HEDINGER
1843
A pure decision.

CERTIFICATE OF ANALYSIS

Acetic Acid, Glacial Ph. Eur. / USP / JP

Testing specification: Ph.Eur.: 11.0; USP: 2023; JP: 18; LSM 288
The product meets all requirements of the listed pharmacopoeias
Product code: 288 **Batch: 288020B**

Parameter / Method	Specification	Result
Identification A Ph.Eur.	conforms	conforms
Identification B Ph.Eur./USP	conforms	conforms
Identification JP	conforms	conforms
Appearance Ph.Eur.	clear and colourless	conforms
Specific gravity 20°C JP	~ 1.049	1.0511
Reducing substances Ph.Eur.	conforms	conforms
Readily oxidizable substances USP	conforms	conforms
Potassium permangenate reducing substances JP	conforms	conforms
Chlorides Ph.Eur.	max. 25 mg/L	conforms
Chloride USP/JP	conforms	conforms
Sulfates Ph.Eur.	max. 50 mg/L	conforms
Sulfate USP/JP	conforms	conforms
Iron Ph.Eur.	max. 5 ppm	conforms
Residue on evaporation Ph.Eur.	Ph.Eur.: max. 0.01%	0.0001 %
Limit of non-volatile residue USP/JP	USP: max. 1.0 mg / 20 ml JP: max. 1.0 mg / 10 ml	0.03 mg
Freezing point Ph.Eur./ Congealing temperature USP/ Congealing point JP	Ph.Eur.: min. 14.8°C / USP: min 15.6°C / JP: min. 14.5°C Additional requirement: min. 16.4°C	16.4 °C
Assay Ph.Eur.	99.0 - 100.5 %	99.8 %
Assay USP/JP	USP: 99.5 - 100.5% / JP: min. 99.0%	99.7 %

Additional Tests		
Parameter / Method	**Specification**	**Result**
Assay (Freezing point / Congealing temperature)	min. 99.9 %	99.9 %
Aluminium AAS LSM 288	max. 0.5 ppm	< 0,5 ppm

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Manufacturer:	INEOS Acetyls UK Limited, Saltend HU12 8DS Hull, GREAT BRITAIN		
Date of manufacture:	15/11/2023	**Supplier:**	Aug. Hedinger GmbH & Co. KG D-06179 Teutschenthal, GERMANY
Analytical release:	30/11/2023		
Delivery Date:	asap	**Customer:**	Pharma Ltd. 12345 City, GERMANY
Net quantity:	1 x 1 Liter		

Shelf life: 36 months from date of release in containers > 1 Liter /
24 months from date of release in 1 L HDPE containers

Customer order no.: 1234567, Hedinger order no.: 7654321

The CoA of the manufacturer is available on request.
The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients.

Residual solvents [ICH Q3C (current version)]:
The product complies with the requirements of the ICH Q3C Residual Solvents Guideline (current version): The class 2 solvent methanol as starting material for the synthesis can occur in trace amounts, but far from the stipulated limit. The class 3 solvents (except from acetic acid) that can occur in trace amounts are below 0.02%.

Elemental impurities [ICH Q3D (current version)]:
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.

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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