HEDINGER 1843 A pure decision.

SPECIFICATION

Acetone Ph. Eur.* / USP-NF*

Testing specifications: Ph. Eur.* / USP-NF* / LSM 011

The material meets all requirements of Ph. Eur.* and USP-NF* **Product code: 011**

Parameter	Ph. Eur.*	USP-NF*	Additional Specification	Test method
Assay (GC)	–	≥ 99.0%	≥ 99.7%	LSM 011
Identification	A / FT-IR	A / B[1]	-	Ph. Eur.*/USP-NF*
Appearance of solution	clear, colourless	–	–	Ph. Eur.*
Colour of substance	–	–	APHA ≤ 5	ASTM D1209
Acidity or alkalinity	conforms	–	–	Ph. Eur.*
Relative density / Specific gravity	d_{20}^{20} = 0.790 – 0.793	d_{25}^{25} ≤ 0.789	-	Ph. Eur.*/USP-NF*
Refractive index n_D^{20}	–	–	1.358 – 1.360	Ph. Eur.* (2.2.6)
Matter insoluble in water	clear solution	–	–	Ph. Eur.*
Reducing substances / Readily oxidizable substances	conforms	conforms	_	Ph. Eur.*/USP-NF*
Residue on evaporation / Non-volatile residue	≤ 50 ppm	≤ 0.004% (m/V)	≤ 0.001% (m/V)	Ph. Eur.*/USP-NF*
Water	≤ 0.3% (m/V)	≤ 0.5% (V/V)[2]	≤ 0.20% (m/m)	Ph. Eur.*/ LSM011
Related substances:				
Benzene	≤ 2 ppm (V/V)	–	≤ 2 ppm (m/m)	Ph. Eur.*/ LSM011
Isopropyl alcohol	≤ 0.05% (V/V)			
Methanol	≤ 0.05% (V/V)			
Any other impurity	each ≤ 0.05% (V/V)			

[1]The requirements of the USP-NF* parameter 'Identification B' are covered by internal validated GC method LSM 011.

[2]The requirements of the USP-NF* parameter 'Water' are covered by internal validated Karl-Fischer-titration method LSM 011.

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production at original manufacturer	ISO 9001:2015
Supply chain	EXCiPACT GMP / GDP
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)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1 (classification and operating conditions), US cGMP]

*current version

Compiled by: 10.10.2022	Approved by: 19.10.2022	Released by: 20.10.2022	Effective:	Supersedes:
Manuel Eliete QA/QC	Dr. Katja Teufel QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.11.2022	31.10.2016

SPECIFICATION

Acetone Ph. Eur.* / USP-NF*

Testing specifications: Ph. Eur.* / USP-NF* / LSM 011
The material meets all requirements of Ph. Eur.* and USP-NF* **Product code: 011**

Packaging and storage:	Preserve in tight containers and prevent exposure to excessive heat. Protect from direct sunlight.
Manufacturing process:	Cumene hydroperoxide process
Shelf life in originally sealed containers:	48 months from date of release in containers ≤ 20 L / 20 kg 24 months from date of release in containers > 20 L / 20 kg
Manufacturer and manufacturing site:	INEOS Phenol GmbH, Gladbeck (Germany)

Regulatory Compliance:

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients.

Allergens:

Allergens listed in Regulation (EU) No 1169/2011 Annex II are not used during the manufacture, are not intentionally added or known to be present in the product.

Batch certification:

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

Elemental impurities (Ph. Eur.* 5.20 / USP* <232> / 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.

Nitrosamines:

Nitrosamines, nitrites, nitrates, nitrosating agents, secondary and tertiary amines, primary amines, amides or ammonium salts are not used in the manufacturing process, are not intentionally added or known to be present in the product. More detailed information is available upon request.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

Within the manufacturing process out of class 1 solvents only benzene can occur in a concentration not more than 2 ppm. Solvents of class 2 and 3 can occur as by-products, but only in concentrations far below the stipulated limits.

*current version

Compiled by: 10.10.2022	Approved by: 19.10.2022	Released by: 20.10.2022	Effective:	Supersedes:
Manuel Eliete QA/QC	Dr. Katja Teufel QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.11.2022	31.10.2016