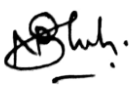



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Quality Control**Standard Test Specifications****Title: EDTA Di Sodium Salt USP****Page No.:** 1 of 3**Specification No.:**
ACPL/FP/SP/054**Revision No.:**
00**Effective Date**
30/07/2021**Review Date**
29/07/2024**Change Control No.**

NA

Prepared By: Date: 27/07/2021Name : Pankaj Patel
(QC Officer / Designee)Reviewed By: Date: 28/07/2021Name : Nilesh Shah
(Unit Head / Designee)Approved By: Date: 29/07/2021Name : Naresh Solanki
(QA/QC In Charge / Designee)**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  30/07/2021

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Quality Control

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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: 372.24 gm/mol.

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

9.0 STORAGE: Preserve in well-closed containers.

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: USP

| 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 Spectroscopic Identification Tests (Infrared Spectroscopy) Identification B The red color is discharged, leaving a yellowish solution. Identification C Identification Tests - General , for Sodium | To Pass test To Pass test To Pass test To Pass test |
| 4. | Assay %(Dried basis) | 99.0 % - 101.0 % |
| 5. | Calcium | To Pass test (No precipitate is formed). |
| 6. | Limit Of Nitrilotriacetic Acid | Max. 0.1 % |
| 7. | pH | 4.0 - 6.0 |
| 8. | Loss On Drying | 8.7 % – 11.4 % |

REVISION HISTORY:

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

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