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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: Sodium Citrate Dihydrate BP


Page No.: 1 of 3

| Specification No.: | Revision No.: | Effective Date | Review Date |
|--------------------|---------------|----------------|-------------|
| ACPL/FP/SP/011 | 00 | 31/08/2021 | 30/08/2024 |
| Change Control No. | NA | | |

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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: 6132-04-3**6.0 MOLECULAR FORMULA:** $C_6H_5Na_3O_7 \cdot 2H_2O$.**7.0 MOLECULAR WEIGHT:** 294.1gm/mol.**8.0 CATEGORY:** Systemic alkalinising substance.**9.0 STORAGE:** In an airtight container.**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 100gm.**UNCONTROLLED COPY**

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NA

TEST PARAMETERS AND SPECIFICATIONS**REF: BP**

| Sr. No. | TEST PARAMETER | SPECIFICATION |
|---------|---|--|
| 1. | Appearance | White or almost white, crystalline powder or white or almost white, granular crystals, slightly deliquescent in moist air. |
| 2. | Solubility | Freely soluble in water, practically insoluble in ethanol (96 per cent) |
| 3. | Identification A Gives the reaction of citrates. Identification B gives reaction (a) of sodium | To pass test To pass test |
| 4. | Appearance of Solution (10 % Soln.) | Solution is clear & colorless |
| 5. | Acidity or alkalinity | To Pass Test |
| 6. | Readily carbonisable substances | The solution is not more intensely colored than reference solution Y ₂ or GY ₂ |
| 7. | Chlorides (Cl) | Max. 50 ppm |
| 8. | Oxalates | Max. 300 ppm |
| 9. | Sulfates (SO ₄) | Max. 150 ppm |
| 10. | Water | 11.0 % to 13.0 % |
| 11. | Pyrogens | To Pass Test |
| 12. | Assay (Dried Basis) | 99.0 % to 101.0 % |

REVISION HISTORY:

| Revision No. | Effective Date | Revision Description | Change Control No. |
|--------------|----------------|----------------------|--------------------|
| 00 | 31/08/2021 | First Issuance | N A |

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