

## CERTIFICATE OF ANALYSIS

### Isopropyl Alcohol GMP Ph. Eur. / USP / JP

Shell IPA-GMP\*

Testing specification: Ph.Eur.: 11.0; USP: 2023; JP: 18; LSM 070

**The product meets all requirements of the listed pharmacopoeias**

Product code: 070

Batch: 0701482

Parameter / Method	Specification	Result
Identification A Ph.Eur. Relative density 20°C	0.785 - 0.789	0.7864
Identification B Ph.Eur. Refractive index	1.376 - 1.379	1.3772
Identification A USP / Identification C Ph.Eur. IR	conforms	conforms
Identification B USP GC	conforms	conforms
Identification C USP GC	conforms	conforms
Identification JP	conforms	conforms
Specific gravity 20°C JP	0.785 - 0.788	0.7864
Specific gravity 25°C USP	0.783 - 0.787	0.7832
Refractive index USP	1.376 - 1.378	1.3772
Appearance Ph.Eur.	clear, colorless, clear solution	conforms
Clarity of Solution JP	clear solution	conforms
Colour ASTM D1209	APHA max. 5	<5
Boiling point (corr.)	81 - 83 °C	81.3 °C
Distilling range ASTM D1078 (corr.)		
Initial Boiling Point	81 °C - 83 °C	81.3 °C
Dry Point	81 °C - 83 °C	81.9 °C
Distilling range JP	min. 94 % (at 81-83°C)	96 %
Acidity or alkalinity Ph.Eur.	max. 0.6 ml 0.01 mol/L NaOH	conforms
Acidity USP	max. 0.70 ml 0.02 mol/L NaOH	conforms
Acidity JP	conforms	conforms
Acidity (as Acetic acid) ASTM D1613	max. 0.001 %	0.0008 %
Absorbance Ph.Eur./USP	steadily descending curve	conforms
230 nm	max. 0.30	0.09
250 nm	max. 0.10	0.02
270 nm	max. 0.03	0.00
290 nm	max. 0.02	0.00
310 nm	max. 0.01	0.00
Peroxides Ph.Eur.	conforms	conforms
Non volatile matter Ph.Eur.	max. 20 ppm Additional Specification max. 10 ppm	1 ppm
Limit of nonvolatile residue USP / Residue on evaporation JP	max. 0.005 %(m/V) Additional Specification max. 0.001%	0.0001 %(m/V)

## CERTIFICATE OF ANALYSIS

### Isopropyl Alcohol GMP Ph. Eur. / USP / JP

Shell IPA-GMP\*

Testing specification: Ph.Eur.: 11.0; USP: 2023; JP: 18; LSM 070

**The product meets all requirements of the listed pharmacopoeias**

**Product code: 070**

**Batch: 0701482**

Parameter / Method	Specification	Result
Water Ph.Eur./USP	max. 0.5 % Additional Specification max. 0.10 %	0.005 %
Water JP	max. 0.75 %(m/V)	0.004 %(m/V)
Related substances Ph.Eur. GC	max. 0.3 %(V/V)	0.023 %(V/V)
Related substances - Benzene Ph.Eur. GC	max. 2 ppm(V/V)	conforms
Limit of volatile impurities USP LSM 070 GC	Methanol: max 0.02% (V/V). Each other individual known impurity: max. 0.1% (V/V). Individual unspecified impurity: max. 0.1% (V/V). Total impurities: max. 1.0% (V/V) Additional spec.: max. 0.3% (m/m)	conforms
Limit of volatile impurities USP LSM 070 GC		
Diethyl ether	max. 0.1% (V/V) (max. 1000 ppm (V/V))	0 ppm (V/V)
Diisopropyl ether	max. 0.1% (V/V) (max. 1000 ppm (V/V))	0 ppm (V/V)
Acetone	max. 0.1% (V/V) (max. 1000 ppm (V/V))	1 ppm (V/V)
Methanol	max. 0.02% (V/V) (max. 200 ppm (V/V))	<10 ppm (V/V)
2-Butanol	max. 0.1% (V/V) (max. 1000 ppm (V/V))	0 ppm (V/V)
n-Propyl alcohol	max. 0.1% (V/V) (max. 1000 ppm (V/V)) Additional spec.: max. 750 ppm (V/V)	226 ppm (V/V)
Assay USP GC	min. 99.0 % Additional Specification: min. 99.80 %	99.97 %

Limit of volatile impurities USP: The requirements of the USP test "Limit of volatile impurities" are covered by internal validated GC method LSM 070.

<b>Manufacturer:</b>	Shell Chemicals Europe B.V., Vondelingenweg 601 3196 KK Rotterdam/Pernis, NETHERLANDS		
<b>Date of manufacture:</b>	01/01/2024	<b>Supplier:</b>	Aug. Hedinger GmbH & Co. KG D-70327 Stuttgart, GERMANY
<b>Analytical release:</b>	29/01/2024	<b>Customer:</b>	Pharma Ltd. 12345 City, GERMANY
<b>Delivery Date:</b>	asap		
<b>Net quantity:</b>	1 x 1 liter		

**Shelf life:** 24 months from date of release for small containers, drums and bulk; 12 months from date of release for IBCs

**Inspection Lot:** Shell 000003276756

Customer order no.: 1234567, Hedinger order no.: 7654321

## CERTIFICATE OF ANALYSIS

### **Isopropyl Alcohol GMP Ph. Eur. / USP / JP**

Shell IPA-GMP\*

Testing specification: Ph.Eur.: 11.0; USP: 2023; JP: 18; LSM 070

**The product meets all requirements of the listed pharmacopoeias**

**Product code: 070**

**Batch: 0701482**

The product is manufactured by Shell (Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam, NETHERLANDS, phone: +31 10 431 9111) according to GMP. The CoA of the manufacturer is available on request.

The material is transported, stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to EU-GMP Part II and EXCiPACT™ GMP.

The material is stored, repacked, tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients and EU-GMP Part II.

#### **Residual solvents [ICH Q3C (current version)]:**

The product complies with the requirements of the ICH Q3C Residual Solvents Guideline (current version):

No solvents of class 1 are used during manufacturing of Shell IPA-GMP\*. Within the manufacturing process out of class 1 only benzene can occur in a concentration lower than 1 ppm. The class 2 solvents cyclohexane, methylisobutylketone, tertiary-butyl alcohol and class 3 solvents can occur, but only in concentrations far below from the stipulated limits.

#### **Elemental impurities [ICH Q3D (current version)]:**

At least three independent batches have been analysed for elemental impurities according to guideline ICH Q3D.

All determined values of elemental impurities 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.

**Hereby I confirm that this batch/lot has been analysed according to all listed tests. This CoA is only valid for originally sealed containers and tank trucks of Aug. Hedinger GmbH & Co. KG, Stuttgart labelled with the same batch/lot number. Copies of this CoA are not valid.**

Product finally released.

Date:

**Elisabeth Bartel , Pharmacist, Qualified Person acc. to EU-GMP**