HEDINGER 1843 A pure decision.

SPECIFICATION

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

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)

Parameter	Specification	Method
Purity	≥ 99.7% (m/m)	GC, LSM 091*

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; actually the product contains not more than 0.3% water.

*current version

Compiled by: 23.03.2021	Approved by: 24.03.2021	Released by: 24.03.2021	Effective:	Supersedes:
Dr. Stefan Heß QA-Manager	Dr. Katja Teufel QC-Manager	Dr. Frank Milek Qualified Person (GMP)	01.04.2021	31.03.2020

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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	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients
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

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

Manufacturing process: synthetic, key raw material: epichlorohydrin

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.

BSE/TSE / GMO / Kosher status / Aflatoxins:

The material has no BSE/TSE 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.

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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 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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