

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

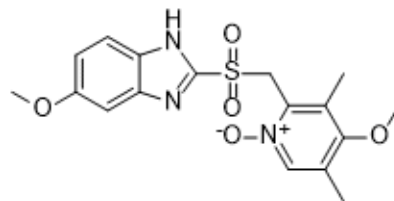
Alt. Name : Omeprazole USP Related Compound I, Omeprazole Sulfone N-Oxide

CAT No. : KMO001001

CAS No. : 158812-85-2

Molecular Formula : C₁₇H₁₉N₃O₅S

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

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

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 20/02/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 20/02/2024 |

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