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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard	Test Sn	ecifications
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Title: Sodium Dihydrogen Phosphate Dihydrate EP Page No.: 1 of 3

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

Change Control No. NA

Prepared By: _____ Date: 31/08/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: 01/09/2021

Name : Nilesh Shah (Unit Head / Designee)

Approved By: _____ Date: 02/09/2021

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):

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03/09/2021

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Quality Control

Standard Test Specifications

Title: Sodium Dihydrogen Phosphate Dihydrate EP **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: 156.0 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 EP **Page No.:** 3 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

TEST PARAMETERS AND SPECIFICATIONS **REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white powder or colorless crystals.	
2.	Solubility	Very soluble in water, very slightly soluble in ethanol (96 per cent).	
Solution S is slightly acid Identification B Solution S gives reaction of phosphates To pass		To pass test To pass test To pass test	
4.	Appearance of Solution	The solution is clear and colorless	
5.	pH(5% Solution)	4.2 to 4.5.	
6.	Reducing substances	To Pass Test. Max. 200 ppm	
7.	Chlorides		
8. Sulfates Max. 300 ppm		Max. 300 ppm	
9.	O. Arsenic Max 2 ppm		
10. Iron Max. 10 ppm 11. Loss on drying 21.5 % to 24.0 %		Max. 10 ppm	
		21.5 % to 24.0 %	
12.	2. Assay (dried basis) 98.0% - 100.5%		

REVISION HISTORY:

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

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