

# CERTIFICATE OF ANALYSIS

(Certificate No. KMR014004-01)

Release Date: 07/08/2024

Re-test Date: 06/08/2027

## Rabeprazole Sulfone(Rabeprazole EP Impurity A)

### Identification

**Chemical Name :**

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

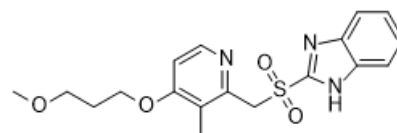
**Alt. Name** : Rabeprazole USP Related Compound  
D ; Rabeprazole Sulfone

**CAT No.** : KMR014004

**CAS No.** : 117976-47-3

**Molecular Formula** : C<sub>18</sub>H<sub>21</sub>N<sub>3</sub>O<sub>4</sub>S

**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

**<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 - 0.18(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)

-Re-tested on 07.08.2024

**Recommendation** : Released

|                        | Department      | Name          | Signature | Date       |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By            | Analytical      | Jignesh Patel |           | 25/07/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel   |           | 25/07/2025 |

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA