## **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Di Sodium Hydrogen Phosphate Dihydrate AR Page No.: 1 of 3

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

 ACPL/FP/SP/006
 00
 26/07/2021
 25/07/2024

Change Control No. NA

Prepared By: \_\_\_\_\_\_ Date: <u>22/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date:23/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: <u>24/07/2021</u>

Name : Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



26/07/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Di Sodium Hydrogen Phosphate Dihydrate AR Page No.: 2 of 3

 Specification No.:
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 26/07/2021
 25/07/2024

**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:** 10028-24-7

6.0 MOLECULAR FORMULA: Na<sub>2</sub>HPO<sub>4</sub>.2H<sub>2</sub>O

**7.0 MOLECULAR WEIGHT:** 178.0gm/mol.

**8.0 CATEGORY:** Excipient.

**9.0 STORAGE:** Preserve in well-closed 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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**Standard Test Specifications** 

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# TEST PARAMETERS AND SPECIFICATIONS REF: AR

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white powder or colorless crystals.
2.	Solubility	Soluble in water
3.	pH (5% Aqueous Solution)	8.7 to 9.3
4.	Chloride as Cl	Max. 20 ppm
5.	Sulphate as SO <sub>4</sub>	Max. 50 ppm
6.	Iron as Fe	Max. 10 ppm
7.	Heavy Metal	Max. 10 ppm
8.	Assay	NLT 99.0%

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	26/07/2021	First Issuance	N A

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