HEDINGER
1 8 4 3
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	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.* / USP*
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*
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*

[x]meets excipient level
*current version

Effective date: 01.10.2025

Supersedes version from: 30.04.2025

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Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
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	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
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]
Primary Packaging material	Specified packaging materials from audited suppliers: 1 L, 2.5 L, 5 L, 10, 20 L Tin Cans 1 L Amber glass bottle 200 L Steel drum 1000 L HDPE EVOH Intermediate Bulk Container with diffusion barrier

[x]meets excipient level
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Packaging and storage: Preserve in tight containers and prevent exposure to excessive heat. Protect from light.

Shelf life: 24 months from date of analytical release

Product in intermediate bulk containers (IBCs) must be used or transferred to another suitable (non-plastic) vessel within 6 weeks from date of final release.

The specified shelf-life relates to originally closed containers.

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 Guidelines*.

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Dietary Laws, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) is available upon request.

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 and date of manufacture. All CoAs are signed by a Qualified Person according to EU-GMP or a responsible QA/QC-Manager.

[x]meets excipient level

*current version

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Dr. Katja Teufel QA-Manager	Dr. Philipp Hoch Head of QA	Dr. Frank Milek Qualified Person (GMP)	01.10.2025	30.04.2025