

## 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.

**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: 05.03.2019        | Approved by: 11.03.2019                    | Released by: 13.03.2019                   | Effective: | Supersedes: |
| Manuel Eliete<br>QA/QC-Manager | Elisabeth Bartel<br>Qualified Person (GMP) | Dr. Frank Milek<br>Qualified Person (GMP) | 20.03.2019 | 31.10.2016  |