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	conforms Ph. Eur.*	–	–	–	Ph. Eur.*
Peroxides	conforms Ph. Eur.*	–	–	–	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*
Water	≤ 0.5%	≤ 0.5%	≤ 0.75% m/V	≤ 0.10% m/m	Ph. Eur.* / USP* / JP*

[x]meets excipient level
*current version

Compiled by: 04.01.2017	Approved by: 04.01.2017	Released by: 09.01.2017	Effective:	Supersedes:
			09.01.2017	23.11.2015
Dr. Philipp Hoch QA/QC-Manager	Dr. Katja Dahms QC-Manager	Dr. Frank Milek Qualified Person (GMP)		

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Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
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: Analysis date plus 2 years

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.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / CPMP/ICH/82 260/06):

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.

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 and residual solvents statement. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

[x]meets excipient level
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