HEDINGER
1843
A pure decision.

SPECIFICATION

Isopropyl Alcohol GMP Ph. Eur.* / USP* / JP*

Shell IPA-GMP[x]

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 070*

The material meets all requirements of Ph. Eur.*, USP* and JP* **Product code: 070**

Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
Assay (GC)	–	≥ 99.0%	–	≥ 99.80%	LSM 070*
Characters / Description	clear, colourless	–	conforms	–	Ph. Eur.* / JP*
Identification	A / B / C	A / B / C	conforms	–	Ph. Eur.* / USP* / JP*
Specific gravity	d_{20}^{20} = 0.785-0.789	d_{25}^{25} = 0.783-0.787	d_{20}^{20} = 0.785-0.788	–	Ph. Eur.* / USP* / JP*
Refractive index n_D^{20}	1.376 – 1.379	1.376 – 1.378	–	–	Ph. Eur.* / USP*
IR-Spectrum	conforms	conforms	–	–	Ph. Eur.* / USP*
Appearance	clear, colourless clear solution	–	–	–	Ph. Eur.*
Clarity of solution	–	–	conforms	–	JP*
Color	–	–	–	APHA ≤ 5	ASTM D1209
Boiling point	–	–	–	81 – 83 °C	Ph. Eur.*
Distilling range	–	–	81 – 83 °C ≥ 94%	81 – 83 °C	JP* / ASTM D1078
Acidity or alkalinity	≤ 0.6 ml 0.01 N NaOH	–	–	–	Ph. Eur.*
Acidity	–	≤ 0.70 ml 0.02 N NaOH	conforms	–	USP* / JP*
Acidity (Acetic acid)	–	–	–	≤ 0.001% (m/m)	ASTM D1613
Absorbance	Steadily descending curve 230 nm: ≤ 0.30 250 nm: ≤ 0.10 270 nm: ≤ 0.03 290 nm: ≤ 0.02 310 nm: ≤ 0.01	–	–	–	Ph. Eur.*
Peroxides	conforms	–	–	–	Ph. Eur.*
Non-volatile substances	≤ 20 ppm = 0.002% (m/m)	–	–	≤ 10 ppm = 0.001% (m/m)	Ph. Eur.*
Limit of nonvolatile residue	–	≤ 0.005% (m/V)	–	≤ 10 ppm = 0.001% (m/m)	USP*
Residue on evaporation	–	–	≤ 1.0 mg / 20.0 ml	≤ 10 ppm = 0.001% (m/m)	JP*

[x]meets excipient level

*current version

Compiled by: 26.01.2022	Approved by: 26.01.2022	Released by: 28.01.2022	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Stefan Heß QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.02.2022	15.03.2020

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Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
Water	≤ 0.5%	≤ 0.5%	≤ 0.75% (m/V)	≤ 0.10% (m/m)	Ph. Eur.* / USP* / JP*
Related substances:	Sum: ≤ 0.3% (V/V)	-	–	–	Ph. Eur.* / LSM 070*
Benzene	≤ 2 ppm (V/V)	–	–	–	Ph. Eur.* / LSM 070*
Limits of volatile impurities: Methanol Each other individual known impurity: Acetone 2-Butanol Diisopropyl ether Diethyl ether n-Propyl alcohol Individual unspecific impurity: Total impurities	–	≤ 0.02% (V/V) ≤ 0.1% (V/V) ≤ 0.1% (V/V) ≤ 0.1% (V/V) ≤ 0.1% (V/V) ≤ 0.1% (V/V) ≤ 0.1% (V/V) Sum: ≤ 1.0% (V/V)	–	≤ 750 ppm (V/V) Sum: ≤ 0.3% (m/m)	LSM 070*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Production	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients
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]

Packaging and storage: Preserve in tight containers and prevent exposure to excessive heat. Protect from light.

Shelf life: Based on stability data the product may be stored as follows:

- bulk: 24 months from date of release
- drums: 24 months from date of release
- IBCs: 12 months from date of release
- Small containers ≤ 20l: 48 months from date of release

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Shell IPA-GMP[x]

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 070*
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Manufacturer and manufacturing site: Shell Chemicals Europe B.V., NL-Rotterdam

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 and EU-GMP Part II.

Allergens:

The product does not contain allergens listed in Regulation (EU) No 1169/2011 Annex II.

Batch certification:

Every batch is analysed according to all parameters of this specification (except Description / Characters and Identification JP*). 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:

The product does not contain nitrosamines, nitrites, nitrates, nitrosating agents, secondary and tertiary amines, primary amines, amides or ammonium salts. More detailed information is available upon request.

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

No solvents of class 1 are used during manufacturing of Shell IPA-GMP[x]. Within the manufacturing process out of class 1 only benzene can occur in a concentration lower than 1 ppm. Solvents of class 2 and 3 can occur as by-products, but only in concentrations far below from the stipulated limits.

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