

SPECIFICATION

Isopropyl Alcohol GMP Ph. Eur.* / USP* / JP* Shell IPA-GMP*

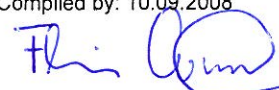
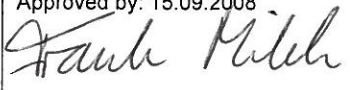
Shell
IPA-GMP
Excipient

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 070*
The material meets all requirements of Ph. Eur.*, USP* and JP*

Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
Assay (GC)	-	≥ 99,0 % (GC)	-	≥ 99,80 %	LSM 070*
Characters / Description	clear, colourless	-	conforms JP*	-	Ph. Eur.* / JP*
Identification	A / B / C	FT-IR	conforms JP*	-	Ph. Eur.* / USP* / JP*
Specific gravity	$d_{20}^{20} = 0,785-0,789$	$d_{25}^{25} = 0,783-0,787$	$d_{20}^{20} = 0,785-0,788$	-	Ph. Eur.* / USP* / JP*
Refractive index n_D^{20}	1,376 - 1,379	1,376 - 1,378	-	-	Ph. Eur.* / USP*
IR-Spectrum	-	conforms USP*	-	-	USP*
Appearance	clear, colourless clear solution	-	-	-	Ph. Eur.* (2.2.1/2.2.2)
Clarity of solution	-	-	conforms JP*	-	JP*
Color	-	-	-	APHA ≤ 5	ASTM D1209
Boiling point	-	-	-	81 - 83 °C	Ph. Eur.* (2.2.12)
Distilling range	-	-	81 - 83 °C ≥ 94%	81 - 83 °C	JP* / ASTM D1078
Acidity or alkalinity	≤ 0,6 ml 0,01 N- NaOH	-	-	-	Ph. Eur.*
Acidity	-	≤ 0,7 ml 0,02 N- NaOH	conforms JP*	-	USP* / JP*
Acidity (Acetic acid)	-	-	-	≤ 0,001% m/m	ASTM D1613
Absorbance	conforms Ph. Eur.*	-	-	-	Ph. Eur.*
Peroxides	conforms Ph. Eur.*	-	-	-	Ph. Eur.*
Non-volatile substances	≤ 20 ppm =0,002% m/m	-	-	≤ 10 ppm =0,001% m/m	Ph. Eur.*
Limit of nonvolatile residue	-	≤ 0,005% m/V	-	≤ 10 ppm =0,001% m/m	USP*
Residue on evaporation	-	-	≤ 1,0 mg / 20.0 ml	≤ 10 ppm =0,001% m/m	JP*
Water	≤ 0,5%	-	≤ 0,75% m/V	≤ 0,10% m/m	Ph. Eur.* / JP*
Related substances:	GC, Σ ≤ 0,3 % V/V	-	-	-	Ph. Eur.* / LSM 070*
Benzene	≤ 2 ppm V/V	-	-	-	Ph. Eur.* / LSM 070*

*meets excipients level

*current version

Compiled by: 10.09.2008  Florian Conzelmann Pharmacist, Qualified Person (GMP)	Approved by: 15.09.2008  Dr. Frank Milek Pharmacist, Qualified Person (GMP)	Effective: 01.10.2008	Supersedes: 05.03.2007	Page 1 of 2
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SPECIFICATION

Isopropyl Alcohol GMP Ph. Eur.* / USP* / JP* Shell IPA-GMP^x

Shell
IPA-GMP
Excipient

Testing specifications: Ph. Eur.* / USP* / JP* / LSM 070*
The material meets all requirements of Ph. Eur.*, USP* and JP*

Parameter	Ph. Eur.*	USP*	JP*	Additional Specification	Test methods
Acetone	–	–	–	–	LSM 070*
Di-isopropyl ether	–	–	–	–	LSM 070*
Diethyl ether	–	–	–	–	LSM 070*
Methanol	–	–	–	–	LSM 070*
n-Propyl alcohol	–	–	–	≤ 750 ppm (m/m)	LSM 070*

Expiry Date: Analysis Date plus 2 years

Manufacturer and manufacturing site: Shell Chemicals Europe B.V., NL-Rotterdam/Pernis

GMP: The material is manufactured, filtered, transported, stored and repacked according to excipient GMP.



Residual solvents (Ph. Eur.* 5.4 / USP* <467> / CPMP/ICH/283/95):

No solvents of class 1 are used during manufacturing of Shell IPA-GMP^x. 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 from the stipulated limits.

Every batch is analysed according to all parameters of this specification (except Description / Characters and Identification JP* / Ph. Eur. C). The Certificate of analysis (COA) provides all results above including analysis date, date of manufacture and residual solvents statement. All COAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

^xmeets excipients level

*current version

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