

## **Certificate of Analysis**

## **Disodium Edetate**

CODE ARTICLE: 97892		<b>BATCH:</b> 0119940			
<b>TEST DATE:</b> 16/05/2023		<b>TEST:</b> QC-00253291			
<b>EXPIRY DATE:</b> 25/04/2026	FABRICATION DATE: 24/04/2023	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	CRISTAL POWDER			Manufacture's Standard*
COLOUR	WHITE			Manufacture's Standard*
SOLUBILITY				
SOLUBLE	108 g/L			Manufacture's Standard
<u>IDENTIFICATION</u>				
IDENTIFICATION A (IR SPECTRUM)	CONFORM			Manufacture's Standard*
IDENTIFICACION [B]	CONFORM			Manufacture's Standard
IDENTIFICACION (C)	CONFORM			Manufacture's Standard
DISSOLUTION ASPECT	CONFORM -		Clear and colorless	Manufacture's Standard
PH	4,5 -	4,3	4,7	Manufacture's Standard*
PH (5%)	4,6 -	4	5	Manufacture's Standard*
CAPACIDAD DE SECUESTRO	268,3 MG CaCO3 / G	266	-	Manufacture's Standard
IRON	<80		80	Manufacture's Standard
LEAD	<10 MG/KG		10	Manufacture's Standard
CALCIUM	CONFORM			Manufacture's Standard
ASSAY	99,8 %	98,5	101	Manufacture's Standard
NTA-H3 CONTENT	<0,1 %		<0,1	Manufacture's Standard
SAMPLING	COLLECT			Manufacture's Standard
CORRECT BATCH	YES			Manufacture's Standard
SPECIFICATION	PH.EUR, FCC			Manufacture's Standard

This product has been handled in a non-sterile room, for batches suitable for sterile use, consult availability.

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

