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Date: 10/09/2021

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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Tri Sodium Phosphate Anhydrous USP Page No.: 1 of 3

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

 ACPL/FP/SP/048
 00
 14/09/2021
 13/09/2024

Change Control No. NA

Prepared By:

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: _____ Date: 11/09/2021

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

Approved By: _____ Date: <u>13/09/2021</u>

Name : <u>Naresh Solanki</u>

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

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14/09/2021

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Quality Control

Standard Test Specifications

Title: Tri Sodium Phosphate Anhydrous USP **Page No.:** 2 of 3

Revision No.: Specification No.: Effective Date Review Date ACPL/FP/SP/048 14/09/2021 13/09/2024 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: 7601-54-9

6.0 MOLECULAR FORMULA: Na₃PO₄.

7.0 MOLECULAR WEIGHT: 163.94 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 Anhydrous USP **Page No.:** 3 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/048 14/09/2021 13/09/2024 00

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. 97.0% of Na PO on the ignited basis.
5.	Loss on Ignition	Max. 2.0 %
6.	Arsenic	Max. 3 ppm
7. Insoluble Substances		Max. 0.2 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	14/09/2021	First Issuance	N A

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