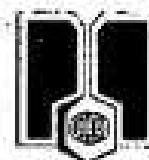


METROCHEM API PRIVATE LIMITED

Unit-I: Plot No.: 62/AC/6, Pipeline Road, Phase-I, I.D.A., Jeedimetla, Outhbullapur Mandal,
Medchal-Malkajgiri District-500055, Telangana State, India. CIN: U24239TG2002PTC039223
contact@metroapi.com | www.metroapi.com



CERTIFICATE OF ANALYSIS

Product Name	:	Esomeprazole Magnesium Trihydrate			
Reference	:	USP- NF 2022	Drug License No.	:	22/RR/AP/99/B/R
Batch No.	:	ESM/2208300	Date of Manufacturing	:	August, 2022
Batch Qty.	:	219.50 kg	Date of Expiry	:	July, 2027
Dispatch Qty.	:	200.00 kg	Date of Release	:	22.08.2022
Customer Name	:	M/s. Grand International Trading Limited.	Market mode	:	Export
Storage Condition	:	Preserve in air tight containers, protected from light. Store at room temperature.			

S. No.	Test	Specification	Results
1.	Description	White to slightly colored powder.	Off white powder
2.	Solubility	Soluble in methanol, Slightly soluble in water and practically insoluble in heptane.	Soluble in methanol, Slightly soluble in water and practically insoluble in heptane.
3.	Identification by		
	a) IR	The infrared absorption spectrum of Esomeprazole Magnesium sample should be concordant to that of the standard.	The infrared absorption spectrum of Esomeprazole Magnesium sample is concordant to that of the standard.
	b) Magnesium	The Sample solution in the test for content of Magnesium exhibits a significant absorption at 285.2nm.	The Sample solution in the test for content of Magnesium exhibits a significant absorption at 285.2nm.
	c) HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.
4.	Magnesium content (% w/w) (on the anhydrous basis)	3.30 to 3.55	3.46
5.	Colour of solution at 440nm (2% solution in methanol)	NMT 0.2	0.10
6.	Water content by KF (% w/w)	6.0 to 8.0	7.2
7.	Enantiomeric purity by HPLC (%) R- Enantiomer	NMT 0.2	0.1



METROCHEM API PRIVATE LIMITED

Unit-I: Plot No.: 62/C/6, Pipeline Road, Phase-I, I.D.A., Jeedimetla, Gouthbullapur Mandal,
Medchal-Malkajgiri District-500055, Telangana State, India. CIN: U24239TG2002PTC039223
contact@metroapi.com | www.metroapi.com



CERTIFICATE OF ANALYSIS

Batch No.	: ESM/2208300	Customer	: M/s. Greend International Trading Limited.
8.	Organic Impurities by HPLC (%)		
	Omeprazole N-oxide	NMT 0.1	Not detected
	Omeprazole Related Compound-A	NMT 0.2	0.04
	Any other individual impurity	NMT 0.1	0.06
	Total impurities	NMT 0.5	0.29
9.	Assay by HPLC (% w/w) (on anhydrous basis)	NLT 98.0 and NMT 102.0	99.1
* 10.	Residual solvents by GC-MS (ppm)		
	Methanol	NMT 3000	Not detected
	Ethanol	NMT 5000	Not detected
	Dichloromethane	NMT 600	Not detected
	Ethyl acetate	NMT 5000	Not detected
	Acetone	NMT 5000	Not detected
	Toluene	NMT 890	BQL
	Additional Test		
11.	Bulk density (gm/ml)		
	Untapped density	NLT 0.10	0.16
	Tapped density	NLT 0.20	0.27
12.	Particle Size by Malvern Mastersizer		
	D (90) μ m	Less than 10 μ m	7.0
* In-house Test			
Remarks: The material complies as per the above specifications.			
Compiled by Y.Ramesh Sr.Chemist - QC		Checked by K.V.S. Sarma Manager - QC	Approved by G.V.L. Narayana AGM - QC

