# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	Test S	specifications
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Title: Sodium Dihydrogen Phosphate Dihydrate IP Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/012	00	02/09/2021	01/09/2024

Change Control No. NA

Prepared By: \_\_\_\_\_ Date: 30/08/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_\_ Date: 31/08/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 01/09/2021

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):



02/09/2021

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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: Sodium Dihydrogen Phosphate Dihydrate IP Page No.: 2 of 3

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

 ACPL/FP/SP/012
 00
 02/09/2021
 01/09/2024

**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:** 13472-35-0

**6.0 MOLECULAR FORMULA**:NaH<sub>2</sub>PO<sub>4</sub>.2H<sub>2</sub>O

7.0 MOLECULAR WEIGHT: 156.0 gm/mol.

**8.0 CATEGORY**: Pharmaceutical aid.

**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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**Quality Control** 

**Standard Test Specifications** 

Title: Sodium Dihydrogen Phosphate Dihydrate IP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/012 02/09/2021 01/09/2024 00

Change Control No. NA

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

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	A white powder or colorless crystals.	
2.	Identification A Solution S gives the reaction of Phosphates Identification B Solution S gives reaction (a) of Sodium	To Pass test  To Pass test	
3.	pH(5% Solution)	4.1 to 4.5	
4.	Insoluble substances	Max. 0.2 %	
5.	Chlorides	Max. 140 ppm	
6.	Sulfates	Max. 0.15 %	
7.	Aluminium, calcium and related elements.	To Pass test	
8.	Arsenic (As)	Max. 8 ppm	
9.	Heavy metals	Max. 20 ppm	
10.	Water	18.0 % to 26.5 %	
11.	Assay (dried basis)	98.0% - 100.5%	

### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	02/09/2021	First Issuance	N A

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02/09/2021