# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

Title: Magnesium Chloride Hexahydrate USP Page No.: 1 of 3

Specification No.:Revision No.:Effective DateReview DateACPL/FP/SP/0310004/08/202103/08/2024

**Change Control No.** NA

Prepared By: \_\_\_\_\_\_ Date: <u>31/07/2021</u>

Name : <u>Pankaj Patel</u>

(QC Officer / Designee)

Reviewed By:

Date: <u>02/08/2021</u>

Name : Nilesh Shah\_

(Unit Head / Designee)

Approved By: \_\_\_\_\_

Date: <u>03/08/2021</u>

Name

: Naresh Solanki\_\_\_\_\_

(QA/QC In Charge / Designee)

**UNCONTROLLED COPY** 

Di O

04/08/2021

# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Magnesium Chloride Hexahydrate USP **Page No.:** 2 of 3

**Revision No.: Specification No.: Effective Date Review Date** ACPL/FP/SP/031 04/08/2021 03/08/2024 00

**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:** 7791-18-6

6.0 MOLECULAR FORMULA: MgCl<sub>2</sub>.6H<sub>2</sub>O

**7.0 MOLECULAR WEIGHT:** 203.3 gm/mol.

**8.0 CATEGORY:** Excipient.

**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 100 gm.

**UNCONTROLLED COPY** 

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

Certified By (Sign/Date):



04/08/2021

# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control** 

**Standard Test Specifications** 

Title: Magnesium Chloride Hexahydrate USP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/031 04/08/2021 03/08/2024 00

**Change Control No.** NA

### TEST PARAMETERS AND SPECIFICATIONS **REF: USP**

Sr. No.	TEST PARAMETER	SPECIFICATION	
1.	Appearance	Colorless crystals, hygroscopic.	
2.	Solubility	Very soluble in water, freely soluble in ethanol (96 %).	
3.	Identification A Test for magnesium Identification B Test for chlorides	To Pass test  To Pass test	
4.	Assay	98.0 % - 101.0 %  Max. 50 ppm  Max. 50 ppm  No turbidity is produced within 2 h	
5.	Insoluble Matter		
6.	Sulfate (SO <sub>4</sub> )		
7.	Barium		
8.	Limit of Calcium Max. 100 ppm		
9.	Potassium No turbidity is produced within 5 min		
10.	Aluminum	Max. 1 ppm	
11.	11. pH 4.5 – 7.0		

### **REVISION HISTORY:**

Revision No.	Effective Date	<b>Revision Description</b>	Change Control No.
00	04/08/2021	First Issuance	N A

**UNCONTROLLED COPY** 

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

Certified By (Sign/Date):



04/08/2021