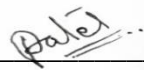




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Plot no. 1116/P, Lamadapura Road,  
Manjusar – 391 775,  
Ta- Savli, Dist. Vadodara, Gujarat, India

**Quality Control****Standard Test Specifications****Title: Magnesium Gluconate BP****Page No.:** 1 of 3

|   |                            |                                     |                                  |
|---|----------------------------|-------------------------------------|----------------------------------|
| <b>Specification No.:</b><br>ACPL/FP/SP/065 | <b>Revision No.:</b><br>00 | <b>Effective Date</b><br>05/08/2021 | <b>Review Date</b><br>04/08/2024 |
| <b>Change Control No.</b>                   | NA                         |                                     |                                  |

Prepared By: Date: 02/08/2021Name : Pankaj Patel  
(QC Officer / Designee)Reviewed By: Date: 03/08/2021Name : Niles Shah  
(Unit Head / Designee)Approved By: Date: 04/08/2021Name : Naresh Solanki  
(QA/QC In Charge / Designee)**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  05/08/2021

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Manjusar – 391 775,  
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## Quality Control

### Standard Test Specifications

Title: Magnesium Gluconate BP

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00

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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: 299-29-6

#### 6.0 MOLECULAR FORMULA: $C_{12}H_{22}MgO_{14}$ .

#### 7.0 MOLECULAR WEIGHT: 414.60 gm/mol.

#### 8.0 CATEGORY: Excipient.

#### 9.0 STORAGE: In an airtight container.

#### 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.

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## Quality Control

### Standard Test Specifications

Title: Magnesium Gluconate BP

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NA

### TEST PARAMETERS AND SPECIFICATIONS

REF: BP

| Sr. No. | TEST PARAMETER   | SPECIFICATION  |
|---------|--|--|
| 1.      | Appearance   | White or almost white, amorphous, hygroscopic, crystalline or granular powder.                                   |
| 2.      | Solubility   | Freely soluble in water, slightly soluble in ethanol (96 per cent), very slightly soluble in methylene chloride. |
| 3.      | <b>Identification A</b><br>Thin-layer chromatography<br><b>Identification B</b><br>A white precipitate is formed that does not dissolve upon the addition of 2 mL of dilute ammonia. | To pass test<br><br>To pass test   |
| 4.      | Appearance of solution   | Solution S is clear and not more intensely colored than reference solution Y7.                                   |
| 5.      | Sucrose and reducing sugars  | To Pass test (No red precipitate is formed)  |
| 6.      | Chloride   | Max. 500 ppm   |
| 7.      | Sulfates (SO <sub>4</sub> )  | Max. 500 ppm   |
| 8.      | Water  | Max. 12.0 %  |
| 9.      | Microbial contamination  | TAMC: acceptance criterion 10 <sup>3</sup> CFU/g.<br>TYMC: acceptance criterion 10 <sup>2</sup> CFU/g.           |
| 10.     | Assay %  | 98.0 % – 102.0 %   |

### REVISION HISTORY:

| Revision No. | Effective Date | Revision Description | Change Control No. |
|--------------|----------------|----------------------|--------------------|
| 00           | 05/08/2021     | First Issuance       | N A                |

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