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*

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.

Additional Parameters		
Parameter	**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 is tested acc. to Ph. Eur., USP and 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.
Final manufacturing steps and supplier	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control at final manufacturer	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release at final manufacturer	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Manufacturing and packaging at final manufacturer	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP (as applicable)]
Primary packaging material at final manufacturer	Specified packaging materials from audited suppliers: 1 L Amber glass bottles 5 L, 10 L HDPE containers 200 L HDPE drums 1000 L HDPE EVOH Intermediate bulk containers

*current version

Effective date: 20.10.2026
Supersedes version from: 01.04.2021

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Storage:	Keep container tightly closed in a dry, cool and well-ventilated place.
Shelf-life:	24 months from date of release The specified shelf-life relates to originally closed containers.
Final manufacturing steps and supplier:	Aug. Hedinger GmbH & Co. KG, 06179 Teutschenthal, Germany

Regulatory Compliance

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.

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.

Batch certification:

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results including analysis date and date of manufacture. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

*current version.

Compiled by: 22.09.2026	Approved by: 22.09.2026	Released by: 25.09.2026	Effective:	Supersedes:
			20.10.2026	01.04.2021
Dr. Katja Teufel QA Manager	Dr. Stefan Heß QA-Manager	Elisabeth Bartel Qualified Person (GMP)		