CERTIFICATE OF ANALYSIS

(Certificate No. KMR014001-01)

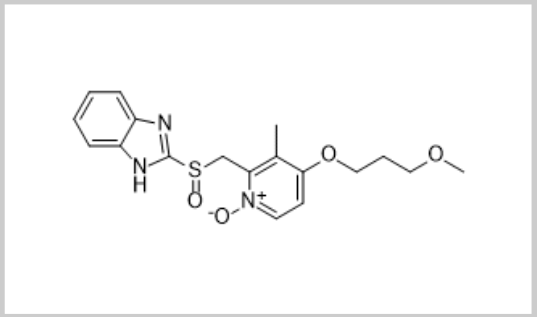
Release Date: 08/07/2024 **Re-test Date:** 07/07/2027

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, 1HNMR, IR and TGA