

SPECIFICATION



Propylene Glycol Ph. Eur.* / USP* / JP* parenteral grade Propylene Glycol USP/EP

Testing specifications: Ph. Eur.* / USP* / LSM 029* / LSM 220*

The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC and 2008/84/EC (E 1520)

Parameter	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Assay (GC)	—	—	≥ 99.80 %	LSM 029*
Characters	conforms	Ph. Eur.*	—	—
Identification	A / B / C / FT-IR	Ph. Eur.*	FT-IR	USP*
Boiling point (Identification C)	184 - 189°C	Ph. Eur.*	—	—
Appearance	clear, colourless	Ph. Eur.*	—	—
Acidity	≤ 0.05ml 0,1 N-NaOH	Ph. Eur.*	≤ 0.20ml 0,1 N-NaOH	USP*
Oxidising substances	≤ 0.2ml 0.05 N-Sodium-thiosulph.	Ph. Eur.*	—	—
Reducing substances	conforms Ph. Eur.*	Ph. Eur.*	—	—
Chloride	—	—	≤ 0.007 %	USP*
Sulfate	—	—	≤ 0.006 %	USP*
Heavy metals	≤ 5 ppm (m/V)	Ph. Eur.*	≤ 5 ppm	USP*
Specific gravity	d_{20}^{20} : 1.035 – 1.040	Ph. Eur.*	d_{25}^{25} : 1.035 – 1.037	USP*
Refractive index n_D^{20}	1.431 – 1.433	Ph. Eur.*	—	—
Residue on ignition	—	—	≤ 3.5 mg / 50 g	USP*
Sulphated ash	≤ 0.01 % m/m	Ph. Eur.*	—	—
Water	≤ 0.2 %	Ph. Eur.*	≤ 0.2 %	USP*

Microbiological Specification

Parameter	Specification	Method
Bioburden (Σ Total aerobic microbial count + Total yeast mould count)	≤ 100 CFU/g	Ph. Eur.* 2.6.12 / USP* <61> (membrane filtration)
Endotoxins	≤ 0.5 IU/mg	Ph. Eur.* / USP* (LAL, kinetic-turbidimetric method)

*current version

Compiled by: 04.03.2009 Florian Conzelmann Pharmacist, Qualified Person (GMP)	Approved by: 05.03.2009 Dr. Frank Milek Pharmacist, Qualified Person (GMP)	Effective: 01.04.2009	Supersedes: --- (first version)	Page 1 of 3
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Parameter	JP*		Additional Specification	
	Specification	Test method	Specification	Test method
Description	conforms JP*	JP*	—	—
Identification	1 / 2	JP*	—	—
Specific Gravity d_{20}^{20}	1.035 – 1.040	JP*	—	—
Acidity	conforms JP*	JP*	—	—
Chloride	$\leq 0.007\%$	JP*	—	—
Sulfate	$\leq 0.002\%$	JP*	—	—
Heavy Metals	≤ 5 ppm	JP*	—	—
Arsenic	≤ 2 ppm	JP*	—	—
Glycerin	conforms JP*	JP*	—	—
Water	$\leq 0.5 \%$	JP*	—	—
Residue on ignition	$\leq 0.005 \%$ (m/m)	JP*	—	—
Distilling Range	184-189°C $\geq 95 \%$ (V/V)	JP*	—	—
Monoethylene Glycol	—	—	$\leq 0.01 \%$ m/m	GC, LSM 029*
1,2-Butanediol	—	—	$\leq 0.01 \%$ m/m	GC, LSM 029*
1,3-Propanediol	—	—	$\leq 0.01 \%$ m/m	GC, LSM 029*
Diethylene Glycol	—	—	$\leq 0.01 \%$ m/m	GC, LSM 029*
Di- and Tripropylene Glycol	—	—	$\leq 0.1 \%$ m/m	GC, LSM 029*

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Quality Assurance and Quality Control	
Process/Operation	Standard / Requirement
Production	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients
Supply chain	WHO – GTDP Guidelines for Pharmaceutical Starting Materials
Analytical quality control	Full analysis of specification for each batch in a GMP qualified laboratory
Batch release	Qualified Person according to EU-GMP (2001/83/EC; Articles 48 & 49)
Packaging	Class D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP)
Packaging	Extended supervision of repackaging process by chemist or pharmacist
Primary packaging material	<u>Specified packaging materials from audited suppliers:</u> 1 L, 2.5 L Amber Glass Bottles 10L, 20L HDPE Containers 200 L HDPE-Steel Combi-drums 1000 L HDPE EVOH Intermediate Bulk Container with diffusion barrier
Packaging material reconciliation	Full seal cap and label reconciliation
End-control of filled containers	First and last container of filling process (water content, color, IR-spectrum)

Storage: It is recommended to store the material in closed containers, below 40°C.

Shelf life: 24 months

Manufacturer and manufacturing site: Dow Deutschland, Stade (Germany)

Manufacturing process: synthetic, key raw material: propylene oxide

The material has no BSE/TSE risk, is not derived from GMO and complies with the German Aflatoxinverbots-Verordnung.

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

Neither solvents of class 1 - 3 are used during manufacturing of this product, nor can they occur within the manufacturing process.

Every batch is analysed according to all parameters of Ph. Eur.* (except Characters), USP*, JP* (except Description and Identification), additional specifications and microbiological specifications. The Certificate of analysis (COA) provides all results like above including date of manufacture, release date, repackaging date and residual solvents statement. All COAs are signed by a Qualified Person according to EU-GMP.

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