SPECIFICATION

Propylene Glycol Ph. Eur.* / USP* / JP* parenteral grade
Propylene Glycol USP/EP **Product code: 220**

Testing specifications: Ph. Eur.* / USP* / LSM 029*/ LSM 220*
The material meets all requirements of Ph. Eur.*, USP*, JP*, FCC* and (EU) No 231/2012 (E1520)

Parameter	Ph. Eur.*		USP*	
	Specification	Test method	Specification	Test method
Assay	—	—	≥ 99.5 %**	GC, LSM 029*/**
Characters	conforms	Ph. Eur.*	—	—
Identification	A / B / C / FT-IR	Ph. Eur.*	A/B/C**	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	—	—	≤ 70 ppm	USP*
Sulfate	—	—	≤ 60 ppm	USP*
Heavy metals	—	—	≤ 5 ppm	USP*
Relative density / 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*
Limit of diethylene glycol and ethylene glycol: - DEG - EG	—	—	 ≤ 0.10 % ≤ 0.10 %	GC, LSM 029*/**

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

*current version
**The Requirements of USP Identity B/C, USP Assay and of JP Ethylene glycol, diethylene glycol and related substances are covered by internal validated GC method LSM 029.

Compiled by: 20.12.2016	Approved by: 22.12.2016	Released by: 23.12.2016	Effective:	Supersedes:
Dr. Philipp Hoch QA/QC-Manager	Elisabeth Bartel Qualified Person (GMP)	Dr. Frank Milek Qualified Person (GMP)	01.01.2017	15.02.2016

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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	≤ 0.007%	JP*	—	—
Sulfate	≤ 0.002%	JP*	—	—
Heavy Metals	≤ 5 ppm	JP*	—	—
Arsenic	≤ 2 ppm	JP*	—	—
Glycerin	conforms JP*	JP*	—	—
Water	≤ 0.5 %	JP*	—	—
Residue on ignition	≤ 0.005 % (m/m)	JP*	—	—
Distilling Range	≥ 95 % (V/V) at 184-189°C	JP*	—	—
Ethylene glycol, diethylene glycol and related substances: - Ethylene glycol - Diethylene glycol - ∑ Impurities - each other related substance	 ≤ 0.1 % ≤ 0.1 % ≤ 1.0 % ≤ 0.1 %	GC, LSM 029*/**	—	—
Assay	—	—	≥ 99.80 % m/m	GC, LSM 029*/**
Monoethylene Glycol	—	—	≤ 0.01 % m/m	GC, LSM 029*/**
1,2-Butanediol	—	—	≤ 0.01 % m/m	GC, LSM 029*/**
1,3-Propanediol	—	—	≤ 0.01 % m/m	GC, LSM 029*/**
Diethylene Glycol	—	—	≤ 0.01 % m/m	GC, LSM 029*/**
Di- and Tripropylene Glycol	—	—	≤ 0.1 % m/m	GC, LSM 029*/**
∑ Impurities	—	—	≤ 1.0 % m/m	GC, LSM 029*/**
Each other related substance	—	—	≤ 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	Specified packaging materials from audited suppliers: 1 L, 2.5 L Amber Glass Bottles 5L, 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 at ambient temperatures in closed containers and protected from sunlight and other sources of UV light.

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/82 260/06):

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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