



SWAPNROOP DRUGS & PHARMACEUTICALS

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CERTIFICATE OF ANALYSIS

Product Name	Esomeprazole Magnesium Trihydrate	CAS No:	217087-09-7
Batch No.	2605001	Manufactured by	Swapnroop Drugs & Pharmaceuticals
Date of Mfg.	MAY-2026	Date of Analysis	20/05/2026
Batch Quantity	-	Retest Date	APR-2031

Sr No	Test	Acceptance Criteria	Results
1	Description	A white to slightly colored powder.	Off white powder
2	Solubility	Soluble in methanol, slightly soluble in water and practically insoluble in heptane.	Complies
3	Identification (IR)	The IR absorption spectrum of the test sample should be concordant with working standard spectrum.	Complies
4	Identification by - HPLC	The retention time of the major peak in the chromatogram of the test solution should correspond to that in the chromatogram of the reference solution in the assay.	Complies
5	Magnesium content (%W/W) (on anhydrous basis)	3.0 to 3.7	3.4
6	Specific optical rotation (°) on anhydrous basis at 25°C (1.0%w/v solution in methanol)	-155° to -135°	-141.4°
7	Related substances by HPLC (%w/w) Individual impurity	NMT 0.5	0.07
8	Related substances by HPLC (%w/w)	NMT 1.0	0.21
9	Heavy metals (ppm)	NMT 20	Less than 20
10	Water by KF (% w/w)	6.0 to 11.0	7.4
11	Assay by HPLC (% w/w) (On anhydrous basis)	NLT 98.0 and NMT 102.0	99.5
12	Residual solvents by GC-HS (ppm) Methanol	NMT 3000	Not detected
13	Residual solvents by GC-HS (ppm) Acetone	NMT 5000	Not detected
14	Residual solvents by GC-HS (ppm) Dichloromethane	NMT 600	Not detected
15	Residual solvents by GC-HS (ppm) Toluene	NMT 890	Not detected

Storage: Store in air tight container below room Temperature

Conclusion: Product Complies as per above Specifications

Prepared By  Sonali Nirmal Date: 23/05/2026	Checked by  Dadarao Kakde Date: 23/05/2026	Approved By  Nayna Nehete Date: 23/05/2026 
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