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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 DodecahydrateUSP Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0490015/09/202114/09/2024

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 : Nilesh Shah (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 DodecahydrateUSP **Page No.:** 2 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

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: 10101-89-0

6.0 MOLECULAR FORMULA:Na₃PO_{4.}12H₂O

7.0 MOLECULAR WEIGHT: 380.12g/mol.

8.0 CATEGORY: Excipient.

9.0 STORAGE: Preserve in tight containers.

10.0 SAFETY PRECAUTIONS TO BE TAKENWHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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Quality Control

Standard Test Specifications

Title: Tri Sodium Phosphate DodecahydrateUSP Page No.: 3 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0490015/09/202114/09/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white powder, hygroscopic.
2.	Solubility	Soluble in water.
3.	Identification Tests for Sodium and for Phosphate	To Pass test
4.	Assay%	Min. 92.0% of Na ₃ PO ₄ on the ignited basis.
5.	Loss on Ignition	45.0%-57.0%
6.	Arsenic	Max. 3 ppm
7.	Insoluble Substances	Max. 0.2 %

REVISION HISTORY:

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

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

Certified By (Sign/Date):



15/09/2021