

CERTIFICATE OF ANALYSIS

(Certificate No. KME013036-01)

Release Date: 27/07/2025

Re-test Date: 26/07/2028

Esomeprazole Magnesium Trihydrate USPRS

Identification

Chemical Name :

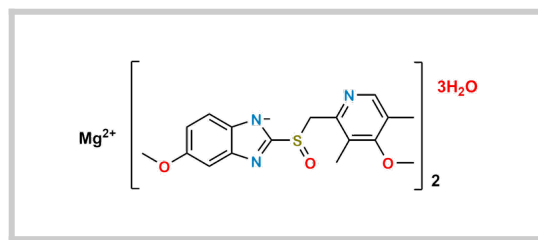
5-Methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl] benzimidazole magnesium salt (2:1), trihydrate ;

CAT No. : KME013036

CAS No. : 217087-09-7

Molecular Formula : C₃₄H₃₆MgN₆O₆S₂ : 3(H₂O)

Molecular Weight : 767.2 : 3(18.0)



Analytical Information

Batch No. : E013036-102-163

Description : White Solid

HPLC Purity : 99.91 %

Weight Loss By TGA : 1.34 %

% Potency : 98.57 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.34(Weight Loss By TGA)] x [99.91(HPLC Purity)]/100 = 98.57 %

USP Catalog No & Lot No : 1249789 - R12610

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		27/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		27/07/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA