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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 IP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/054


Revision No.:
00

Effective Date
29/07/2021

Review Date
28/07/2024

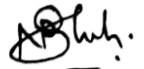
Change Control No.

NA

Prepared By: 

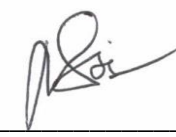
Date: 26/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 27/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 28/07/2021

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

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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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS

REF: IP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder.
2.	Solubility	Soluble in water, practically insoluble in ethanol (96 %)
3.	Identification A Compare the spectrum with that obtained with disodium edetate RS. Identification B No precipitate is formed. Identification C No precipitate is formed. Identification D It gives the reactions of sodium	To Pass test To Pass test To Pass test 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.	Heavy Metals	Max. 20 ppm
8.	Iron	Max. 80 ppm
9.	Assay %	98.5 % - 101.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	29/07/2021	First Issuance	N A

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