## **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

## **Quality Control**

Standard	Test S	Specifica	tions
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Title: Sodium Acetate Anhydrous USP Page No.: 1 of 3

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

 ACPL/FP/SP/040
 00
 24/08/2021
 23/08/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_\_ Date: <u>20/08/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By: \_\_\_\_\_ Date: 21/08/2021

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

Approved By: \_\_\_\_\_ Date: 23/08/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):



24/08/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Sodium Acetate Anhydrous USP Page No.: 2 of 3

 Specification No.:
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 23/08/2024

**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:** 127-09-3

6.0 MOLECULAR FORMULA: CH3COONa

**7.0 MOLECULAR WEIGHT**: 82.03 gm/mol.

**8.0 CATEGORY**: Excipient.

**9.0 STORAGE**: Preserve in tight 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 100 gm.

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**Quality Control** 

**Standard Test Specifications** 

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# TEST PARAMETERS AND SPECIFICATIONS REF: USP

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, crystalline powder.	
2.	Solubility	Soluble in water	
3.	Identification A Test for sodium. Identification C Test for acetates	To Pass test  To Pass test	
4.	Assay % (Dried Basis)	99.0 % to 101.0 %	
5.	Chlorides (Cl)	Max. 350 ppm	
6.	Sulfates (SO <sub>4</sub> )	Max. 50 ppm	
7.	Calcium and Magnesium	To Pass test	
8.	Potassium	To Pass test	
9.	Aluminium (Al)	Max. 0.2 μg/g	
10.	рН	7.5 – 9.2	
11.	Loss on Drying	Max. 1.0 %	
12.	Insoluble Matter	Max. 0.05 %	

#### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	24/08/2021	First Issuance	N A

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