## **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Title: Sodium Dihydrogen phosphate Monohydrate LR Page No.: 1 of 3

Specification No.:	Revision No.:	<b>Effective Date</b>	<b>Review Date</b>
ACPL/FP/SP/044	00	03/09/2021	02/09/2024

**Change Control No.** NA

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

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(QC Officer / Designee)

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

Name : <u>Nilesh Shah</u>

(Unit Head / Designee)

Approved By: \_\_\_\_\_\_ Date: 02/09/2021

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

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



03/09/2021

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

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**Quality Control** 

**Standard Test Specifications** 

Title: Sodium Dihydrogen phosphate Monohydrate LR **Page No.:** 2 of 3

**Revision No.: Specification No.: Effective Date Review Date** ACPL/FP/SP/044 03/09/2021 02/09/2024 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 RETESTG DATE:** Three year

**5.0 CAS No:** 10049-21-5

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

**7.0 MOLECULAR WEIGHT**: 138.0 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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**Quality Control** 

**Standard Test Specifications** 

Title: Sodium Dihydrogen phosphate Monohydrate LR Page No.: 3 of 3

 Specification No.:
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 00
 03/09/2021
 02/09/2024

Change Control No. NA

# TEST PARAMETERS AND SPECIFICATIONS REF: LR

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	Colorless crystals or a white powder.
2.	Solubility	Soluble in water
3.	pH (5% Aqueous Solution)	4.2 to 4.8
4.	Water	10 % – 15 %
5.	Chloride as Cl	Max. 50 ppm
6.	Sulphate as SO <sub>4</sub>	Max. 100 ppm
7.	Iron as Fe	Max. 20 ppm
8.	Assay(On Anhydrous Basis)	Min. 97.0 %

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	03/09/2021	First Issuance	N A

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