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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 USP 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

Prepared By:

Name : Pankaj Patel

(QC Officer / Designee)

Reviewed By:

Date: 28/08/2021

Date: <u>27/08/2021</u>

Name : Nilesh Shah_

(Unit Head / Designee)

Approved By: _____

Date:30/08/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Di

31/08/2021

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Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Standard Test Specifications

Title: Sodium Citrate Dihydrate USP Page No.: 2 of 3

 Specification No.:
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 ACPL/FP/SP/011
 00
 31/08/2021
 30/08/2024

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: 6132-04-3

6.0 MOLECULAR FORMULA: C₆H₅Na₃O₇.2H₂O_.

7.0 MOLECULAR WEIGHT: 294.1gm/mol.

8.0 CATEGORY: Systemic alkalinising substance..

9.0 STORAGE: Preserve in tight containers.

10.0 SAFETY PRECAUTIONS TO BE TAKENWHILE SAMPLING AND HANDLING:

Use hand gloves, goggles and apron during Handling.

11.0 CONTROL SAMPLE: 3 X 100gm.

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Quality Control

Standard Test Specifications

Title: Sodium Citrate Dihydrate USP **Page No.:** 3 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

TEST PARAMETERS AND SPECIFICATIONS **REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Description	White or almost white, crystalline powder or white or almost white, granular crystals, slightly deliquescent in moist air.	
	Identification A	To pass test	
2.	Test of Sodium Identification B Test of Citrate Identification C Upon ignition, it yields an alkaline residue that effervesces when treated with 3 N hydrochloric acid.	To pass test To pass test	
3.	Assay % (Dried Basis)	99.0 % to 100.5 %	
4.	Tartrate	To Pass Test	
5.	Alkalinity	To Pass Test	
6.	Water determination	Max. 1.0 %	

REVISION HISTORY:

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

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

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

