

CERTIFICATE OF ANALYSIS

Acetic Acid, Glacial 99% Ph. Eur. / USP / JP parenteral grade

Testing specification: Ph.Eur.: 11.0; USP: 2023; JP: 18; LSM 288/289

The product meets all requirements of the listed pharmacopoeias

Product code: 289

Batch: 289020

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 permanganate 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 %

Microbiological Specification		
Parameter / Method	Specification	Result
Bioburden (Sum TAMC/TYMC) Ph.Eur./USP/JP	max. 100 CFU/g	<1 CFU/g
Endotoxins Ph.Eur./USP/JP	max. 0.5 IU/mg	<0.5 IU/mg

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Additional Tests		
Parameter / Method	Specification	Result
Assay (Freezing point / Congealing temperature)	min. 99.9 %	99.9 %
Aluminium LSM 288	max. 0.5 ppm	< 0,5 ppm
Volatile impurities LSM 288/289 Acetic anhydride Methanol Acetone Methyl acetate	max. 100 ppm max. 100 ppm max. 100 ppm max. 100 ppm	<15 ppm <10 ppm 10 ppm <10 ppm

Manufacturer:	INEOS Acetyls UK Limited, Saltend HU12 8DS Hull, GREAT BRITAIN		
Manufacturer Lot-No.:	83920201	Supplier:	Aug. Hedinger GmbH & Co. KG
Date of manufacture:	15/11/2023		D-06179 Teutschenthal, GERMANY
Expiry Date:	05/12/2026	Customer:	Pharma Ltd.
Analytical release:	05/12/2024		12345 City, GERMANY
Date of repackaging:	16/02/2024		
Delivery Date:	asap		
Net quantity:	1 x 1 Liter		

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.

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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

sample