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Plot no. 1116/P, Lamadapura Road,
Manjusar – 391 775,
Ta- Savli, Dist. Vadodara, Gujarat, India

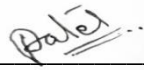
Quality Control

Standard Test Specifications

Title: Calcium Acetate EP


Page No.: 1 of 4

Specification No.:	Revision No.:	Effective Date	Review Date
ACPL/FP/SP/018	00	07/07/2021	06/07/2024
Change Control No.	NA		

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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: Ca (CH₃COO)₂.

7.0 MOLECULAR WEIGHT: 158.20 gm/mol.

8.0 CATEGORY: Used in solutions for hemodialysis and peritoneal dialysis.

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.

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Quality Control**Standard Test Specifications****Title: Calcium Acetate EP****Page No.:** 3 of 4**Specification No.:**
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TEST PARAMETERS AND SPECIFICATIONS**REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION
1.	Appearance	White or almost white, hygroscopic powder.
2.	Solubility	Freely soluble in water, slightly soluble in ethanol (96 per cent)
3.	Identification A It gives reaction (b) of calcium Identification B It gives reaction (b) of acetates	To pass test To pass test
4.	Appearance of Solution	Solution is clear & colorless
5.	pH(5 % Solution)	7.2 to 8.2
6.	Readily Oxidisable substances	To Pass test
7.	Chloride	Max. 330 ppm
8.	Fluorides	Max. 50 ppm
9.	Nitrates	To Pass test
10.	Sulfates	Max. 600 ppm
11.	Aluminium	Max. 1 ppm
12.	Arsenic	Max. 3 ppm
13.	Barium	Max. 50 ppm
14.	Iron	Max. 20 ppm
15.	Magnesium	Max. 500 ppm

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16.	Potassium	Max. 500 ppm
17.	Sodium	Max. 500 ppm
18.	Strontium	Max. 500 ppm
19.	Water	Max. 7 %
20.	Assay (Dried basis)	99.0 % to 101.0 %

REVISION HISTORY:

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

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