SPECIFICATION

Acetic Acid, Glacial Ph. Eur.* / USP* / JP* parenteral grade product code: 224

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 223* / LSM 224*
The material meets all requirements of Ph. Eur.*, USP* and JP*

Parameter	Ph. Eur.*		USP*		JP*	
	Specification	Method	Specification	Method	Specification	Method
Characters Ph. Eur.* / Description JP*	conforms	Ph. Eur.*	-	-	conforms	JP*
Assay	99.0 – 100.5 %	Ph. Eur.*	99.5 –100.5%	USP*	≥ 99.0 %	JP*
Identification	A / B	Ph. Eur.*	conforms Acetate test	USP*	Acidity and Acetate	JP*
Appearance	clear / colourless	Ph. Eur.*	-	-	-	-
Freezing point Ph. Eur.* / Congealing point JP* / Congealing temperature USP*	≥ 14.8 °C	Ph. Eur.*	≥ 15.6 °C	USP*	≥ 14.5 °C	JP*
Reducing substances Ph. Eur.* / Potassium permanganate reducing substances JP*	conforms	Ph. Eur.*	-	-	conforms	JP*
Readily oxidizable substances	-	-	conforms	USP*	-	-
Chloride(s)	≤ 25 mg/l	Ph. Eur.*	conforms	USP*	conforms	JP*
Sulfate(s)	≤ 50 mg/l	Ph. Eur.*	conforms	USP*	conforms	JP*
Iron	≤ 5 ppm	Ph. Eur.*	-	-	-	-
Heavy metals	-	-	≤ 5 ppm	USP*	≤ 10 ppm	JP*
Residue on evaporation Ph. Eur.* / Limit of non-volatile residue USP* / Non-volatile residue JP*	≤ 0.01 %	Ph. Eur.*	≤ 0.005 % (m/V)	USP*	≤ 0.01 % (m/V)	JP*
Specific Gravity	-	-	-	-	$d\ ^{20}_{20} \approx 1.049$	JP*

Parameter	Additional Parameters (by Hedinger)	
	Specification	Method
Assay (Freezing point / Congealing temperature)	≥ 99.9 %	Freezing point/Congealing temperature
Aluminium	≤ 0.5 ppm	AAS LSM 223*
Acetic anhydride	≤ 100 ppm	GC LSM 223 / 224

*current version
**typical value, should not be interpreted as specification

Compiled by: 06.12.2016	Approved by: 16.12.2016	Released by: 23.12.2016	Effective:	Supersedes:
Dr. Katja Dahms QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2017	31.10.2016

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Property	Typical Properties** (by Wacker)	
	Typical Value	Method
Color Hazen (APHA)	≤ 5	ISO 6271

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)

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 0.02%.

Residual solvents		
Parameter	**Specification**	**Method**
Methanol	≤ 100 ppm	GC LSM 223 / 224
Acetone	≤ 100 ppm	GC LSM 223 / 224
Methyl acetate	≤ 100 ppm	GC LSM 223 / 224

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)

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Shelf life:	36 months
Manufacturer:	Wacker Chemie AG
Manufacturing site:	Burghausen (Germany)
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.

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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