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

Ta- Savli, Dist. Vadodara, Gujarat, India

| Qualit | y Control |
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| Standard | Test Specification | S |
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Title: Magnesium Sulphate Heptahydrate EP **Page No.:** 1 of 3

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

Change Control No. NA

> Prepared By: Date: 04/08/2021

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(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):

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Quality Control

Standard Test Specifications

Title: Magnesium Sulphate Heptahydrate EP **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: MgS0₄.7H₂0

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 EP **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: EP**

| Sr. No. | TEST PARAMETER | SPECIFICATION | |
|---------|------------------------------------|---|--|
| 1. | Appearance | White or almost white, crystalline powder or brilliant, colorless crystals. | |
| 2. | Solubility | Freely soluble in water, very soluble in boiling water, practically insoluble in ethanol (96 %) | |
| 3. | Identification A | To pass test | |
| | It gives the reactions of sulfates | | |
| | Identification B | To pass test | |
| | It gives the reaction of magnesium | | |
| 4. | Appearance of solution | Clear and Colorless | |
| 5. | Acidity or alkalinity | Not more than 0.2 mL of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide. | |
| 6. | Chlorides | Max. 300 ppm | |
| 7. | Arsenic (As) | Max 2 ppm | |
| 8. | Iron (Fe) | Max. 20 ppm | |
| 9. | Loss on Drying | 48.0 % to 52.0 % | |
| 10. | Assay (Dried basis) | 99.0 % - 100.5 % | |

REVISION HISTORY:

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

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