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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 USP

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

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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:** C₁₂H₂₂MgO₁₄.**7.0 MOLECULAR WEIGHT:** 414.60 gm/mol.**8.0 CATEGORY:** Excipient.**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 100 gm.**UNCONTROLLED COPY****Format No.** QC/017/F/01-00**Certified By (Sign/Date) :**  05/08/2021

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TEST PARAMETERS AND SPECIFICATIONS**REF: USP**

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 Test for Magnesium Identification B Thin-Layer Chromatography	To pass test To pass test
4.	Assay % (Dried Basis)	98.0 % to 102.0 %
5.	Chlorides (Cl)	Max. 500 ppm
6.	Sulfates (SO ₄)	Max. 500 ppm
7.	Reducing Substances	Max. 1.0 %
8.	pH	6.0–7.8
9.	Water Determination	3.0 % – 12.0 %

REVISION HISTORY:

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

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