

Disodium Edetate

CODE ARTICLE: 91596	BATCH: 0132746
TEST DATE: 10/05/2024	TEST: QC-00264257
EXPIRY DATE: 04/07/2026	FABRICATION DATE: 04/07/2023
CAS: [6381-92-6]	MR: 372,20
SYNONYMS / BOTANICAL NAME: Disódica 2-hidratos	FORMULA: C10H18N2Na2O10
STORAGE: Store in tightly closed containers in a cool, dry place.	

TEST	RESULTS	Units	MIN	MAX	METHOD
APPEARANCE	PASS -			Crystal powder	PH.EUR.*
COLOUR	PASS -			White	PH.EUR.*
<u>SOLUBILITY</u>					
SOLUBLE	PASS -			Soluble in water	PH.EUR.*
SOLUBLE	PASS -			Practically insoluble in ethanol (96 per cent)	PH.EUR.*
<u>IDENTIFICATION</u>					
IDENTIFICATION	PASS				PH.EUR.*
DISSOLUTION ASPECT	PASS -			Solution S clear and colourless	PH.EUR.
PH (5%)	4,4 -		4	5,5	PH.EUR.*
IMPURITY A	<0,1 %			0,1	PH.EUR.
IRON	0,6 ppm			80	PH.EUR.
ASSAY	99,4 %		98,5	101	PH.EUR.
PH (1%)	4,6 -		4,3	4,7	Manufacture's Standard*
CALCIUM	PASS				Manufacture's Standard
SEQUESTERING CAPACITY FOR CALCIUM	267,2 MG	CaCO3 / G	266	-	Manufacture's Standard
HEAVY METALS	0,9 ppm			20	Manufacture's Standard
LEAD	<0,1 ppm			10	Manufacture's Standard
SAMPLING	COLLECT				Manufacture's Standard
CORRECT BATCH	YES				Manufacture's Standard
SPECIFICATION	PH.EUR 11, FCC				Manufacture's Standard

NON-sterile



Silvia Sancho-Tello Ripoll
Technical Director.

The product has been handled in NON-sterile rooms, therefore this product IS NOT STERILE

The data expressed in this certificate of analysis is facilitated by our supplier and/or obtained in our control laboratory, in no case being exempted of the controls demanded by each sector. Tests marked with (*) are verified in Guinama.

Manufacturer Batch: J07041049 Manufacturer Code: 56843 Supplier Code: 405029

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