HEDINGER 1843 A pure decision.

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%	≤ 0.005% (m/V)	≤ 0.01% (m/V)
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: 36 months

Manufacturer: BP Chemicals Ltd.

Manufacturing site: Saltend, Hull (UK)

Storage: Store in air tight containers

*current version

Compiled by: 13.08.2019	Approved by: 13.08.2019	Released by:	Effective:	Supersedes:
Dr. Anne Reiff QA/QC-Manager	Dr. Katja Teufel QC-Manager	Dr. Frank Milek Qualified Person (GMP)	15.08.2019	31.01.2019

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No plant or animal derived raw materials are used for the manufacture (no BSE risk); the material 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: 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 0.05%.

Elemental Impurities (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.

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.

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