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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 USP Page No.: 1 of 3

	Review Date	
ACPL/FP/SP/012 00 03/09/2021	02/09/2024	

Change Control No. NA

Prepared By: ______ Date:31/08/2021

Name : Pankaj Patel

(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):

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03/09/2021

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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 USP **Page No.:** 2 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/012 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 EXPIRY:

Five years from the Date of Manufacturing.

5.0 CAS No: 13472-35-0

6.0 MOLECULAR FORMULA:NaH₂PO₄.2H₂O

7.0 MOLECULAR WEIGHT: 156.01gm/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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Page No.: 3 of 3

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 USP

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/012 03/09/2021 02/09/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS **REF: USP**

Sr.No.	TEST PARAMETER	SPECIFICATION		
1.	Appearance	White or almost white powder or colorless crystals.		
	Identification A	To pass test		
2.	Test for Sodium			
	Identification B	To pass test		
	Test for Phosphate			
3.	Assay (dried basis)	98.0% - 103.0 %		
4.	Insoluble Substances	Max. 0.2 %		
5.	Chlorides	Max. 140 ppm		
6.	Sulfates	Max. 1500 ppm		
7.	Aluminum, Calcium, And Related Elements	To Pass test		
8.	Arsenic	Max. 8 ppm		
9.	pH (5% Solution)	4.1 to 4.5.		
10.	Water Determination	18.0 to 26.5		

REVISION HISTORY:

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

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