## **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 Dodecahydrate USP 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 : <u>Pankaj Patel</u>

(QC Officer / Designee)

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

Name : Nilesh Shah\_\_\_\_\_

(Unit Head / Designee)

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

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):

Di

28/07/2021

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**Quality Control** 

**Standard Test Specifications** 

Title: Di Sodium Hydrogen Phosphate Dodecahydrate USP **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>HPO<sub>4</sub>.12H<sub>2</sub>O

**7.0 MOLECULAR WEIGHT:** 358.14 gm/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 100gm.

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

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

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white powder, hygroscopic.	
2.	Identification A Test for Sodium Identification B Test for phosphates	To Pass test  To Pass test	
3.	Assay (dried basis)	98.0 % - 100.5 %	
4.	Insoluble substance	Max. 4000 ppm	
5.	Chlorides	Max. 600 ppm	
6.	Sulfates	Max. 2000 ppm	
7.	rsenic Max 2 ppm		
8. Loss on drying Min. 55.0 % to Max. 64.0 %		Min. 55.0 % to Max. 64.0 %	

#### **REVISION HISTORY:**

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

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28/07/2021