CERTIFICATE OF ANALYSIS

(Certificate No. KMR014006-01)

Release Date: 08/07/2024 **Re-test Date:** 07/07/2027

Rabeprazole EP Impurity E

Identification

Chemical Name :
2-(((4-methoxy-3-methylpyridin-2-yl)methyl)sulfinyl)-1H-benzo[d]imidazole

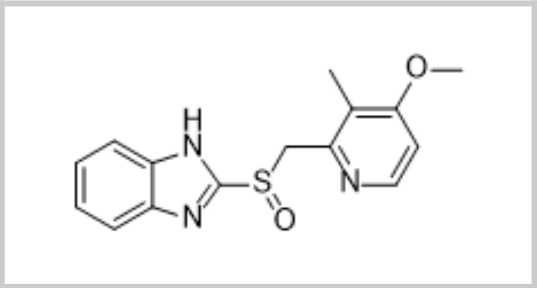
Alt. Name : Rabeprazole 4-Methoxy Impurity

CAT No. : KMR014006

CAS No. : 102804-77-3

Molecular Formula : C15H15N3O2S

Molecular Weight : 301.36



Analytical Information

Batch No. : RAB-EPE-073-284

Description : Light Brown Solid

HPLC Purity : 97.57 %

Weight Loss By TGA : 0.03 %

% Potency : 97.54 %

Solubility : Refer Additional information

Mass : Confirm

IR : Confirm

1H 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 - 0.03(Weight Loss By TGA)] x [97.57(HPLC Purity)]/100 = 97.54 %
-Buffer Solution : Dissolve 17.4 g of dibasic potassium phosphate in 950 mL of water, adjust pH with 2N potassium hydroxide to a pH of 11.3, and dilute with water to 1000 mL.
-Solubility : Methanol : Buffer Solution (20:80)

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		09/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/07/2024

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