

# CERTIFICATE OF ANALYSIS

(Certificate No. KMO001003-01)

Release Date: 21/02/2024

Re-test Date: 20/02/2027

## Omeprazole OME III

### Identification

**Chemical Name :**

2-(((3,5-dimethylpyridin-2-yl)methyl)sulfinyl)-5-methoxy-1H-benzo[d]imidazole

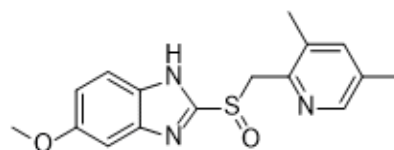
**Alt. Name** : Esomeprazole EP Impurity B , 4-Desmethoxy Omeprazole

**CAT No.** : KMO001003

**CAS No.** : 110374-16-8

**Molecular Formula** : C<sub>16</sub>H<sub>17</sub>N<sub>3</sub>O<sub>2</sub>S

**Molecular Weight** : 315.39



### Analytical Information

**Batch No.** : OME-DM-045-019

**Description** : Brown Solid

**HPLC Purity** : 99.20 %

**Weight Loss By TGA** : 1.53 %

**% Potency** : 97.68 %

**Solubility** : ACN : Water (1:1)

**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 - 1.53(Weight Loss By TGA)] x [99.20(HPLC Purity)]/100 = 97.68 %

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/02/2024
Reviewed & Approved By	Quality Control	Jatin Patel		21/02/2024

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