HEDINGER 1843 A pure decision.

SPECIFICATION

Isopropyl Alcohol 70% (V/V) API grade / USP

Isopropyl alcohol 70% (V/V) ≈ Isopropyl alcohol 62.8% (m/m)
Testing specifications: Ph. Eur.* / USP* / LSM 057
The material meets all requirements of USP* Monograph "Isopropyl Rubbing Alcohol"** **Product code: 057**

Parameter	USP*		Additional Parameters	
	Specification	Test method	Specification	Test method
Identification	—	—	conforms	Ph. Eur.* (2.2.24; FT-IR)
Appearance of solution	—	—	conforms	Ph. Eur.* (2.2.1; 2.2.2)
Specific gravity (d_{20}^{20})	0.872 – 0.883	USP*	0.875 – 0.878	Ph. Eur.*
Acidity	≤1.0 ml 0.020 N NaOH	USP*	—	—
Limit of nonvolatile residue	≤ 0.01% (m/v)	USP*	—	—
Water	—	—	36.2 – 38.3% (m/m)	Karl Fischer (Ph. Eur.* 2.5.12)
Assay	68.0 – 72.0% (v/v)	USP*	61.7 – 63.8% (m/m)	LSM 057*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Starting materials	**Isopropyl Alcohol GMP Ph. Eur. / USP / JP** (IPA-GMP) by Shell Chemicals and tested according to Ph. Eur. / USP / JP methods by Aug. Hedinger GmbH & Co. KG. **Purified Water Ph. Eur.* / USP*** produced by Aug. Hedinger GmbH & Co. KG according to EU-GMP and tested acc. to Ph. Eur. / USP methods by Aug. Hedinger GmbH & Co. KG.
Manufacturing process	Final manufacturing steps, packaging, testing and release of the product are carried out by Aug. Hedinger GmbH & Co. KG
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]

Storage: In tight containers, remote from heat

Shelf-life in originally sealed containers: 24 months after manufacturing date

Manufacturer and manufacturing site: Aug. Hedinger GmbH & Co. KG
D-70327 Stuttgart / D-06179 Teutschenthal

*current version
**The material does not contain any stabilisers, perfume oils, or color additives.

Compiled by: 04.04.2023	Approved by: 06.04.2023	Released by: 12.04.2023	Effective:	Supersedes:
Dr. Katja Teufel QA-Manager	Tanja Natterer QC-Manager	Dr. Frank Milek Qualified Person (GMP)	20.04.2023	15.01.2020

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Isopropyl Alcohol 70% (V/V) API grade / USP

Regulatory Compliance:

The material is manufactured, stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to GMP principles (EU-GMP II Guideline for Active Pharmaceutical Ingredients).

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. The Certificate of Analysis (CoA) provides all results like analysis date, manufacturing date, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person (QP) according to EU-GMP.

Elemental impurities (Ph. Eur.* 5.20 / USP* <232> / ICH Q3D*):

At least three independent batches of each starting material of Isopropyl Alcohol 70% (V/V) API grade / USP were analysed by Hedinger for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities according to guideline ICH Q3D 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*):

No solvents of class 1 are used during manufacturing of Shell Isopropyl Alcohol GMP Ph. Eur./USP/JP. 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 the stipulated limits.

*current version
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