

Certificate of Analysis

Disodium Edetate

CODE ARTICLE: 91596		BATCH: 0122501			
TEST DATE: 05/10/2023		TEST: QC-00257399			
EXPIRY DATE: 25/04/2026	FABRICATION DATE: 25/04/2023	MR: 372,20			
CAS: [6381-92-6]		FORMULA: C10H18N2Na2O10			
SYNONYMS / BOTANICAL NAME: Disódica 2-hidratos					
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%)	4,6 -	4	5,5	PH.EUR.*
IMPURITY A	<0,1 %		0,1	PH.EUR.
IRON	<80 MG/KG		80	PH.EUR.
ASSAY	99,8 %	98,5	101	PH.EUR.
PH	4,6 -	4,3	4,7	Manufacture's Standard
CALCIUM	PASS			Manufacture's Standard
SEQUESTERING CAPACITY FOR CALCIUM	268,3 MG CaCO3 / G	266	-	Manufacture's Standard
HEAVY METALS	<20 MG/KG		20	Manufacture's Standard
LEAD	<10 MG/KG		10	Manufacture's Standar
SAMPLING	COLLECT			Manufacture's Standard
CORRECT BATCH	YES			Manufacture's Standard
SPECIFICATION	PH.EUR 11, FCC			Manufacture's Standard

NON-sterile

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

Silvia Sancho-Tello Ripoll Technical Director.

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: J04251049 Supplier Code: 405029

