

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-benzimidazole

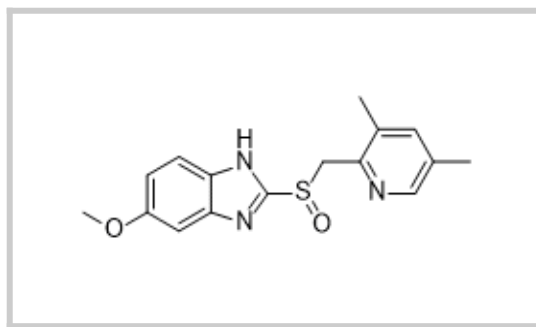
Alt. Name : Esomeprazole EP Impurity B , 4-Desmethoxy Omeprazole

CAT No. : KMO001003

CAS No. : 110374-16-8

Molecular Formula : C₁₆H₁₇N₃O₂S

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

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 = $[100 - 1.53(\text{Weight Loss By TGA})] \times [99.20(\text{HPLC Purity})]/100 = 97.68 \%$

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, ¹H NMR, IR and TGA