SPECIFICATION

HEDINGER 1843 A pure decision.

Disodium Edetate Ph. Eur.* / USP*
VERSENE NA Chelating Agent** **Product code: 214**

Testing specifications: Ph. Eur.* / USP* / LSM 214*
The material meets all requirements of Ph. Eur.*, USP* and FCC*

Parameter	Ph. Eur.*		USP*	
	Specification	Method	Specification	Method
Characters	White or almost white crystalline powder, soluble in water	Ph. Eur.*	–	–
Assay	98.5 – 101.0%	Ph. Eur.*	99.0 – 101.0%	USP*
Identification	A / B / D	Ph. Eur.*	A / B / C	USP*
Appearance of solution	clear / colourless	Ph. Eur.*	–	–
pH	4.0 – 5.5	Ph. Eur.*	4.0 – 6.0	USP*
Limit of nitrilotriacetic acid[1]	≤ 0.1% (Impurity A)	Ph. Eur.*	≤ 0.1%	USP*
Iron	≤ 80 ppm	Ph. Eur.*	–	–
Loss on Drying	–	–	8.7 – 11.4%	USP*
Calcium	–	–	conforms	USP*

Quality Assurance and Quality Control	
Process/Operation	**Standard / Requirement**
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	Grade D (100,000) clean room according to GMP (EU-GMP Part I Annex 1, US cGMP)

Storage: It is recommended to store the material in well closed containers and protected from light.

Shelf life: 36 months from date of manufacture

Manufacturer / manufacturing site: The Dow Chemical Company, Freeport, Texas, USA

Manufacturing process: synthetic, key raw material: EDTA acid

[1]Limit of nitrilotriacetic acid is only analysed according to USP*

*current version **Trademark of The Dow Chemical Company

Compiled by: 23.07.2021	Approved by: 23.07.2021	Released by: 23.07.2021	Effective:	Supersedes:
Dr. Stefan Heß QA-Manager	Dr. Katja Teufel QC- Manager	Dr. Frank Milek Qualified Person (GMP)	26.07.2021	01.10.2019

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Regulatory Compliance

The material is stored, (repacked,) tested and released at Aug. Hedinger GmbH & Co. KG according to IPEC PQG – GMP Guidelines for Pharmaceutical Excipients.

BSE/TSE / GMO / Kosher status / Aflatoxins:

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

Residual solvents (Ph. Eur.* 5.4 / ICH Q3C*):

No organic solvents are used in the manufacture or as raw materials. The raw materials used to manufacture VERSENE** NA also do not incorporate solvents. This includes the class 1, 2 and 3 solvents listed in ICH Q3C.

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

At least three independent batches were analysed 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.

Batch certification:

Every batch is analysed according to all parameters of this specification[1]. The Certificate of Analysis (CoA) provides all results including release date, manufacturing date, residual solvents statement and elemental impurities statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

[1]Limit of nitrilotriacetic acid is only analysed according to USP*

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