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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications	Standard	Test	Specific	ations
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Title: Di Sodium Hydrogen Phosphate Anhydrous LR Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/005	00	24/07/2021	23/07/2024

Change Control No. NA

Prepared By: ______ Date:21/07/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: <u>22/07/2021</u>

Name : Nilesh Shah_____

(Unit Head / Designee)

Approved By: ______ Date:23/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



24/07/2021

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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: Di Sodium Hydrogen Phosphate Anhydrous LR Page No.: 2 of 3

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

 ACPL/FP/SP/005
 00
 24/07/2021
 23/07/2024

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: 7758-11-4

6.0 MOLECULAR FORMULA:Na₂HPO₄

7.0 MOLECULAR WEIGHT: 142.0gm/mol.

8.0 CATEGORY: Cathartic; pharmaceutical aid (buffering agent).

9.0 STORAGE: In an airtight container.

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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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Di Sodium Hydrogen Phosphate Anhydrous LR Page No.: 3 of 3

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

 ACPL/FP/SP/005
 00
 24/07/2021
 23/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: LR

Sr. No.	TEST PARAMETER	SPECIFICATION	
1. Description		White or almost white powder, hygroscopic.	
2.	Solubility	Soluble in water	
3. pH (5% Aqueous Solution)		8.7 to 9.3	
4.	Chloride as Cl	Max. 100 ppm	
5.	Sulphate as SO ₄	Max. 200 ppm	
6.	Iron as Fe	Max. 20 ppm	
7.	Heavy Metal	Max. 20 ppm	
8. Assay %		Min. 97.0%	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	24/07/2021	First Issuance	N A

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24/07/2021