

SPECIFICATION

Isopropyl Alcohol 70% (V/V) API grade

Isopropyl alcohol 70% (V/V) \approx Isopropyl alcohol 62.8% (m/m)

Product code: 053

Parameter	Specification	Method
Appearance of solution	conforms	Ph. Eur.* (2.2.1; 2.2.2)
Identification	conforms	Ph. Eur.* (2.2.24; FT-IR)
Specific gravity (d_{20}^{20})	0.875 – 0.878	Ph. Eur.*
Water	36.2 – 38.3% (m/m)	Karl Fischer (Ph. Eur.* 2.5.12)
Isopropyl alcohol	61.7 – 63.8% (m/m)	LSM 053*

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 Part 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 Austria, France and Germany as biocidal product according to the Regulation (EU) No 528/2012 (Biocidal Products Regulation) with the notification numbers 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

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	31.10.2016