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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 JP

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: 

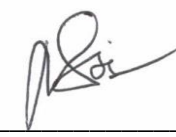
Date: 27/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 28/07/2021

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Date: 29/07/2021

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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:** 372.24 gm/mol.**8.0 CATEGORY:** Pharmaceutical aid; chelating agent in metal poisoning.**9.0 STORAGE:** Containers—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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS**REF: JP**

| Sr. No. | TEST PARAMETER | SPECIFICATION |
|---------|--|---|
| 1. | Description | White, crystals or crystalline powder. It is odorless and has a slight, acid taste. |
| 2. | Solubility | Soluble in water, and practically insoluble in ethanol (95 %) and in diethyl ether. |
| 3. | Identification (1) A purple color develops. Identification (2) The precipitate melts between 240 °C and 244 °C. Identification (3) Responds to the Qualitative Tests for sodium salt | To Pass test To Pass test To Pass test |
| 4. | pH (1 % solution) | Between 4.3 and 4.7 |
| 5. | Clarity and color of solution | The solution is clear and colorless. |
| 6. | Cyanide | To Pass test |
| 7. | Heavy metals | Max. 10 ppm |
| 8. | Arsenic | Max. 2 ppm |
| 9. | Residue on ignition | 37.0 % – 39.0 % |
| 10. | Assay % | Min. 99.0 % |

REVISION HISTORY:

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

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