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SPECIFICATION

Acetic Acid, Glacial Ph. Eur.* / USP* / JP* parenteral grade product code: 289

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 288* / LSM 289*
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*
Acetic anhydride	≤ 100 ppm	GC LSM 288* / 289*

Microbiological Specification		
Parameter	**Specification**	**Method**
Bioburden (∑ Total aerobic microbial count + Total yeast mould count)	≤ 100 CFU/ml	Ph. Eur.* 2.6.12 / USP* <61> / JP*
Endotoxins	≤ 0.5 IU/mg	Ph. Eur.* / USP* / JP* (LAL, kinetic-turbidimetric method)

*current version

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

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Residual solvents		
Parameter	**Specification**	**Method**
Methanol	≤ 100 ppm	GC LSM 288* / 289*
Acetone	≤ 100 ppm	GC LSM 288* / 289*
Methyl acetate	≤ 100 ppm	GC LSM 288* / 289*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients
Supply chain	WHO – GTDP Guidelines for Pharmaceutical Starting Materials
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	Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP)
Packaging	Extended supervision of repackaging process by head of manufacturing
Primary packaging material	Specified packaging materials from audited suppliers: 1 L, 2.5 L amber glass bottles 5L, 10L HDPE containers 200 L HDPE drums 1000 L HDPE EVOH Intermediate Bulk Container with diffusion barrier (electrostatically safe)
Labelling of seal caps	Labelling with filling date and batch no.
Packaging material reconciliation	Full seal cap and label reconciliation
End control of filled containers	First and last container of filling process (freezing point)

Shelf life: 36 months
Manufacturer: BP Chemicals Ltd.
Manufacturing site: Saltend, Hull (UK)
Storage: Store in air tight containers

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.

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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 (Ph. Eur.* 5.20 / 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 (except Characters / Description) 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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