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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 USP

Page No.: 1 of 3

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

Prepared By: 

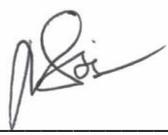
Date: 20/08/2021

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Reviewed By: 

Date: 21/08/2021

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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:** $C_2H_3NaO_2 \cdot 3H_2O$.**7.0 MOLECULAR WEIGHT:** 136.1 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.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**

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TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

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.	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 ₄)	Max. 50 ppm
7.	Calcium and Magnesium	To Pass test
8.	Potassium	To Pass test
9.	Aluminium (Al)	Max. 0.2 µg/g
10.	pH	7.5 – 9.2
11.	Loss on Drying	38.0 % – 41.0 %
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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