TEMAD CO.
(Active Pharmaceutical Ingredient Manufacturer Co.)

Title: Specification Form			
Code: TEM-QA-SOP-017-F/01	**Effective Date:** 21 January 2023	**Revision date:** 21 January 2025	Page 1 of 1

Trade Name: -					
Chemical Name: **Esomeprazole Magnesium**					
CAS No.: [217087-09-7]					
Raw material/ Excipient □	Starting material/ Intermediate □	API product ■	Semi-finished product □		Finished product□
Method of analysis:	USP ■	BP □	EP □	JP □	In House □
Handling and storage: Preserve in tight containers, protected from light. Store at room temperature. If it is labeled as amorphous, store at 2 °- 8 ° under nitrogen atmosphere.					

Chemical specification

No.	Item	Standard-Specification	Ref.	Recommendation
1	**Description**	White to slightly colored powder.	USP43	
2	**Solubility**	Soluble in methanol, slightly soluble in water. Practically insoluble in heptane.	USP43	
3	**Identification**	A: IR	USP43	
		B: Content of magnesium		
4	**Assay**	98.0-102.0% calculated on the anhydrous basis.	USP43	
5	**Magnesium**	3.3-3.55	USP43	
6	**Related Substance (HPLC)**	Omeprazole N-Oxide: Not more than 0.1%	USP43	
		Omeprazole Related compound A: Not more than 0.2%		
		Any other impurity: Not more than 0.1%		
		Total impurity: Not more than 0.5%		
7	**Enantiomeric Purity**	R-enantiomer: Not more than 0.2%	USP43	
8	**Water(KF)**	6.0-8.0%	USP43	
9	**Colour of solution**	At 440 nm not more than 0.2	USP43	
10	**Residual solvents**	Methanol: Not more than 3000 ppm	USP43	
		Dichloromethane: Not more than 600 ppm		
		Benzene: Not more than 2 ppm		
		Toluene: Not more than 890 ppm		

Written by	Reviewed by		Approved by	
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Documentation stamp