

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 Dodecahydrate BP Page No.: 1 of 4

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

 ACPL/FP/SP/025
 00
 28/07/2021
 27/07/2024

Change Control No. NA

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Date: <u>27/07/2021</u>

Date: <u>24/07/2021</u>

Date: 26/07/2021

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Name

Certified By (Sign/Date):

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28/07/2021



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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: 10039-32-4

6.0 MOLECULAR FORMULA: Na₂HP0₄.12H₂O

7.0 MOLECULAR WEIGHT: 358.1 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, transparent crystals, very efflorescent.	
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 per cent).	
	Identification A Solution S is slightly alkaline Identification B	To pass test	
3.	Loss on drying (see Tests) Identification C Solution S gives reaction (b) of	To pass test To pass test	
	phosphates Identification D Solution S gives reaction (a) of Sodium	To pass test	
4.	Appearance of Solution	The solution is clear and colorless	
5.	Reducing substances	To Pass Test. Max. 2.5 %	
6.	Mon potassium phosphate		
7.	Chlorides	Max. 200 ppm	
8.	Sulfates	Max. 500 ppm Max 2 ppm	
9.	Arsenic		
10.	Iron	Max. 20 ppm	

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11.	Loss on drying	57.0 % to 61.0 %
12.	Assay (dried basis)	98.5 % - 102.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	28/07/2021	First Issuance	N A

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