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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 USP **Page No.:** 1 of 3

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

: Nilesh Shah (Unit Head / Designee)

Approved By: _ Date: 10/07/2021

Name : Naresh Solanki_

(QA/QC In Charge / Designee)

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Name

Certified By (Sign/Date):

12/07/2021

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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 Chloride Dihydrate USP 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: 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.

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Quality Control

Standard Test Specifications

Title: Calcium Chloride Dihydrate USP Page No.: 3 of 3

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 00
 12/07/2021
 11/07/2024

Change Control No. NA

TEST PARAMETERS AND SPECIFICATIONS

REF: USP

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 Test for Calcium Identification B Test for Chloride	To pass test To pass test	
4.	Assay(Dried basis)	99.0 % to 107.0 %	
5.	Aluminium	Max. 1.0 ppm	
6.	Iron, Aluminum and Phosphate	No turbidity or precipitate is produced.	
7.	Limit of Magnesium and Alkali Salts	Max. 1.0 %	
8.	рН	4.5 - 9.2	

REVISION HISTORY:

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

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