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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Di Sodium Hydrogen Phosphate Anhydrous BP Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/005	00	26/07/2021	25/07/2024

Change Control No. NA

Prepared By: ______ Date: <u>22/07/2021</u>

Name : Pankaj Patel

(QC Officer / Designee)

Reviewed By: _____ Date:23/07/2021

Name : Nilesh Shah_____

(Unit Head / Designee)

Approved By: ______ Date:24/07/2021

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):



26/07/2021

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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: Di Sodium Hydrogen Phosphate Anhydrous BP Page No.: 2 of 3

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

 ACPL/FP/SP/005
 00
 26/07/2021
 25/07/2024

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: 7758-11-4

6.0 MOLECULAR FORMULA: Na₂HPO₄

7.0 MOLECULAR WEIGHT: 142.0gm/mol.

8.0 CATEGORY: Cathartic; pharmaceutical aid (buffering agent).

9.0 STORAGE: In an airtight container.

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: Di Sodium Hydrogen Phosphate Anhydrous BP Page No.: 3 of 3

 Specification No.:
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 ACPL/FP/SP/005
 00
 26/07/2021
 25/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: BP

		KEF: BP	
Sr. No.	TEST PARAMETER	SPECIFICATION	
 Appearance Solubility 		White or almost white powder, hygroscopic. Soluble in water, practically insoluble in ethanol (96 per cent).	
	Solution S is slightly alkaline		
	Identification C	To pass test	
3.	Solution S gives reaction (b) of phosphates		
	Identification D	To pass test	
	Solution S gives reaction (a) of Sodium		
4.	Appearance of Solution	The solution is clear and colorless	
5.	Reducing substances	To Pass Test.	
6.	Mon potassium phosphate	Max. 2.5 %	
7. Chlorides8. Sulfates9. Arsenic		Max. 200 ppm	
		Max. 500 ppm	
		Max 2 ppm	
10.	Iron	Max. 20 ppm	
11.	Loss on drying	Max 1.0 %	
12.	Assay (dried basis)	98.0% - 101.0%	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	26/07/2021	First Issuance	N A

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Format No. QC/017/F/01-00

Certified By (Sign/Date):



26/07/2021