MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Di Potassium Hydrogen Phosphate USP Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/004	00	23/07/2021	22/07/2024

Change Control No. NA

Prepared By: ______ Date: <u>20/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date:21/07/2021

Name : Nilesh Shah_____

(Unit Head / Designee)

Approved By: ______ Date:22/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

UNCONTROLLED COPY

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

Certified By (Sign/Date):



23/07/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Di Potassium Hydrogen Phosphate USP Page No.: 2 of 3

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

 ACPL/FP/SP/004
 00
 23/07/2021
 22/07/2024

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: K₂HP0₄

7.0 MOLECULAR WEIGHT: 174.2gm/mol.

8.0 CATEGORY: Excipients.

9.0 STORAGE: Preserve in well-closed containers.

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.

UNCONTROLLED COPY

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

Certified By (Sign/Date):



23/07/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Di Potassium Hydrogen Phosphate USP Page No.: 3 of 3

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

 ACPL/FP/SP/004
 00
 23/07/2021
 22/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1. Appearance		White or almost white powder or colorless crystals, very hygroscopic.	
	Identification A	To pass test	
2.	Test For Potassium		
2.	Identification B	To Pass test	
	Test for Phosphates		
3.	Assay (dried basis)	98.0% - 100.5%	
4.	Insoluble Substances	Max. 0.2 %	
5.	Carbonate	NMT a few bubbles are evolved.	
6.	Chlorides	Max. 300 ppm	
7.	Sulphate	Max. 1000 ppm	
8.	Arsenic	Max. 3 ppm	
9.	Iron	Max. 30 ppm	
10.	Limit of Fluoride	Max. 10 ppm	
11.	Limit of Monobasic or Tribasic Salt	To Pass test	
12.	pН	8.5 - 9.6	
13.	Loss on drying	Max 1.0 %	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	23/07/2021	First Issuance	N A

UNCONTROLLED COPY

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

Certified By (Sign/Date):



23/07/2021