

# CERTIFICATE OF ANALYSIS

(Certificate No. KMO001001-01)

Release Date: 20/02/2024

Re-test Date: 19/02/2027

## Omeprazole OME I

### Identification

**Chemical Name :**

4-methoxy-2-(((5-methoxy-1H-benzo[d]imidazol-2-yl)sulfonyl)methyl)-3,5-dimethylpyridine 1-oxide

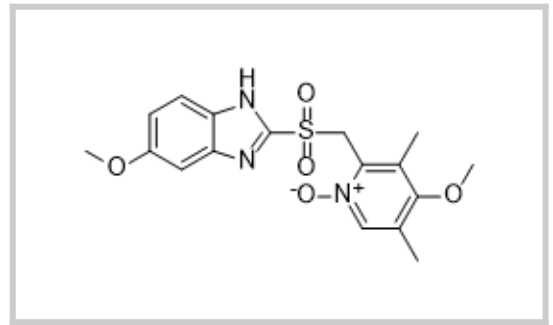
**Alt. Name** : Omeprazole USP Related Compound I, Omeprazole Sulfone N-Oxide

**CAT No.** : KMO001001

**CAS No.** : 158812-85-2

**Molecular Formula** : C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>5</sub>S

**Molecular Weight** : 377.41



### Analytical Information

**Batch No.** : ESO-SUL-NO-030-218

**Description** : Off White Solid

**HPLC Purity** : 97.70 %

**Weight Loss By TGA** : 1.67 %

**% Potency** : 96.07 %

**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 - 1.67(Weight Loss By TGA)] x [97.70(HPLC Purity)]/100 = 96.07 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		20/02/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		20/02/2024

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