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Annexe
CHEM PVT. LTD.

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 BP

Page No.: 1 of 4

Specification No.:
ACPL/FP/SP/004

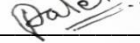
Revision No.:
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Effective Date
23/07/2021

Review Date
22/07/2024

Change Control No.


NA

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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: 7758-11-4

6.0 MOLECULAR FORMULA: K_2HP0_4

7.0 MOLECULAR WEIGHT: 174.2gm/mol.

8.0 CATEGORY: Excipients.

9.0 STORAGE: In an airtight container.

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: BP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white powder or colorless crystals, very hygroscopic.
2.	Solubility	Very soluble in water, very slightly soluble in ethanol (96 per cent).
3.	Identification A Solution S is slightly alkaline Identification B Solution S gives reaction (b) of phosphates Identification C Solution S gives reaction (a) of potassium	To pass test To pass test To pass test
4.	Appearance of Solution	The solution is clear and colorless
5.	Reducing substances	The solution remains faintly pink.
6.	Mon potassium phosphate	Max. 2.5 %
7.	Chlorides	Max. 200 ppm
8.	Sulfates	Max. 0.1%
9.	Arsenic	Max 2 ppm
10.	Iron	Max. 10 ppm
11.	Sodium	Max 0.1 %

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12.	Loss on drying	Max 2.0 %
13.	Bacterial endotoxins	Less than 1.1 IU/mg
14.	Assay (dried basis)	98.0% - 101.0%

REVISION HISTORY:

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

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