HEDINGER
1843
A pure decision.

SPECIFICATION

Isopropyl Alcohol 70% (V/V) API grade

Isopropyl alcohol 70% (V/V) ≈ 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.

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 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 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.

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

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	20.03.2019