SPECIFICATION

Glycerol 85 % Ph. Eur.*

product code: 040

OPTIM™ Glycerine 99.7% USP/EP

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	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.*
Relative density d_{20}^{20}	d_{20}^{20} = 1.221 – 1.232	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: - ∑ 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.*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Starting materials	**Glycerol Ph. Eur.* / USP* 99.7% (synth.)** (OPTIM™ Glycerine 99.7% USP/EP) produced by Blue Cube Germany Assets GmbH & Co. KG, Stade (Germany) according to IPEC-PQG GMP guideline and tested acc. to Ph. Eur. and USP methods by Aug. Hedinger GmbH & Co. KG. **Purified Water Ph. Eur.* / USP*** produced by Aug. Hedinger GmbH & Co. KG according to EU-GMP and tested acc. to Ph. Eur. / USP methods by Aug. Hedinger GmbH & Co. KG.

*current version

Compiled by: 16.11.2018	Approved by: 23.11.2018	Released by: 29.11.2018	Effective:	Supersedes:
Dr. Philipp Hoch QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2019	10.01.2018

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OPTIM™ Glycerine 99.7% USP/EP

Testing specifications: Ph. Eur.* / LSM 040
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Process/Operation	Standard / Requirement
Manufacturing process	Final manufacturing steps, packaging, testing and release of the product are carried out by Aug. Hedinger GmbH & Co. KG
Supply chain	WHO – GTDP Guidelines for Pharmaceutical Starting Materials
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1,US cGMP)

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

Shelf life: 36 months packed in containers

Regulatory Compliance:

Manufacturing process:

Final manufacturing step, packaging, testing and release of the product are carried-out in compliance with EXCiPACT™ GMP.

BSE/GMO/Kosher Status:

Key raw materials for the production of Glycerol 85% Ph. Eur.* are Glycerol Ph. Eur.* / USP* 99.7% (synth.) (OPTIM™ Glycerine 99.7% USP/EP) and Purified Water Ph. Eur.* / USP*. Glycerol has been produced only from synthetic raw materials. No vegetable or animal derived precursors are used. Glycerol 85% Ph. Eur.* has no BSE/TSE risk, is not derived from GMO and is kosher.

Elemental impurities (Ph. Eur.* 5.20 / ICH Q3D*):

At least three independent batches of each starting material of Glycerol 85% Ph. Eur. were analysed for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities according to guideline ICH Q3D 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.

Residual solvents (Ph. Eur.* 5.4 / 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.

Batch certification:

Every batch is analysed according to all parameters of this specification (except Characters). The Certificate of Analysis (CoA) provides all test results including release date, manufacturing date and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP.

Application:

The product is only for use in non-parenteral and non-biopharmaceutical applications. Hedinger accepts no liability for damages resulting from use in parenteral and biopharmaceutical applications.

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Dr. Philipp Hoch QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2019	10.01.2018