

CERTIFICATE OF ANALYSIS

(Certificate No. KMR014005-01)

Release Date: 08/07/2024

Re-test Date: 07/07/2027

Rabeprazole Related Compound F

Identification

Chemical Name :

2-(((4-chloro-3-methylpyridin-2-yl)methyl)sulfinyl)-1H-benzo[d]imidazole

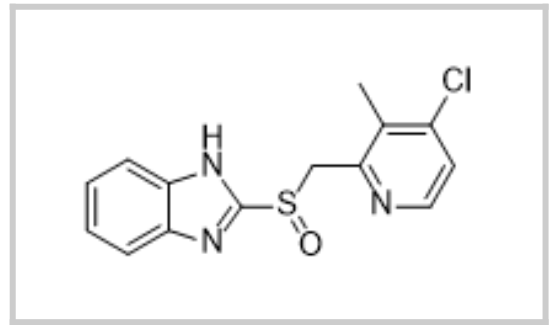
Alt. Name : Rabeprazole USP Related Compound F

CAT No. : KMR014005

CAS No. : 168167-42-8

Molecular Formula : C₁₄H₁₂ClN₃O₃S

Molecular Weight : 305.78



Analytical Information

Batch No. : RAB-EPH-073-283

Description : Light Yellow Solid

HPLC Purity : 97.69 %

Weight Loss By TGA : 0.19 %

% Potency : 97.5 %

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 = $[100 - 0.19(\text{Weight Loss By TGA})] \times [97.69(\text{HPLC Purity})]/100 = 97.5 \%$

-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, ¹H NMR, IR and TGA