphated ash
- ≤ 0.01 %

#### Water¹
- ≤ 2.0 %

#### Limit of diethylene glycol and ethylene glycol:
- DEG
- EG

#### Related compounds:
- Total impurities
- Any individual impurity

¹ The limits are given in the monographs; actually the product contains not more than 0.3% water.

*current version

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Compiled by: 27.02.2020

Approved by: 06.03.2020

Released by: 10.03.2020

Effective: 31.03.2020

Supersedes: 01.01.2019

Dr. Frank Milek
Qualified Person (GMP)
SPECIFICATION

Glycerol Ph. Eur.* / USP* 99.7 % (synth.)
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<tr>
<td>Impurity A and related substances:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ∑ Impurities with retention time &gt; retention time of glycerol</td>
<td>≤ 0.5 % m/m</td>
<td>Ph. Eur.*</td>
</tr>
<tr>
<td>- Each impurity with retention time &lt; retention time of glycerol</td>
<td>≤ 0.1 % m/m</td>
<td>—</td>
</tr>
<tr>
<td>- Diethylene glycol (Impurity A)</td>
<td>≤ 0.1 % m/m</td>
<td>—</td>
</tr>
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</table>

Storage: It is recommended to store the material in closed containers, below 30°C

Shelf life: 36 months packed in containers

Manufacturer and manufacturing site: Blue Cube Germany Assets GmbH & Co. KG, Stade (Germany)

Manufacturing process: synthetic, key raw material: epichlorohydrin

Regulatory compliance:

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

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C):
Based on the process knowledge only one Class 3 solvent is likely to be present. The level of this Residual Solvent is less than 100 ppm.

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.

Batch certification:
Every batch is analysed according to all parameters of this specification (except Characters). The Certificate of Analysis (CoA) provides all results like 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.

Application:
This product is not for use as a pharmaceutical excipient in parenteral and biopharmaceutical finished dosage forms. Hedinger accepts no liability for damages resulting from use as pharmaceutical excipient in parenteral and biopharmaceutical finished dosage forms.

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