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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 Citrate Dihydrate EP


Page No.: 1 of 3

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/011	00	31/08/2021	30/08/2024
Change Control No.	NA		

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Certified By (Sign/Date) :  31/08/2021

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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: 6132-04-3**6.0 MOLECULAR FORMULA:** $C_6H_5Na_3O_7 \cdot 2H_2O$.**7.0 MOLECULAR WEIGHT:** 294.1gm/mol.**8.0 CATEGORY:** Systemic alkalinising substance..**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 100gm.**UNCONTROLLED COPY**

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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, crystalline powder or white or almost white, granular crystals, slightly deliquescent in moist air.
2.	Solubility	Freely soluble in water, practically insoluble in ethanol (96 per cent)
3.	Identification A Gives the reaction of citrates. Identification B gives reaction (a) of sodium	To pass test To pass test
4.	Appearance of Solution (10 % Soln.)	Solution is clear & colorless
5.	Acidity or alkalinity	To Pass Test
6.	Readily carbonisable substances	The solution is not more intensely colored than reference solution Y ₂ or GY ₂
7.	Chlorides (Cl)	Max. 50 ppm
8.	Oxalates	Max. 300 ppm
9.	Sulfates (SO ₄)	Max. 150 ppm
10.	Water	11.0 % to 13.0 %
11.	Pyrogens	To Pass Test
12.	Assay (Dried Basis)	99.0 % to 101.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	31/08/2021	First Issuance	N A

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