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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: Calcium Acetate USP

Page No.: 1 of 3

Specification No.:
ACPL/FP/SP/018

Revision No.:
00

Effective Date
07/07/2021

Review Date
06/07/2024

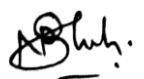
Change Control No.

NA

Prepared By: 


Date: 03/07/2021

Name : Pankaj Patel
(QC Officer / Designee)

Reviewed By: 

Date: 05/07/2021

Name : Nilesh Shah
(Unit Head / Designee)

Approved By: 

Date: 06/07/2021

Name : Naresh Solanki
(QA/QC In Charge / Designee)

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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: 62-54-4**6.0 MOLECULAR FORMULA:** $\text{Ca}(\text{CH}_3\text{COO})_2$ **7.0 MOLECULAR WEIGHT:** 158.17gm/mol.**8.0 CATEGORY:** Used in solutions for hemodialysis and peritoneal dialysis.**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 100gm.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  07/07/2021

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TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, hygroscopic powder.
2.	Identification A Test of Calcium and Acetate	To pass test
3.	Assay (Dried basis)	99.0 % to 100.5 %
4.	Arsenic	Max. 3 ppm
5.	Chloride	Max. 500 ppm
6.	Sulfates	Max. 600 ppm
7.	Lead	Max. 10 ppm
8.	Aluminium	Max. 2 ppm
9.	Barium	To Pass test
10.	Fluorides	Max. 50 ppm
11.	Magnesium	Max. 500 ppm
12.	Nitrate	The blue color persists for NLT 10 min.
13.	Potassium	Max. 500 ppm
14.	Sodium	Max. 5000 ppm
15.	Strontium	Max. 500 ppm
16.	Readily Oxidisable substances	To Pass test
17.	pH (5 % Solution)	6.3 to 9.6
18.	Water Determination	Max. 7.0 %

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	07/07/2021	First Issuance	N A

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