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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: Sodium Acetate Trihydrate EP**

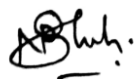
**Page No.:** 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/041	00	24/08/2021	23/08/2024
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:** 6131-90-4

**6.0 MOLECULAR FORMULA:** C<sub>2</sub>H<sub>3</sub>NaO<sub>2</sub>.3H<sub>2</sub>O.

**7.0 MOLECULAR WEIGHT:** 136.1 gm/mol.

**8.0 CATEGORY:** Excipient.

**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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NA

**TEST PARAMETERS AND SPECIFICATIONS****REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder or colorless crystals.
2.	Solubility	Very soluble in water, soluble in ethanol (96 %).
3.	<b>Identification A</b> 1 mL of solution S gives reaction (b) of acetates. <b>Identification B</b> 1 mL of solution S gives reaction (a) of sodium. <b>Identification C</b> Loss on drying (see Tests)	To pass test  To pass test  To pass test
4.	Appearance of Solution (10 % Soln.)	Solution is clear & colorless
5.	pH	7.5 to 9.0
6.	Reducing substances	To pass test
7.	Chlorides (Cl)	Max.200 ppm
8.	Sulfates (SO <sub>4</sub> )	Max. 200 ppm
9.	Aluminium (Al)	Max. 0.2 ppm
10.	Arsenic (AS)	Max. 2 ppm
11.	Calcium and magnesium	Max. 50 ppm
12.	Iron	Max. 10 ppm
13.	Loss on drying (at 130 °C)	39.0 % to 40.5 %
14.	Assay % (Dried Basis)	99.0 % to 101.0 %

**REVISION HISTORY:**

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

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