MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

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

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

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

Change Control No. NA

Prepared By:

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By:

Name : Nilesh Shah___

(Unit Head / Designee)

Approved By: _

Name

: Naresh Solanki___

(QA/QC In Charge / Designee)

Date: 07/08/2021

Date: <u>05/08/2021</u>

Date: 06/08/2021

UNCONTROLLED COPY

Bi

09/08/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Potassium Acetate BP Page No.: 2 of 3

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

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

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.

UNCONTROLLED COPY

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

Certified By (Sign/Date):



09/08/2021

MASTER COPY



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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Potassium Acetate BP Page No.: 3 of 3

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

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

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS REF: BP

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) Max. 200 ppm Max. 200 ppm		
7.	Chlorides			
8.	Sulfates			
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	09/08/2021	First Issuance	N A

UNCONTROLLED COPY

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

Certified By (Sign/Date):



09/08/2021