CERTIFICATE OF ANALYSIS

(Certificate No. KMO001002-01)

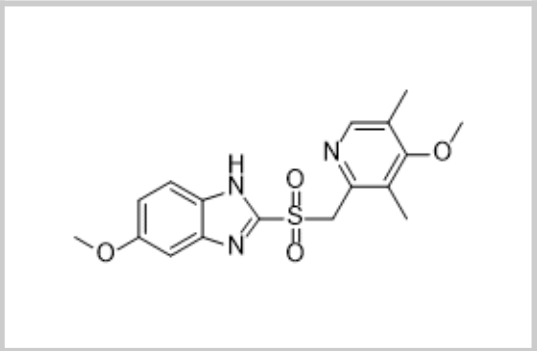
Release Date: 15/07/2022 **Re-test Date:** 14/07/2025

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	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.26 %	**IR**	: Confirm
Weight Loss By TGA	: 0.43 %	**1H NMR**	: Confirm
% Potency	: 98.83 %		

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(Weight Loss By TGA)] x [99.26(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