

CERTIFICATE OF ANALYSIS

(Certificate No. KMR014001-01)

Release Date: 08/07/2024

Re-test Date: 07/07/2027

Rabeprazole Related Compound B

Identification

Chemical Name :

2-(((1H-benzo[d]imidazol-2-yl)sulfinyl)methyl)-4-(3-methoxypropoxy)-3-methylpyridine 1-oxide

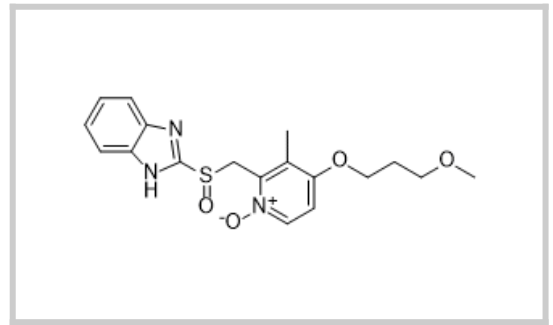
Alt. Name : Rabeprazole USP Related Compound B ; Rabeprazole N-Oxide

CAT No. : KMR014001

CAS No. : 924663-38-7

Molecular Formula : C₁₈H₂₁N₃O₄S

Molecular Weight : 375.44



Analytical Information

Batch No. : RAB-N-OXIDE-045-079

Description : Off White Solid

HPLC Purity : 98.92 %

Weight Loss By TGA : 0.87 %

% Potency : 98.06 %

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 - 0.87(Weight Loss By TGA)] x [98.92(HPLC Purity)]/100 = 98.06 %

-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