

CERTIFICATE OF ANALYSIS

(Certificate No. KMO001007-01)

Release Date: 22/02/2024

Re-test Date: 21/02/2027

Omeprazole OME VII

Identification

Chemical Name :

9-methoxy-1,3-dimethyl-12-thioxobenzo[4',5']imidazo[2',1':2,3]imidazo[1,5-a]pyridin-2(12H)-one

Alt. Name

: Omeprazole BP Impurity G , Isomer
of Omeprazole EP Impurity F ,
Omeprazole USP Related Compound G

CAT No.

: KMO001007

CAS No.

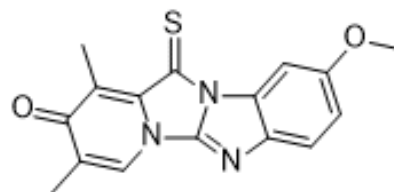
: 125656-83-9

Molecular Formula

: C₁₆H₁₃N₃O₂S

Molecular Weight

: 311.36



Analytical Information

Batch No.

: OME-RCG-073-087

Solubility

: THF

Description

: Brown Solid

Mass

: Confirm

HPLC Purity

: 93.15 %

IR

: Confirm

Weight Loss By TGA

: 1.92 %

¹H NMR

: Confirm

% Potency

: 91.36 %

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 - 1.92(Weight Loss By TGA)] x [93.15(HPLC Purity)]/100 = 91.36 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/02/2024
Reviewed & Approved By	Quality Control	Jatin Patel		22/02/2024

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