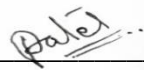




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Manjusar – 391 775,
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Quality Control**Standard Test Specifications****Title: Magnesium Gluconate EP****Page No.:** 1 of 3

Specification No.: ACPL/FP/SP/065	Revision No.: 00	Effective Date 05/08/2021	Review Date 04/08/2024
Change Control No.	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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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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TEST PARAMETERS AND SPECIFICATIONS

REF: EP

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.	Identification A Thin-layer chromatography Identification B A white precipitate is formed that does not dissolve upon the addition of 2 mL of dilute ammonia.	To pass test 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 ₄)	Max. 500 ppm
8.	Water	Max. 12.0 %
9.	Microbial contamination	TAMC: acceptance criterion 10 ³ CFU/g. TYMC: acceptance criterion 10 ² 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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