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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 Dihydrate USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/006


Revision No.:
00

Effective Date
27/07/2021

Review Date
26/07/2024

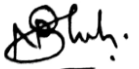
Change Control No.

NA

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Date: 23/07/2021

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Date: 24/07/2021

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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: 10028-24-7**6.0 MOLECULAR FORMULA:** $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$ **7.0 MOLECULAR WEIGHT:** 178.0gm/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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white powder, hygroscopic.
2.	Identification A Test for Sodium	To Pass test
	Identification B Test for phosphates	To Pass test
3.	Assay (dried basis)	98.0 % - 100.5 %
4.	Insoluble substance	Max. 4000 ppm
5.	Chlorides	Max. 600 ppm
6.	Sulfates	Max. 2000 ppm
7.	Arsenic	Max 2 ppm
8.	Loss on drying	Min.18.5 % to Max. 21.5 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	27/07/2021	First Issuance	N A

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