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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality Control

Title: Calcium Chloride Dihydrate EP Page No.: 1 of 3

 Specification No.:
 Revision No.:
 Effective Date
 Review Date

 ACPL/FP/SP/057
 00
 12/07/2021
 11/07/2024

Change Control No. NA

Prepared By: ______ Date: <u>08/07/2021</u>

Name : Pankaj Patel_____

(QC Officer / Designee)

Reviewed By: _____ Date: <u>09/07/2021</u>

Name : <u>Nilesh Shah</u>
(Unit Head / Designee)

Approved By: _____ Date: 10/07/2021

Name : Naresh Solanki

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):

Ri

12/07/2021

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Plot no. 1116/P, Lamadapura Road, Manjusar – 391 775,

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Quality Control

Standard Test Specifications

Title: Calcium Chloride Dihydrate EP Page No.: 2 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0570012/07/202111/07/2024

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: 10035-04-8

6.0 MOLECULAR FORMULA: CaCl₂.2H₂O.

7.0 MOLECULAR WEIGHT: 147.0 gm/mol.

8.0 CATEGORY: Calcium replenisher.

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 Chloride Dihydrate EP **Page No.:** 3 of 3

Specification No.: Revision No.: Effective Date Review Date ACPL/FP/SP/057 12/07/2021 11/07/2024 00

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS **REF: EP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	White or almost white, crystalline powder, hygroscopic.	
2.	Solubility	Freely soluble in water, soluble in ethanol (96 %).	
3.	Identification A Solution S gives reaction (a) of chlorides	To pass test	
	Identification B	To pass test	
	It gives the reactions of calcium		
	Identification C	To pass test	
	It complies with the limits of the assay		
4.	Appearance of Solution	Solution S is clear and not more intensely colored than reference solution Y6.	
5.	Acidity or Alkalinity	NMT 0.2 mL of 0.01 M sodium hydroxide is required to turn it red	
6.	Sulfates	Max. 300 ppm	
7.	Aluminium	Max. 1.0 ppm	
8.	Barium (Ba)	To Pass test	
9.	Iron (Fe)	Max. 10 ppm	
10.	Magnesium and alkaline metals	Max. 0.5 %	
11.	Assay(Dried basis)	97.0 % to 103.0 %	

REVISION HISTORY:

Revision No.	Effective Date	Revision Description	Change Control No.
00	12/07/2021	First Issuance	N A

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

Certified By (Sign/Date):



12/07/2021