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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: Di Sodium Hydrogen Phosphate Dodecahydrate LR Page No.: 1 of 3

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

 ACPL/FP/SP/025
 00
 28/07/2021
 27/07/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_\_ Date: 24/07/2021

Name : Pankaj Patel

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 26/07/2021

Name : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 27/07/2021

Name : <u>Naresh Solanki</u>

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):



28/07/2021

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**Standard Test Specifications** 

Title: Di Sodium Hydrogen Phosphate Dodecahydrate LR **Page No.:** 2 of 3

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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:** 10039-32-4

**6.0 MOLECULAR FORMULA**: Na<sub>2</sub>HP0<sub>4</sub>.12H<sub>2</sub>O

7.0 MOLECULAR WEIGHT: 358.1 gm/mol.

8.0 CATEGORY: Excipient.

**9.0 STORAGE**: Preserve in well-closed 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 100gm.

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### TEST PARAMETERS AND SPECIFICATIONS **REF: LR**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	Colorless, transparent crystals, very efflorescent.
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %).
3.	Identification Test for Sodium and phosphate	To Pass test
4.	Chloride as Cl	Max. 200 ppm
5.	Sulphate as SO <sub>4</sub>	Max. 500 ppm
6.	Heavy Metal (as Pb)	Max. 10 ppm
7.	Iron as Fe	Max. 20 ppm
8.	Arsenic as As	Max. 2 ppm
9.	Assay as Na <sub>2</sub> HPO <sub>4.</sub> 12H <sub>2</sub> O	98.5 % – 101.0 %

### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	28/07/2021	First Issuance	N A

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