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% (GC)	–	≥ 99.80%	LSM 070*
Characters / Description	clear, colourless	–	conforms JP*	–	Ph. Eur.* / JP*
Identification	A / B / C	A (FT-IR) / B (GC)	conforms JP*	–	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 Ph. Eur.*	conforms USP*	–	–	Ph. Eur.* / USP*
Appearance	clear, colourless clear solution	–	–	–	Ph. Eur.* (2.2.1/2.2.2)
Clarity of solution	–	–	conforms JP*	–	JP*
Color	–	–	–	APHA ≤ 5	ASTM D1209
Boiling point	–	–	–	81 - 83°C	Ph. Eur.* (2.2.12)
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 JP*	–	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.*	–	–	–	Ph. Eur.*

[x]meets excipient level
*current version

Compiled by: 18.02.2020	Approved by: 03.03.2020	Released by: 04.03.2020	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Anne Reiff QA-Manager	Dr. Frank Milek Qualified Person (GMP)	15.03.2020	05.12.2018

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
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*
Water	≤ 0.5%	≤ 0.5%	≤ 0.75% m/V	≤ 0.10% m/m	Ph. Eur.* / USP* / JP*
Related substances:	GC, Σ ≤ 0.3% V/V	-	–	–	Ph. Eur.* / LSM 070*
Benzene	≤ 2 ppm V/V	–	–	–	Ph. Eur.* / LSM 070*
Limits of volatile impurities:	–	Each individual: ≤ 0.1% Sum: ≤ 1.0%	–	Sum: ≤ 0.3%	LSM 070*
Acetone	–	≤ 0.1%	–	–	LSM 070*
2-Butanol	–	≤ 0.1%	–	–	LSM 070*
Diisopropyl ether	–	≤ 0.1%	–	–	LSM 070*
Diethyl ether	–	≤ 0.1%	–	–	LSM 070*
n-Propyl alcohol	–	≤ 0.1%	–	≤ 750 ppm (m/m)	LSM 070*

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

Manufacturer and manufacturing site: Shell Chemicals Europe B.V., NL-Rotterdam/Pernis

GMP compliance: The material is manufactured, filtered, transported, stored, repacked, tested and released according to IPEC-GMP Standard.

[x]meets excipient level
*current version

Compiled by: 18.02.2020	Approved by: 03.03.2020	Released by: 04.03.2020	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Anne Reiff QA-Manager	Dr. Frank Milek Qualified Person (GMP)	15.03.2020	05.12.2018

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**

BSE / TSE / GMO / Aflatoxins:

The material has no BSE / TSE risk, is not derived from GMO and complies with the German Aflatoxinverbots-Verordnung.

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.

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 parameters of this specification (except Description / Characters and Identification JP*). The Certificate of Analysis (CoA) provides all results above including analysis date, 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.

[x]meets excipient level
*current version

Compiled by: 18.02.2020	Approved by: 03.03.2020	Released by: 04.03.2020	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Anne Reiff QA-Manager	Dr. Frank Milek Qualified Person (GMP)	15.03.2020	05.12.2018