

CERTIFICATE OF ANALYSIS

(Certificate No. KMO001002-01)

Release Date: 15/07/2022

Re-test Date: 14/07/2025

Omeprazole EP Impurity D

Identification

Chemical Name :

5-methoxy-2-(((4-methoxy-3,5-dimethylpyridin-2-yl)methyl)sulfonyl)-1H-benzo[d]imidazole

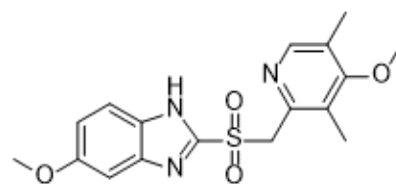
Alt. Name : Omeprazole USP Related Compound A , Omeprazole sulphone ,
Esomeprazole EP Impurity D

CAT No. : KMO001002

CAS No. : 88546-55-8

Molecular Formula : C17H19N3O4S

Molecular Weight : 361.42



Analytical Information

Batch No. : ESO-SUL-030-217

Description : Off White Solid

HPLC Purity : 99.26 %

Weight Loss By TGA : 0.43 %

% Potency : 98.83 %

Solubility : ACN

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 = $[100 - 0.43(\text{Weight Loss By TGA})] \times [99.26(\text{HPLC Purity})]/100 = 98.83 \%$

Remarks : COA Re-generated on 16.07.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		02/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		02/12/2024

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