

MASTER COPY



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 USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/005

Revision No.:
00

Effective Date
26/07/2021

Review Date
25/07/2024


Change Control No.

NA

Prepared By: 

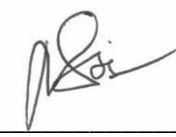
Date: 22/07/2021

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 : Naresh Solanki
(QA/QC In Charge / Designee)

UNCONTROLLED COPY

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

Certified By (Sign/Date) :  26/07/2021

MASTER COPY



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 USP

Page No.: 2 of 3

Specification No.:
ACPL/FP/SP/005

Revision No.:
00

Effective Date
26/07/2021

Review Date
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: 7558-79-4

6.0 MOLECULAR FORMULA: Na_2HPO_4

7.0 MOLECULAR WEIGHT: 141.96gm/mol.

8.0 CATEGORY: pharmaceutical aid (buffering agent).

9.0 STORAGE: Preserve in tight 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) :

26/07/2021

MASTER COPY

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 USP****Page No.:** 3 of 3**Specification No.:**
ACPL/FP/SP/005**Revision No.:**
00**Effective Date**
26/07/2021**Review Date**
25/07/2024**Change Control No.**

NA

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	Max 5.0 %

REVISION HISTORY:

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

UNCONTROLLED COPY**Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  26/07/2021