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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

| Standard | Test Specification | S |
|----------|---------------------------|---|
|----------|---------------------------|---|

Title: Sodium Citrate Anhydrous USP Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0670028/08/202127/08/2024

Change Control No. NA

Prepared By: ______ Date: <u>25/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: <u>26/08/2021</u>

Name : Nilesh Shah

(Unit Head / Designee)

Approved By: ______ Date: <u>27/08/2021</u>

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



28/08/2021

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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 Anhydrous USP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0670028/08/202127/08/2024

Change Control No. NA

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: 68-04-2

6.0 MOLECULAR FORMULA: C₆H₅Na₃O₇.

7.0 MOLECULAR WEIGHT: 258.07 gm/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: Preserve in tight 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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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Sodium Citrate Anhydrous USP Page No.: 3 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/067
 00
 28/08/2021
 27/08/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: USP

| Sr. No. | TEST PARAMETER | SPECIFICATION | |
|---------|--|---|--|
| 1. | Description | White To Extra White Crystalline Powder | |
| 2. | Soluble In Water And Very Soluble In Boilin Water Assay % (Dried Basis) Soluble In Water And Very Soluble In Boilin Water 99.0 % to 100.5 % | | |
| 3. | | | |
| 4. | Tartrate | To Pass Test | |
| 5. | Alkalinity To Pass Test | | |
| 6. | Water determination | Max. 1.0 % | |

REVISION HISTORY:

| Revision No. | Effective Date | Revision Description | Change Control No. |
|--------------|----------------|-----------------------------|--------------------|
| 00 | 28/08/2021 | First Issuance | N A |

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