HEDINGER 1843 A pure decision.

SPECIFICATION

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

OPTIM™ Glycerine 99.7% USP/EP **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*	USP*
Acidity or alkalinity	≤ 0.2ml 0,1N NaOH	Ph. Eur.*	—	—
Esters (Ph. Eur.*) Fatty acids and esters (USP*)	conforms Ph. Eur.*	Ph. Eur.*	conforms USP*	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.*	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*
Sulphated ash	≤ 0.01 % m/m	Ph. Eur.*	—	—
Water[1]	≤ 2.0 %	Ph. Eur.*	≤ 5.0 %	USP*
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*

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

*current version

Compiled by: 15.11.2018	Approved by: 19.11.2018	Released by: 23.11.2018	Effective:	Supersedes:
Dr. Philipp Hoch QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2019	18.09.2017

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Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
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.*	—	—

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:

BSE/GMO/Kosher status/Aflatoxins:

The material has no BSE 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.

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 like above including analysis date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

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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