SPECIFICATION

Acetic Acid 80%
API grade

product code: 291

Testing specifications: LSM 291*

Parameter	Specification	Method	Specification	Method
Assay	79.2 – 80.4 %	Ph. Eur.*	79.2 – 80.4 %	USP*
Identification	A / B	Ph. Eur.*	conforms Acetate test	USP*
Appearance	clear / colourless	Ph. Eur.*	-	USP*
Reducing substances	conforms	Ph. Eur.*	-	USP*
Readily oxidizable substances	-	Ph. Eur.*	conforms	USP*
Chloride	≤ 25 mg/l	Ph. Eur.*	conforms	USP*
Sulfate	≤ 50 mg/l	Ph. Eur.*	conforms	USP*
Iron	≤ 5 ppm	Ph. Eur.*	-	USP*
Residue on evaporation Ph. Eur.* / Limit of non-volatile residue USP*	≤ 0.01%	Ph. Eur.*	≤ 0.005% (m/V)	USP*

Parameter	Additional Parameters	
	Specification	Method
Aluminium	≤ 0.5 ppm	AAS LSM 291*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Starting materials	**Acetic Acid, Glacial Ph. Eur.* / USP* / JP*** is produced by INEOS Acetyls UK Ltd., Saltend, Hull (UK), complies with Commission Regulation (EU) No 231/2012 (E260) and tested acc. to Ph. Eur., USP, JP methods by Aug. Hedinger GmbH & Co. KG. **Purified Water Ph. Eur.* / USP*** produced by Aug. Hedinger GmbH & Co. KG according to EU-GMP and tested acc. to Ph. Eur. and USP methods by Aug. Hedinger GmbH & Co. KG.
Manufacturing process	Final manufacturing step, packaging, testing and release of the product are carried out by Aug. Hedinger GmbH & Co. KG in compliance with EU-GMP part II.
Supply chain	WHO – GTDP Guidelines for Pharmaceutical Starting Materials
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Manufacturing and packaging	Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1,US cGMP)

*current version.

Ph. Eur. and USP tests are performed as the tests in the Acetic Acid, Glacial monographs: The amount of Acetic Acid 80% is increased to apply the same amount of Acetic Acid, Glacial as required by the test methods in Ph. Eur. and USP.

Compiled by: 23.03.2021	Approved by: 23.03.2021	Released by: 23.03.2021	Effective:	Supersedes:
Dr. Anne Reiff QA Manager	Dr. Katja Teufel QC-Manager	Dr. Frank Milek Qualified Person (GMP)	01.04.2021	05.04.2019

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Shelf life: 24 months packed in containers

Storage: Store in air tight containers

Regulatory Compliance

Manufacturing, packaging, testing and release of the product are carried out in compliance with EU-GMP part II.

BSE/TSE / GMO / Aflatoxin Status:

Key raw materials are Acetic Acid and Purified Water. Acetic Acid has been produced only from synthetic raw materials. No vegetable or animal derived precursors are used. Acetic Acid 80% API grade has no BSE/TSE risk and is not derived from GMO. Aflatoxin content exceeding the limits of the German Aflatoxin Directive is not expected because of the manufacturing process.

Residual solvents (ICH Q3C*):

The product complies with the requirements of the ICH Q3C* Residual Solvents Guideline: Methanol as starting material for the synthesis of acetic acid can occur in trace amounts, but the concentrations are far below the stipulated limits.

Elemental impurities (Ph. Eur.* 5.20 / ICH Q3D*):

At least three independent batches of each starting material of Acetic Acid 80% API grade were analysed by Hedinger 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.

Batch certification:

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

*current version.

Ph. Eur. and USP tests are performed as the tests in the Acetic Acid, Glacial monographs: The amount of Acetic Acid 80% is increased to apply the same amount of Acetic Acid, Glacial as required by the test methods in Ph. Eur. and USP.

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