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	Ph. Eur.*		USP*	
	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})	0.875 – 0.878	Ph. Eur.*	0.872 – 0.883	USP*
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	61.7 – 63.8% (m/m)	LSM 057*	68.0 – 72.0 % (v/v)	USP*

Storage: In tight containers, remote from heat

Shelf life in originally sealed containers: 24 months

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

Raw Materials: Isopropyl Alcohol GMP Ph. Eur. / USP / JP (IPA-GMP) by Shell Chemicals
Purified Water Ph. Eur. / USP by Aug. Hedinger GmbH & Co. KG

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.

Elemental impurities (Ph. Eur.* 5.20 / 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.

Manufacturing process:
The product is manufactured according to GMP principles (EU-GMP II Guideline for Active Pharmaceutical Ingredients). The product is filled in a clean room (class D).

Batch certification:
Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all results above including date of analytical release, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

Biocides Regulation:
The product is notified as biocidal product according to national regulations in Germany, Austria and France. The application for authorisation according to the Biocidal Product Regulation (EU) No 528/2012 has been submitted in due time for these countries. In all three countries the product can be used as surface and skin disinfectant (Product Types 1, 2 and 4).

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

Compiled by: 07.05.2019	Approved by: 15.05.2019	Released by: 16.05.2019	Effective:	Supersedes:
Dr. Philipp Hoch QA/QC-Manager	Dr. Katja Teufel QC-Manager	Elisabeth Bartel Qualified Person (GMP)	17.05.2019	07.07.2017