

CERTIFICATE OF ANALYSIS

(Certificate No. KMO001006-01)

Release Date: 22/02/2024

Re-test Date: 21/02/2027

ESOMEPRAZOLE THIOL IMPURITY

Identification

Chemical Name :

5-methoxy-1H-benzo[d]imidazole-2-thiol

Alt. Name

: Esomeprazole EP Impurity A ,
Omeprazole USP Related Compound B

CAT No.

: KMO001006

CAS No.

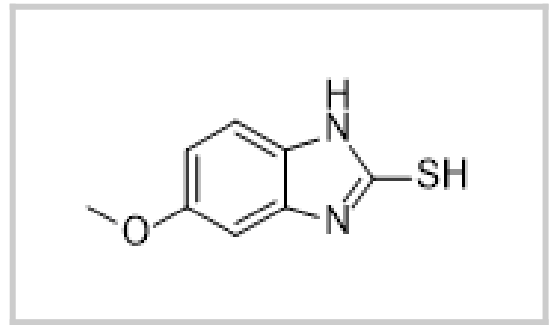
: 37052-78-1

Molecular Formula

: C8H8N2OS

Molecular Weight

: 180.23



Analytical Information

Batch No.

: OME-EPA-073-062

Solubility

: ACN : Water (1:1)

Description

: Off White Solid

Mass

: Confirm

HPLC Purity

: 99.66 %

IR

: Confirm

Weight Loss By TGA

: 0.04 %

1H NMR

: Confirm

% Potency

: 99.62 %

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 = $[100 - 0.04(\text{Weight Loss By TGA})] \times [99.66(\text{HPLC Purity})]/100 = 99.62 \%$

Recommendation

: Released

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

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