

# MASTER COPY



Plot no. 1116/P, Lamadapura Road,  
Manjusar – 391 775,  
Ta- Savli, Dist. Vadodara, Gujarat, India

## Quality Control

### Standard Test Specifications

Title: EDTA Di Sodium Salt EP

Page No.: 1 of 3

Specification No.:  
ACPL/FP/SP/054

Revision No.:  
00

Effective Date  
30/07/2021

Review Date  
29/07/2024

Change Control No.

NA

Prepared By: Pankaj Patel

Date: 27/07/2021

Name : Pankaj Patel  
(QC Officer / Designee)

Reviewed By: Nilesh Shah

Date: 28/07/2021

Name : Nilesh Shah  
(Unit Head / Designee)

Approved By: Naresh Solanki

Date: 29/07/2021

Name : Naresh Solanki  
(QA/QC In Charge / Designee)

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Format No. QC/017/F/01-00

Certified By (Sign/Date) : Naresh Solanki 30/07/2021

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#### 1.0 SAMPLING LEVEL :

As mentioned in the “Sampling procedure” SOP.

#### 2.0 SAMPLING METHOD TO BE FOLLOWED:

100% sampling to be done from each container.

#### 3.0 TOTAL COMPOSITE SAMPLE TO BE COLLECTED :

100 gm

#### 4.0 EXPIRY :

Five years from the Date of Manufacturing.

#### 5.0 CAS No: 6381-92-6

#### 6.0 MOLECULAR FORMULA: $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$

#### 7.0 MOLECULAR WEIGHT: 372.2 gm/mol.

#### 8.0 CATEGORY: Pharmaceutical aid; chelating agent in metal poisoning.

#### 9.0 STORAGE: Protected from light.

#### 10.0 SAFETY PRECAUTIONS TO BE TAKEN WHILE SAMPLING AND HANDLING :

Use hand gloves, goggles and apron during Handling.

#### 11.0 CONTROL SAMPLE: 3 X 100 gm.

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## TEST PARAMETERS AND SPECIFICATIONS

REF: BP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder.
2.	Solubility	Soluble in water, practically insoluble in ethanol (96 %)
3.	<b>Identification A</b> Comparison disodium edetate CRS	To Pass test
	<b>Identification B</b> No precipitate is formed.	To Pass test
	<b>Identification C</b> No precipitate is formed.	To Pass test
	<b>Identification D</b> It gives the reactions of sodium	To Pass test
4.	Appearance of solution	Clear and Colorless.
5.	pH (5 % solution)	4.0 to 5.5
6.	Impurity A	Max. 0.1 %
7.	Iron	Max. 80 ppm
8.	Assay %	98.5 % - 101.0 %

### REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	30/07/2021	First Issuance	N A

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