HEDINGER 1843 A pure decision.

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 thiosulphate	Ph. Eur.*	—	—
Reducing substances	conforms Ph. Eur.*	Ph. Eur.*	—	—
Chloride	—	—	≤ 70 ppm	USP*
Sulfate	—	—	≤ 60 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: 16.12.2019	Approved by: 17.12.2019	Released by: 20.12.2019	Effective:	Supersedes:
Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA-Manager	Dr. Frank Milek Qualified Person (GMP)	01.01.2020	01.01.2017

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JP*		
Parameter	**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*/**

Additional Parameter		
Parameter	**Specification**	**Method**
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*/**

*current version
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Propylene Glycol USP/EP **Product code: 220**

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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
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
Labelling of seal caps	Labelling with Hedinger tamper-evident-label
Packaging material reconciliation	Full tamper-evident-label and label reconciliation
End-control of filled containers	First and last container of filling process (water content, colour, 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

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

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

BSE/TSE / GMO / Kosher status / Aflatoxins:

The material has no BSE/TSE risk, is not derived from GMO, is kosher and complies with the German “Aflatoxin Verbotsverordnung”.

Residual solvents (Ph. Eur.* 5.4 / USP* <467> / ICH Q3C*):

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

Elemental Impurities (Ph. Eur.* 5.20 / ICH Q3D*):

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.

Batch certification:

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.

*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.

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