

SPECIFICATION

Glycerol 85 % Ph. Eur.*

product code: 040

Testing specifications: Ph. Eur.* / LSM 040

The material meets all requirements of Ph. Eur.*

| Parameter | Ph. Eur.* | |
|--|---|--------------------------------|
| | Specification | Test method |
| Characters | conforms Ph. Eur.* | Ph. Eur.* |
| Identification | A / B / C / D | Ph. Eur.* |
| Appearance of solution | clear and colourless | Ph. Eur.* |
| Acidity or alkalinity | conforms Ph. Eur.* | Ph. Eur.* |
| Esters | ≥ 8.0 ml 0.1 N HCl | Ph. Eur.* |
| Halogenated compounds | ≤ 30 ppm | Ph. Eur.* |
| Sugars | conforms Ph. Eur.* | Ph. Eur.* |
| Aldehydes | ≤ 10 ppm | Ph. Eur.* |
| Chlorides | ≤ 10 ppm | Ph. Eur.* |
| Refractive index n_D^{20} | $n_D^{20} = 1.449-1.455$ | Ph. Eur.* |
| Sulphated ash | ≤ 0.01 % m/m | Ph. Eur.* |
| Water | 12.0 – 16.0 % m/m | Ph. Eur.* |
| Assay | 83.5 – 88.5 % m/m | Ph. Eur.* |
| Impurity A and related substances: <ul style="list-style-type: none"> - Σ Impurities with retention time > retention time of glycerol - Each impurity with retention time < retention time of glycerol - Diethylene glycol (Impurity A) | ≤ 0.5 % m/m ≤ 0.1 % m/m ≤ 0.1 % m/m | Ph. Eur.* |
| Additional Tests | | |
| Parameter | Specification | Test method |
| Specific gravity d_{20}^{20} | ----- | Ph. Eur.* |
| Starting materials tested according Ph. Eur.* and USP* | Specification | Test methods |
| Glycerol Ph. Eur.* / USP* 99.7% (synth.) | Ph. Eur.* / USP* | Methods of relating monographs |
| Purified Water Ph. Eur.* / USP* | Ph. Eur.* / USP* | Methods of relating monographs |

*current version

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|-------------------------------|---|------------|-------------|-------------|
| Compiled by: 06.12.2016 | Approved by: 30.12.2016 | Effective: | Supersedes: | Page 1 of 2 |
| Dr. Katja Dahms QC-Manager | Dr. Frank Milek Pharmacist, Qualified Person (GMP) | 01.01.2017 | 16.11.2015 | |

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

(OPTIM™ Glycerine 99.7% USP/EP):

Blue Cube Germany Assets GmbH & Co. KG,
Stade (Germany)

Purified Water Ph. Eur.* / USP* and blending: Aug. Hedinger GmbH & Co. KG

Manufacturing process: synthetic, key raw material: epichlorohydrin, Purified Water

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

Shelf life: 36 months packed in containers

The material has no BSE risk, is not derived from GMO and kosher.

Residual solvents (Ph. Eur.* 5.4 / CPMP/ICH/82 260/06):

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.

Every batch is analysed according to all parameters of this specification (except characters, identification C and D). The Certificate of analysis (CoA) provides all results like above plus analysis date, manufacturing date and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

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*current version

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|--|--|------------------------------|-------------------------------|-------------|
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