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 / D	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*
Heavy metals	—	—	≤ 5 ppm	USP*
Specific gravity	—	—	$d_{25}^{25} \geq 1.249$	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*

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

*current version

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Compiled by: 14.09.2017	Approved by: 14.09.2017	Released by: 18.09.2017	Effective:	Supersedes:
Manuel Eliete QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	18.09.2017	01.01.2017

HEDINGER 1843 A pure decision.

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Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Related compounds: - total impurities - any individual impurity	—	—	≤ 1.0 % ≤ 0.1 % each	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.*	—	—

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.

Batch certification:

Every batch is analysed according to all parameters of this specification (except Characters and Ph. Eur.* Identification C and D). 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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