HEDINGER
1843
A pure decision.

CERTIFICATE OF ANALYSIS

Glycerol Ph. Eur. / USP (vegetable)

Testing specification: Ph.Eur.: 11.0; USP: 2023; LSM 250
The product meets all requirements of the listed pharmacopoeias
Product code: 250 **Batch: 250038**

Parameter / Method	Specification	Result
Identification B Ph.Eur./ Identification A USP IR	conforms	conforms
Identification A Ph.Eur. Refractive index	1.470 - 1.475	1.4738
Identification B USP - Limit of DEG and EG GC		
Diethylene glycol	max. 0.10 %	<0.10 %
Ethylene glycol	max. 0.10 %	<0.10 %
Identification C Ph.Eur. Relative density 20°C	1.258 - 1.268	1.2629
Identification C USP GC	conforms	conforms
Appearance of solution Ph.Eur.	clear and colourless	conforms
Color USP	conforms	conforms
Acidity or alkalinity Ph.Eur.	max. 0.2 ml 0.1 N NaOH	conforms
Esters Ph.Eur.	min. 8.0 ml 0.1 N hydrochloric acid	9.1 ml
Fatty acids and esters USP	conforms	conforms
Halogenated compounds Ph.Eur.	max. 35 ppm	conforms
Chlorinated compounds USP	max. 30 ppm	conforms
Aldehydes Ph.Eur.	max. 10 ppm	conforms
Sugars Ph.Eur.	conforms	conforms
Chloride(s) Ph.Eur./USP	max. 10 ppm	conforms
Sulfate USP	max. 20 ppm	conforms
Relative density 20°C Ph.Eur.	1.258 - 1.268	1.2629
Specific gravity 25°C USP	min. 1.249	1.2613
Residue on ignition USP	max. 5.0 mg/50g	0.4 mg/50g
Sulfated ash Ph.Eur.	max. 0.01 %	0.0007 %
Water Ph.Eur.	max. 2.0 %	0.171 %
Water USP	max. 5.0 %	0.171 %
Related compounds USP GC		
Total impurities	max. 1.0 %	<1.0 %
Any individual impurity	max. 0.1 %	<0.1 %
Impurity A, related substances Ph.Eur. GC		
Sum Impurities with RT > RT Glycerol	max. 0.5 %	<0.5 %
Each impurity with RT < RT Glycerol	max. 0.1 %	<0.1 %
Impurity A (Diethylene glycol)	max. 0.1 %	<0.1 %

Aug. Hedinger GmbH & Co. KG, Heiligenwiesen 26, D-70327 Stuttgart, T. +49 (0)711 402050, F. +49 (0)711 4020535

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Parameter / Method	Specification	Result
Assay Ph.Eur.	98.0 % - 101.0 %	99.2 %
Assay USP	99.0 % - 101.0 %	99.2 %

Manufacturer: Oleon SAS, Rue Les Rives de l'Oise F-60280 Venette, FRANCE

Date of manufacture: 22/01/2024
Analytical release: 31/01/2024
Delivery Date: asap
Net quantity: 1 x 1 liter

Supplier: Aug. Hedinger GmbH & Co. KG
D-70327 Stuttgart, GERMANY

Customer: Pharma Ltd.
12345 City, GERMANY
,

Shelf life: 24 months

Costumer order no.: 1234567, Hedinger order no.: 7654321
The product has no BSE/TSE risk, is not drived from GMO and complies with the german "Aflatoxinverbots-Verordnung".
The product is kosher.

The product is manufactured by Oleon SAS, Rue Les Rives de l'Oise, 60280 Venette, France. The CoA of the manufacturer is available on request.
Application: This product is not for use as a pharmaceutical excipient in parenteral and biopharmaceutial finished dosage forms. Hedinger accepts no liability for damages resulting from use as pharmaceutical excipient in parenteral and biopharmaceutical finished dosage forms.
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.

Residual solvents [ICH Q3C (current version)]:
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.

Elemental impurities [ICH Q3D (current version)]:
The product complies with the requirements of the ICH Q3D Guideline for Elemental Impurities in medicinal products (Ph. Eur. 5.20).

Hereby I confirm that this batch/lot has been analysed according to all listed tests. This CoA is only valid for originally sealed containers and tank trucks of Aug. Hedinger GmbH & Co. KG, Stuttgart labelled with the same batch/lot number. Copies of this CoA are not valid.

Product finally released.

Date:

Elisabeth Bartel, Pharmacist, Qualified Person acc. to EU-GMP

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