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.**

Parameter	Specification	Method	Specification	Method
	Ph. Eur.*		USP*	
Acidity or alkalinity	conforms	Ph. Eur.*	—	—
Oxidisable substances	conforms	Ph. Eur.*	conforms	USP*
Chloride	conforms	Ph. Eur.*	—	—
Nitrates	≤ 0.2 ppm	Ph. Eur.*	—	—
Sulfate	conforms	Ph. Eur.*	—	—
Ammonium	≤ 0.2 ppm	Ph. Eur.*	—	—
Calcium, Magnesium	conforms	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.*	conforms	USP*
Microbial contamination	≤ 10^2 CFU/ml	Ph. Eur.*	—	—

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
Manufacturing process	Softening of water, reverse osmosis, electrodeionisation and ultrafiltration. Manufacturing steps, packaging, testing and release of the product are carried out by Aug. Hedinger GmbH & Co. KG in compliance with IPEC PQG-GMP Guidelines for Pharmaceutical Excipients*. Purified water in the water treatment plant is monitored continuously for all parameters of this specification. TOC and conductivity are tested online, bacterial endotoxins and microbiological contamination on a daily and physico-chemical parameters on a weekly basis.
Supply chain	IPEC PQG – GMP Guidelines for Pharmaceutical Excipients* & IPEC GDP Guideline*
Analytical quality control	Full analysis of specification in a GMP qualified laboratory (in compliance with EU-GMP Part I, Chapter 6*)
Batch release	Qualified Person according to EU-GMP* (2001/83/EC; Articles 48 & 49)
Packaging	Grade D (100,000) clean room according to GMP [EU-GMP Part I Annex 1* (classification and operating conditions), US cGMP]
Primary packaging material	Specified packaging material from audited suppliers: 1 l, 5 l, 10 l, 20 l HDPE Containers 1000 l HDPE Intermediate Bulk Container

*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.

Effective date: 25.02.2025

Supersedes version from: 01.04.2018

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Shelf life:
- Small containers ≤ 20 l: 12 months from date of release in originally sealed containers.
- IBCs: 3 months from date of release in originally sealed containers.

Regulatory Compliance:

Regulatory information for this product, e.g., information on Aflatoxins, Allergens, BSE/TSE, Elemental Impurities (ICH Q3D*), GMO, Nitrosamines and Residual Solvents (ICH Q3C*) is available upon request.

Batch certification:

Every batch is analysed according to all parameters of this specification. The Certificate of Analysis (CoA) provides all test results including analysis date and date of manufacture. All CoAs are signed by a Qualified Person according to GMP.

*current version
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Compiled by: 05.02.2025	Approved by: 06.02.2025	Released by: 12.02.2025	Effective:	Supersedes:
Dr. Katja Teufel QA-Manager	Dr. Stefan Heß QA-Manager	Elisabeth Bartel Qualified Person	25.02.2025	01.04.2018