

# 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

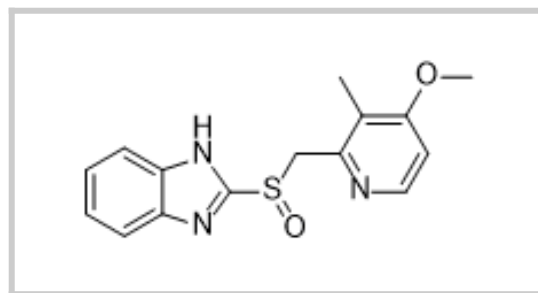
**Alt. Name** : Rabeprazole 4-Methoxy Impurity

**CAT No.** : KMR014006

**CAS No.** : 102804-77-3

**Molecular Formula** : C<sub>15</sub>H<sub>15</sub>N<sub>3</sub>O<sub>2</sub>S

**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

**<sup>1</sup>H 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, <sup>1</sup>HNMR, IR and TGA