

SPECIFICATION

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.* and USP*

Parameter	Ph. Eur.*		USP*	
	Specification	Test Method	Specification	Test Method
Characters	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*

Shelf life: 24 months from date of manufacture
Manufacturer: The Dow Chemical Company
Manufacturing Site: USA, Freeport, Texas
Storage conditions: protected from light in well closed containers

Residual Solvents (Ph. Eur.* 5.4 / USP* <467> / 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 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 this specification¹. The certificate of analysis (CoA) provides all results like above plus analysis date, date of manufacture and residual solvents statement. All CoAs are signed by a Qualified Person according to GMP or a responsible QA/QC-Manager.

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

*current version

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Dr. Katja Teufel QC-Manager	Dr. Philipp Hoch QA/QC- Manager	Dr. Frank Milek Qualified Person (GMP)	01.10.2019	15.07.2019