

CERTIFICATE OF ANALYSIS

(Certificate No. KMR014004-01)

Release Date: 08/07/2024

Re-test Date: 07/07/2027

Rabeprazole EP Impurity A

Identification

Chemical Name :

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

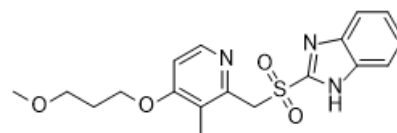
Alt. Name : Rabeprazole USP Related Compound D ; Rabeprazole Sulfone

CAT No. : KMR014004

CAS No. : 117976-47-3

Molecular Formula : C₁₈H₂₁N₃O₄S

Molecular Weight : 375.44



Analytical Information

Batch No. : RAB-S-OXIDE-019-012

Description : Off White Solid

HPLC Purity : 99.45%

Weight Loss By TGA : 0.18%

% Potency : 99.27 %

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 - 0.18(Weight Loss By TGA)] x [99.45(HPLC Purity)]/100 = 99.27 %

-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			09/07/2024
Reviewed & Approved By	Quality Control	Jatin Patel		09/07/2024

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