SPECIFICATION

Glycerol Ph. Eur.* / USP* (vegetable)

Product code: 250

Testing specifications: Ph. Eur.* / USP* / LSM 250*
The material meets all requirements of Ph. Eur.*, USP*, 21 CFR 182.1320, (EU) No 231/2012 (E422)

Parameter	Specification	Method
Purity	≥ 99.7% (m/m)	APAG-GL-009

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Characters	viscous, colourless, clear, very hygroscopic	Ph. Eur.*	—	—
Assay	98.0 – 101.0%	Ph. Eur.*	99.0 – 101.0%	USP*
Identification	A / B / C	Ph. Eur.*	A / B / C	USP*
Appearance of solution	clear, colourless	Ph. Eur.*	—	—
Color	—	—	conforms	USP*
Acidity or alkalinity	≤ 0.2 ml 0.1N NaOH	Ph. Eur.*	—	—
Esters (Ph. Eur.*) Fatty acids and esters (USP*)	conforms	Ph. Eur.*	conforms	USP*
Halogenated compounds (Ph. Eur.*) / Limit of chlorinated compounds (USP*)	≤ 35 ppm	Ph. Eur.*	≤ 30 ppm	USP*
Aldehydes	≤ 10 ppm	Ph. Eur.*	—	—
Sugars	conforms	Ph. Eur.*	—	—
Chloride(s)	≤ 10 ppm	Ph. Eur.*	≤ 10 ppm	USP*
Sulfate	—	—	≤ 20 ppm	USP*
Relative density (Ph. Eur.*) Specific gravity (USP*)	d_{20}^{20} 1.258 – 1.268	Ph. Eur.*	$d_{25}^{25} \geq 1.249$	USP*
Refractive index n_D^{20}	1.470 – 1.475	Ph. Eur.*	—	—
Residue on ignition	—	—	≤ 0.01%	USP*
Sulfated ash	≤ 0.01% (m/m)	Ph. Eur.*	—	—
Water[1]	≤ 2.0%	Ph. Eur.*	≤ 5.0%	USP*
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.*	—	—

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

*current version

Compiled by: 08.01.2024	Approved by: 11.01.2024	Released by: 11.01.2024	Effective:	Supersedes:
Manuel Eliete QA/QC	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	05.02.2024	01.10.2021

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Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Limit of diethylene glycol and ethylene glycol: - DEG - EG	—	—	 ≤ 0.10% ≤ 0.10%	USP*
Related compounds: - total impurities - any individual impurity	—	—	≤ 1.0% ≤ 0.1% each	USP*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at original manufacturer	EU-GMP Part II
Supply chain	EXCiPACT GMP / GDP
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	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions),US cGMP]

Storage: It is recommended to store the material in closed containers at not more than 25°C.

Shelf life: 24 months packed in containers

Manufacturing site: Oleon SAS, Rue les Rives de l'Oise, 60280 Venette, France

Manufacturing process: from crude glycerol of vegetable origin

Regulatory compliance

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients and EU-GMP Part II.

BSE/TSE / GMO / Kosher status / Aflatoxins:

The material has no BSE/TSE risk, is not derived from GMO, is kosher and complies with the limits of the German "Aflatoxin VerbotsV" (Aflatoxin prohibition directive).

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

The product complies with the requirements of the ICH Q3C* Residual Solvents Guideline: The class 2 solvent methanol can occur. Methanol content complies with ICH limit of 3000 ppm, with a typical value far below the stipulated limit.

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

The product complies with the requirements of the ICH Q3D* Guideline for Elemental Impurities in medicinal products (current edition) (Ph. Eur. 5.20).

Batch certification:

Every batch is analysed according to all parameters of this specification (except Characters and Purity). The Certificate of Analysis (CoA) provides all results 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.

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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