

## Sodium Calcium Edetate [Versene<sup>2</sup> CA]

Testing specifications: Ph. Eur.\* / USP\*

The material meets all requirements of the related monographs in Ph. Eur.\* and USP\*

Parameter	Ph. Eur.*		USP*	
	Specification	Test Method	Specification	Test Method
Assay	98.0 – 102.0 %	Ph. Eur.*	97.0 – 102.0 %	USP*
Identification A (IR-Spectrum)	conforms	Ph. Eur.* (2.2.24)	conforms	USP* <197M>
Identification B	conforms	Ph. Eur.*	conforms	USP* <191>
Identification C	conforms	Ph. Eur.* (2.3.1)	conforms	USP*
Identification D	conforms	Ph. Eur.* (2.3.1)	-	-
Appearance of Solution	clear/colourless	Ph. Eur.* (2.2.1/2.2.2)	-	-
pH	6.5 – 8.0	Ph. Eur.* (2.2.3)	6.5 - 8.0	USP* <791>
Limit of nitrilotriacetic acid <sup>1</sup>	≤ 0.1% (Impurity A)	Ph. Eur.* (2.2.29)	≤ 0.1%	USP* <621>
Chlorides	≤ 0.1 %	Ph. Eur.* (2.4.4)	-	-
Disodium edetate	≤ 1.0 %	Ph. Eur.*	-	-
Iron	≤ 80 ppm	Ph. Eur.* (2.4.9)	-	-
Heavy Metals	≤ 20 ppm	Ph. Eur.* (2.4.8)	≤ 0.002 %	USP* <231>
Water	5.0 – 13.0 %	Ph. Eur.* (2.5.12)	≤ 13.0 %	USP* <921>
Magnesium Chelating Substances	-	-	≤ 2.0 ml	USP*

**Shelf life:** 2 years  
**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 / CPMP/ICH/283/95):

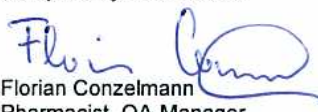
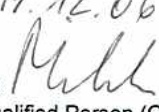
No organic solvents are used in the manufacture or as raw materials. The raw materials used to manufacture Versene<sup>2</sup> CA also do not incorporate solvents. This includes the class 1, 2 and 3 solvents listed in CPMP/ICH/283/95.

Every batch is analyzed according to all parameters of this specification<sup>1</sup>. 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.

<sup>1</sup>Limit of nitrilotriacetic acid is analysed only according to USP\*

<sup>2</sup>Trademark of the Dow Chemical Company

\*current version

Compiled by: 12.12.2006  Florian Conzelmann Pharmacist, QA-Manager	Approved by: 19.12.06  Dr. Frank Milek Pharmacist, Qualified Person (GMP)	Effective: 01.01.2007	Supersedes: 01.01.2006	Page 1 of 1
--	---	--------------------------	---------------------------	-------------