

SPECIFICATION

Glycerol 85% Ph. Eur.*

product code: 040

(synthetic)

Testing specifications: Ph. Eur.* / LSM 040

The material meets all requirements of Ph. Eur.*

Parameter	Ph. Eur.*	
	Specification	Test method
Characters	conforms	Ph. Eur.*
Identification	A / B / C	Ph. Eur.*
Appearance of solution	clear and colourless	Ph. Eur.*
Acidity or alkalinity	conforms	Ph. Eur.*
Esters	≥ 8.0 ml 0.1 N HCl	Ph. Eur.*
Halogenated compounds	≤ 30 ppm	Ph. Eur.*
Sugars	conforms	Ph. Eur.*
Aldehydes	≤ 10 ppm	Ph. Eur.*
Chlorides	≤ 10 ppm	Ph. Eur.*
Refractive index n_D^{20}	1.449 – 1.455	Ph. Eur.*
Relative density d_{20}^{20}	1.221 – 1.232	Ph. Eur.*
Sulfated 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) 	<p style="text-align: center;">≤ 0.5% (m/m)</p> <p style="text-align: center;">≤ 0.1% (m/m)</p> <p style="text-align: center;">≤ 0.1% (m/m)</p>	Ph. Eur.*

Quality Assurance and Quality Control	
Process/Operation	Standard / Requirement
Starting materials	<p>Glycerol Ph. Eur.* / USP* 99.7% (synth.) 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.</p> <p>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.</p>
Manufacturing process	Final manufacturing steps, packaging, testing and release of the product are carried out by Aug. Hedinger GmbH & Co. KG in compliance with IPEC PQG-GMP Guidelines for Pharmaceutical Excipients.
Supply chain	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP]

*current version

Effective date: 01.04.2026
Supersedes version from: 03.12.2025

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Process/Operation	Standard / Requirement
Primary packaging material	Specified packaging materials from audited suppliers: 1 L amber glass bottles 5 L, 10 L, 20 L HDPE containers 200 L HDPE-steel combi-drums 640 L, 1000 L HDPE IBC 1000 L HDPE EVOH IBC

Storage: It is recommended to store the material in closed containers, storage temperature: 15 – 25 °C

Shelf life: 24 months from manufacturing date

Regulatory Compliance

Final manufacturing step, packaging, testing and release of the product are carried-out in compliance with IPEC PQG – GMP Guidelines for Pharmaceutical Excipients*.

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Dietary Laws, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) 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 test results including analysis date and manufacturing date. All CoAs are signed by a Qualified Person according to GMP.

*current version

Compiled by: 17.03.2026	Approved by: 18.03.2026	Released by: 25.03.2026	Effective:	Supersedes:
Dr. Katja Teufel QA-Manager	Dr. Stefan Heß QA-Manager	Elisabeth Bartel Qualified Person (GMP)	01.04.2026	03.12.2025