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Date: 20/08/2021

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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Standard	<b>Test</b>	<b>Specifica</b>	tions
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Title: Sodium Acetate Trihydrate BP Page No.: 1 of 3

Charification No.	Revision No.:	Effective Date	Daview Date
Specification No.:	Kevision No.:	Effective Date	Review Date
ACPL/FP/SP/041	00	24/08/2021	23/08/2024
Change Control No.	NA		

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

Certified By (Sign/Date):



24/08/2021

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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: Sodium Acetate Trihydrate BP Page No.: 2 of 3

Specification No.:	Revision No.:	Effective Date	<b>Review Date</b>
ACPL/FP/SP/041	00	24/08/2021	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:**

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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<sub>.</sub>

**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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**Quality Control** 

# **Standard Test Specifications**

Title: Sodium Acetate Trihydrate BP Page No.: 3 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

# TEST PARAMETERS AND SPECIFICATIONS REF: BP

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 %).	
	Identification A  1 mL of solution S gives reaction (b) of acetates.	To pass test	
3.	<b>Identification B</b> 1 mL of solution S gives reaction (a)	To pass test	
	of sodium.  Identification C  Loss on drying (see Tests)	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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