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 | ц |
|-------------------|---|----------------|
| CAT No. | : KMO001006 | N. |
| CAS No. | : 37052-78-1 |)SH |
| Molecular Formula | : C8H8N2OS | ~ <u>o</u> ~~N |
| 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(Weight Loss By TGA)] x [99.66(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