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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: Tri Sodium Phosphate Dodecahydrate AR Page No.: 1 of 3

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

 ACPL/FP/SP/049
 00
 15/09/2021
 14/09/2024

Change Control No. NA

Prepared By: _____ Date: 11/09/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: 13/09/2021

Name : <u>Nilesh Shah</u>
(Unit Head / Designee)

Approved By: _____ Date: 14/09/2021

Name : Naresh Solanki_____

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Pai

15/09/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Tri Sodium Phosphate Dodecahydrate AR Page No.: 2 of 3

 Specification No.:
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 Effective Date
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 ACPL/FP/SP/049
 00
 15/09/2021
 14/09/2024

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 RETEST DATE: One year

5.0 CAS No: 10101-89-0

6.0 MOLECULAR FORMULA: Na₃PO_{4.12}H₂O

7.0 MOLECULAR WEIGHT: 380.12 g/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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Quality Control

Standard Test Specifications

Title: Tri Sodium Phosphate Dodecahydrate AR **Page No.:** 3 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/049 15/09/2021 14/09/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: AR

| Sr. No. | TEST PARAMETER | SPECIFICATION |
|---------|-----------------------------|--|
| 1. | Description | White or almost white powder, hygroscopic. |
| 2. | Solubility | Soluble in water |
| 3. | Free Alkali | Max. 2.0 % |
| 4. | Chloride as Cl | Max. 50 ppm |
| 5. | Sulphate as SO ₄ | Max. 50 ppm |
| 6. | Iron as Fe | Max. 10 ppm |
| 7. | Water Insoluble Matter | Max. 50 ppm |
| 8. | Heavy Metal | Max. 10 ppm |
| 9. | Total Nitrogen | Max. 10 ppm |
| 10. | Assay | Min. 98.0 % |

REVISION HISTORY:

| Revision No. | Effective Date | Revision Description | Change Control No. |
|--------------|----------------|----------------------|--------------------|
| 00 | 15/09/2021 | First Issuance | N A |

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