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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality	Control
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Title: Potassium Dihydrogen Phosphate USP Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	<b>Review Date</b>
ACPL/FP/SP/007	00	19/08/2021	18/08/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_ Date: 16/08/2021

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: <u>17/08/2021</u>

Name : <u>Nilesh Shah</u> (Unit Head / Designee)

Approved By: \_\_\_\_\_ Date: 18/08/2021

Name : Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Ri

19/08/2021

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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: Potassium Dihydrogen Phosphate USP Page No.: 2 of 3

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

 ACPL/FP/SP/007
 00
 19/08/2021
 18/08/2024

**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:** 7778-77-0

**6.0 MOLECULAR FORMULA**:KH<sub>2</sub>P0<sub>4</sub>

**7.0 MOLECULAR WEIGHT**: 136.0.9gm/mol.

8.0 CATEGORY: Excipient.

**9.0 STORAGE**: Preserve in tight containers.

### 10.0 SAFETY PRECAUTIONS TO BETAKENWHILE 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: Potassium Dihydrogen Phosphate USP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/007 19/08/2021 18/08/2024 00

**Change Control No.** NA

## TEST PARAMETERS AND SPECIFICATIONS

**REF: USP** 

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, crystalline powder or colorless crystals.	
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 %).	
	Identification A	To Pass test	
3.	Test for Potassium		
3.	Identification B	To Pass test	
	Test For Phosphate		
4.	Assay (dried basis)	98.0 % - 100.5 %	
5.	Arsenic	Max. 3 µg/g	
6.	ead Max. 5 μg/g		
7.	Limit of Fluoride	Max. 10 μg/g	
8.	Insoluble Substances	Max. 0.2 %	
9.	Loss On Drying	Max. 1.0 %	

### **REVISION HISTORY:**

Revision No.	Effective Date	<b>Revision Description</b>	Change Control No.
00	19/08/2021	First Issuance	N A

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