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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 Monohydrate BP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/044

Revision No.:
00

Effective Date
04/09/2021

Review Date
03/09/2024

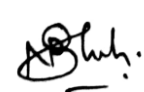
Change Control No.

NA

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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: 10049-21-5

6.0 MOLECULAR FORMULA: $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$

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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TEST PARAMETERS AND SPECIFICATIONS**REF: BP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	Colorless crystals or a white powder.
2.	Solubility	Very soluble in water; very slightly soluble in ethanol (96%).
3.	Identification A Solution S is slightly acid Identification B Solution S yields the reactions characteristic of phosphates Identification C Solution S neutralized with a 10% w/v solution of potassium hydroxide yields reaction A characteristic of sodium salts Identification D Complies with the test for Loss on drying.	To pass test To pass test To pass test To pass test
4.	Acidity	4.2 to 4.5
5.	Clarity and colour of solution	The solution is clear and colorless
6.	Arsenic	Max 2 ppm
7.	Iron	Max. 10 ppm
8.	Chlorides	Max. 200 ppm
9.	Sulfates	Max. 300 ppm
10.	Reducing substances	To Pass test
11.	Loss on drying	11.5 % to 14.5 %
12.	Assay (dried basis)	98.0 % - 100.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	04/09/2021	First Issuance	N A

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