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*

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

Applications:
The product can be used exclusively in Germany, Austria and France as a biocidal product for hygienic hand disinfection (PT1) and for the disinfection of hard surfaces up to and including 5 m^2 by wiping or spraying (PT2 and PT4). This application is applicable only for HDPE containers up to and including 10 litres distributed by Hedinger.

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

Compiled by: 18.12.2019	Approved by: 18.12.2019	Released by: 20.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA/QC-Manager	Dr. Frank Milek Qualified Person (GMP)	15.01.2020	17.05.2019