# **MASTER COPY**



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

Ta- Savli, Dist. Vadodara, Gujarat, India

| Quality C | Contro | l |
|-----------|--------|---|
|-----------|--------|---|

Title: Magnesium Sulphate Heptahydrate LR **Page No.:** 1 of 3

| Specification No.: | Revision No.: | Effective Date | <b>Review Date</b> |
|--------------------|---------------|----------------|--------------------|
| ACPL/FP/SP/032     | 00            | 06/08/2021     | 05/08/2024         |

Change Control No. NA

Prepared By: Date: 03/08/2021

Name : Pankaj Patel\_\_\_

(QC Officer / Designee)

Reviewed By: Date: 04/08/2021

Name : Nilesh Shah\_

(Unit Head / Designee)

Approved By: Date: <u>05/08/2021</u>

Name : Naresh Solanki\_

(QA/QC In Charge / Designee)

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

Certified By (Sign/Date):



06/08/2021

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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 LR Page No.: 2 of 3

 Specification No.:
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 ACPL/FP/SP/032
 00
 06/08/2021
 05/08/2024

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 RETEST DATE:** Three years.

**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**: Preserve in well-closed 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: Magnesium Sulphate Heptahydrate LR **Page No.:** 3 of 3

**Specification No.: Revision No.: Effective Date Review Date** ACPL/FP/SP/032 06/08/2021 05/08/2024 00

**Change Control No.** NA

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

| Sr. No. | TEST PARAMETER  | SPECIFICATION   |  |
|---------|---|---|--|
| 1.      | Appearance  | White or almost white, crystalline powder or brilliant, colorless crystals. |  |
| 2.      | 2. Solubility Freely soluble in water, very soluble in boiling water, very soluble in boiling water, very soluble in ethanol (96 %) |   |  |
| 3.      | pH (5% Aqueous Solution)  | 5.0 – 8.2   |  |
| 4.      | ARSENIC as As   | Max. 1 ppm  |  |
| 5.      | HEAVY METAL as Pb   | Max. 5 ppm  |  |
| 6.      | . IRON as Fe Max. 10 ppm  |   |  |
| 7.      | CHLORIDE as Cl  | Max. 100 ppm  |  |
| 8.      | ZINC as Zn  | Max. 10 ppm   |  |
| 9.      | . ASSAY Min. 99.0%  |   |  |

#### **REVISION HISTORY:**

| Revision No. | <b>Effective Date</b> | Revision Description | Change Control No. |
|--------------|-----------------------|----------------------|--------------------|
| 00           | 06/08/2021            | First Issuance       | N A                |

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