HEDINGER 1843 A pure decision.

SPECIFICATION

Purified Water Ph. Eur.*/USP*,** product code: 219

Testing specifications: Ph. Eur.* / USP*

The product complies with the monograph Purified Water in containers Ph. Eur.* and Purified Water USP*, for commercial use elsewhere.**

Requirement	Specification	Method	Specification	Method
	Ph. Eur.*		USP*	
Description / Characters	clear, colourless, odourless and tasteless liquid	Ph. Eur.*	—	—
Acidity or alkalinity	conforms Ph. Eur.*	Ph. Eur.*	—	—
Oxidisable substances	conforms Ph. Eur.*	Ph. Eur.*	conforms USP*	USP*
Chloride	conforms Ph. Eur.*	Ph. Eur.*	—	—
Nitrates	≤ 0.2 ppm	Ph. Eur.*	—	—
Sulphate	conforms Ph. Eur.*	Ph. Eur.*	—	—
Ammonium	≤ 0.2 ppm	Ph. Eur.*	—	—
Calcium, Magnesium	conforms Ph. Eur.*	Ph. Eur.*	—	—
Total organic carbon	≤ 0.5 mg / l	Ph. Eur.*	≤ 0.50 mg / l	USP*
Residue on evaporation	≤ 0.001 % (m/V)	Ph. Eur.*	—	—
Conductivity	conforms Ph. Eur.*	Ph. Eur.*	conforms USP*	USP*
Microbial contamination	≤ 10^2 CFU / ml	Ph. Eur.*	—	—

Shelf life: 1 L, 5 L, 10 L, 20 L: One year in originally sealed containers.
1000 kg: Three months in originally sealed containers.

Manufacturer and manufacturing site: Aug. Hedinger GmbH & Co. KG, Stuttgart.

Manufacturing process: Softening of water, reverse osmosis, electrodeionisation and ultrafiltration.

Containers: 1 L, 5 L, 10 L, 20 L, 1000 kg brand new polyethylene containers with tamper evident closures.

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

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

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

*current version

**It is the user's responsibility to ensure fitness for use of this packaged article when it is used in manufacturing, clinical or analytical applications where the purer bulk form of the water is indicated.

Compiled by: 13.03.2018	Approved by: 19.03.2018	Released by: 23.03.2018	Effective:	Supersedes:
Tanja Natterer Head of QC, Qualified Person	Elisabeth Bartel Head of QC, Qualified Person	Dr. Frank Milek Head of GMP/SHEQ, Qualified Person	01.04.2018	01.01.2017

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Elemental impurities (ICH Q3D*):

At least three independent batches of Purified Water Ph. Eur. / USP were analysed by Hedinger for elemental impurities according to guideline ICH Q3D. All determined values of elemental impurities according to guideline ICH Q3D 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.

Every batch is analysed according to the above mentioned parameters of Ph. Eur.* and USP* required for water used in pharmaceutical manufacturing. Methods of the pharmacopoeial monographs are applied. The Certificate of Analysis (CoA) provides all results like above plus analysis date and date of manufacture. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

*current version

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