

CERTIFICATE OF ANALYSIS

(Certificate No. KMR014002-01)

Release Date: 08/07/2024

Re-test Date: 07/07/2027

Rabeprazole EP Impurity F

Identification

Chemical Name :
1H-benzo[d]imidazole-2-thiol

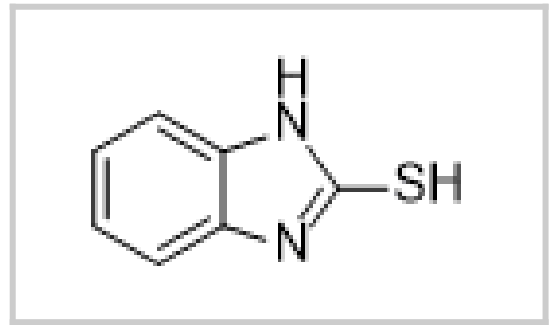
Alt. Name : Rabeprazole USP Related Compound
C ; 2-Mercaptobenzimidazole

CAT No. : KMR014002

CAS No. : 583-39-1

Molecular Formula : C7H6N2S

Molecular Weight : 150.20



Analytical Information

Batch No. : MISC-2-MER-019-335

Description : White Solid

HPLC Purity : 99.76 %

Weight Loss By TGA : 0.2 %

% Potency : 99.56 %

Solubility : Refer Additional
information

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 = $[100 - 0.2(\text{Weight Loss By TGA})] \times [99.76(\text{HPLC Purity})]/100 = 99.56 \%$

-Buffer Solution : Dissolve 17.4 g of dibasic potassium phosphate in 950 mL of water, adjust pH with 2N potassium hydroxide to a pH of 11.3, and dilute with water to 1000 mL.

-Solubility : Methanol : Buffer Solution (20:80)

Recommendation : Released

| | Department | Name | Signature | Date |
|-----------------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 09/07/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 09/07/2024 |

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