

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.

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 in Germany, Austria and France as biocidal product according to the EU Biocidal Regulation 528/2012 with the registration number BAuA-Nr.: N-54419 (PT2) and N-62514 (PT4) for Germany and France. In all three countries the product can be used as surface disinfectant, in Austria and France also as skin disinfectant.

*current version

**The material does not contain any stabilizers, perfume oils, or color additives.

Compiled by: 08.06.2017	Approved by:	Released by:	Effective:	Supersedes:
Dr. Philipp Hoch QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	07.07.2017	01.09.2013