

CERTIFICATE OF ANALYSIS

Propylene Glycol Ph. Eur. / USP

Propylene Glycol USP/EP

Testing specification: Ph.Eur.: 11.6; USP: 2024; LSM 029

The product meets all requirements of the listed pharmacopoeias

Product code: 029

Batch: 0291178B

Parameter / Method	Specification	Result
Identity A USP / Identity D Ph. Eur. IR	conforms	conforms
Limit of DEG und EG USP GC		
Diethylene glycol	max. 0.10 %	<0.10 %
Ethylene glycol	max. 0.10 %	<0.10 %
Identification C USP GC	conforms	conforms
Appearance Ph.Eur.	clear and colourless	conforms
Relative density 20°C Ph.Eur.	1.035 - 1.040	1.0380
Specific gravity 25°C USP	1.035 - 1.037	1.0355
Refractive index Ph.Eur.	1.431 - 1.433	1.4329
Acidity USP / Ph. Eur.	max. 8.3 ml 0.01 N NaOH	conforms
Oxidising substances Ph.Eur.	max. 0.2 ml 0.05 N sodium thiosulfate sol.	conforms
Reducing substances Ph.Eur.	conforms	conforms
Chloride USP	max. 70 ppm	conforms
Sulfate USP	max. 60 ppm	conforms
Water Ph.Eur./USP	max. 0.2 %	0.010 %
Residue on ignition USP	max. 3.5 mg/50g	0.0 mg/50g
Sulfated ash Ph.Eur.	max. 0.01 %	0.0000 %
Ethylene glycol and diethylene glycol Ph.Eur. GC		
Ethylenglycol	max. 0.0620 % (= max. 620 ppm)	<0.0620 %
Diethylene Glycol	max. 0.10 %	<0.10 %
Assay USP GC	min. 99.5 %	99.9 %

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Additional Tests		
Parameter / Method	Specification	Result
Purity, Assay GC LSM 029		
Monoethylene Glycol	max. 0.01 %	<0.005 %
Diethylene Glycol	max. 0.01%	<0.005 %
1,3-Propanediol	max. 0.01 %	<0.005 %
1,2-Butanediol	max. 0.01 %	<0.005 %
Sum Di- & Tripropylene Glycol	max. 0.1 %	0.047 %
Purity, Assay Propylene Glycol	min. 99.80 %	99.94 %

The requirements of USP Identity B/C and Assay and the Ph. Eur. GC test Ethylene glycol and diethylene glycol are covered by internal validated GC method LSM 029.

Manufacturer: Dow Deutschland Anlagengesellschaft mbH, Buetzflether Sand D-21683 Stade, GERMANY
Date of manufacture: 25/11/2024
Analytical release: 02/12/2024
Delivery Date: 10.12.2024
Net quantity: 25 x 215 kg

Supplier: Aug. Hedinger GmbH & Co. KG
70327 Stuttgart
Customer: Pharma Ltd.
12345 City, GERMANY

Shelf life: 24 months after manufacturing date
 Customer order no.: 1234567, Hedinger order no.: 7654321

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Dietary Laws, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) is available upon request. (* = current version)

The material is manufactured, 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 Guidelines*. (* = current version)

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