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SPECIFICATION

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

product code: 288

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 288*
The material meets all requirements of Ph. Eur.*, USP* and JP*

Parameter	Ph. Eur.*	USP*	JP*
	Specification	Specification	Specification
Assay	99.0 – 100.5%	99.5 –100.5%	≥ 99.0%
Identification	A / B	conforms Acetate test	Acidity and Acetate
Appearance	clear / colourless	-	-
Freezing point Ph. Eur.* / Congealing point JP* / Congealing temperature USP*	≥ 14.8°C	≥ 15.6°C	≥ 14.5°C
Reducing substances Ph. Eur.*/ Potassium permanganate reducing substances JP*	conforms	-	conforms
Readily oxidizable substances	-	conforms	-
Chloride(s)	≤ 25 mg/l	conforms	conforms
Sulfate(s)	≤ 50 mg/l	conforms	conforms
Iron	≤ 5 ppm	-	-
Heavy metals	-	-	≤ 10 ppm
Residue on evaporation Ph. Eur.*/ Limit of non-volatile residue USP*/ Non-volatile residue JP*	≤ 0.01%	≤ 1.0 mg / 20 ml	≤ 1.0 mg / 10 ml
Specific Gravity	-	-	$d\,^{20}_{20} \approx 1.049$

Parameter	Additional Parameters	
	Specification	Method
Assay (Freezing point / Congealing temperature)	≥ 99.9%	Freezing point / Congealing temperature
Aluminium	≤ 0.5 ppm	AAS LSM 288*

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

Storage: Store in air tight containers, storage temperature > 16 °C is recommended

Manufacturer: INEOS Acetyls UK Ltd.

Manufacturing site: Saltend, Hull (UK)

*current version

Compiled by: 25.07.2022	Approved by: 08.08.2022	Released by: 08.08.2022	Effective:	Supersedes:
Manuel Eliete QA-Expert	Dr. Katja Teufel QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.09.2022	01.11.2021

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Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production	ISO 9001:2015
Supply chain	EXCiPACT GMP / GDP
Analytical quality control	Full analysis of specification for each batch in a GMP laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP)

Regulatory compliance

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG-GMP Guidelines for Pharmaceutical Starting Materials.

Allergens:

Allergens listed in Regulation (EU) No 1169/2011 Annex II are not used during the manufacture, are not intentionally added or known to be present in the product.

Batch certification:

Every batch is analysed according to all Ph. Eur.*, USP*, JP* and Additional Parameters of this specification. The Certificate of Analysis (CoA) provides all results like above including batch release date and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

Elemental Impurities (Ph. Eur.* 5.20 / USP* <232> / ICH Q3D*):

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.

Nitrosamines:

A review of raw materials and processing aids used during manufacture of the product has not identified the use of either nitrosylating agents or secondary and tertiary amines. No recycled or recovered nitrogen substances are used in the manufacturing process which takes place in dedicated fully enclosed equipment.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

The product complies with the requirements of the ICH Q3C* Residual Solvents Guideline: 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%.

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