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

Ta- Savli, Dist. Vadodara, Gujarat, India

Quality	<b>Control</b>
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Title: Magnesium Sulphate Heptahydrate IP **Page No.:** 1 of 3

Specification No.:	Revision No.:	<b>Effective Date</b>	<b>Review Date</b>
ACPL/FP/SP/032	00	07/08/2021	06/08/2024

Change Control No. NA

> Prepared By: Date: 04/08/2021

Name : Pankaj Patel\_\_\_

(QC Officer / Designee)

Reviewed By: Date: 05/08/2021

Name : Nilesh Shah\_ (Unit Head / Designee)

Approved By: Date: 06/08/2021

Name : Naresh Solanki\_

(QA/QC In Charge / Designee)

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Certified By (Sign/Date):



07/08/2021

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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: Magnesium Sulphate Heptahydrate IP **Page No.:** 2 of 3

**Revision No.: Specification No.: Effective Date Review Date** ACPL/FP/SP/032 07/08/2021 06/08/2024 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:** 10034-99-8

**6.0 MOLECULAR FORMULA**: MgS0<sub>4</sub>.7H<sub>2</sub>0

**7.0 MOLECULAR WEIGHT**: 246.5 gm/mol.

**8.0 CATEGORY**: Osmotic laxative; used in the treatment of electrolyte deficiency.

**9.0 STORAGE**: Store protected from moisture.

#### 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: Magnesium Sulphate Heptahydrate IP **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/032 07/08/2021 06/08/2024 00

**Change Control No.** NA

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

Sr. No.	No. TEST PARAMETER SPECIFICATION		
1.	Description	Colorless crystals or a white, crystalline powder.	
2.	Identification A	entification A To pass test	
	It gives the reactions of sulfates		
	Identification B To pass test		
	It gives reaction (A)of magnesium salts		
3.	Appearance of solution Clear and Colorless		
4.	Acidity or alkalinity	Not more than 0.2 mL of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide.	
5.	Arsenic (As)	Max 2 ppm	
6.	Heavy metals	Max. 10 ppm	
7.	ron (Fe) Max. 200 ppm		
8.	Chlorides	Max. 300 ppm	
9.	9. Loss on Drying 48.0 % to 52.0 %   10. Assay (Dried basis) 99.0 % - 100.5 %		
10.			

### **REVISION HISTORY:**

Revision No.	Effective Date	Revision Description	Change Control No.
00	07/08/2021	First Issuance	N A

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