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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 EP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/007

Revision No.:
00

Effective Date
19/08/2021

Review Date
18/08/2024


Change Control No.

NA

Prepared By: 

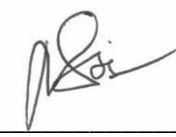
Date: 16/08/2021

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Reviewed By: 

Date: 17/08/2021

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Approved By: 

Date: 18/08/2021

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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: 7778-77-0

6.0 MOLECULAR FORMULA: KH_2PO_4

7.0 MOLECULAR WEIGHT: 136.1gm/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.

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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

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 %).
3.	Identification A Solution S is faintly acid Identification B Solution S gives reaction (b) of phosphates Identification C 0.5 mL of solution S gives reaction (b) of potassium	To Pass test To Pass test To Pass test
4.	Appearance of Solution	The solution is clear and colorless
5.	pH	4.2 to 4.5
6.	Reducing substances	To Pass Test.
7.	Chlorides	Max. 200 ppm
8.	Sulfates	Max. 300 ppm
9.	Arsenic	Max 2 ppm
10.	Iron	Max. 10 ppm
11.	Sodium	Max. 1 %
12.	Loss on drying	Max 2.0 %
13.	Assay (dried basis)	98.0% - 100.5%

REVISION HISTORY:

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

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