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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Potassium Acetate EP Page No.: 1 of 3

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

 ACPL/FP/SP/066
 00
 10/08/2021
 09/08/2024

Change Control No. NA

Prepared By: ______ Date: <u>06/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: ______ Date: 07/08/2021

Name : Nilesh Shah_____

(Unit Head / Designee)

Approved By: _____ Date: 09/08/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Ri

10/08/2021

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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 Acetate EP Page No.: 2 of 3

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

 ACPL/FP/SP/066
 00
 10/08/2021
 09/08/2024

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: 127-08-2

6.0 MOLECULAR FORMULA: C₂H₃K0₂

7.0 MOLECULAR WEIGHT: 98.1 gm/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 100 gm.

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Quality Control

Standard Test Specifications

Page No.: 3 of 3 **Title: Potassium Acetate EP**

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/066 10/08/2021 09/08/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: EP

Sr. No.	TEST PARAMETER	SPECIFICATION		
1.	Appearance	White or almost white, crystalline powder or colorless crystals, deliquescent		
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 %).		
	Identification A	To Pass test		
3.	It gives reaction of acetates Identification B It gives reaction of potassium	To Pass test		
4.	Appearance of Solution	The solution is clear and colorless		
5.	pН	7.5 to 9.0.		
6.	Reducing substances	To Pass test (The solution remains pink)		
7.	Chlorides	Max. 200 ppm		
8.	Sulfates	Max. 200 ppm		
9.	Aluminium	Max. 1 ppm		
10.	Iron	Max. 20 ppm		
11.	Sodium	Max. 0.5 %		
12.	Loss on drying	Max. 3.0 %		
13.	Assay % (Dried substance)	99.0 % - 101.0 %		

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	10/08/2021	First Issuance	N A

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Certified By (Sign/Date):



10/08/2021