CERTIFICATE OF ANALYSIS

(Certificate No. KMP012073-01)

Release Date: 03/08/2022 **Re-test Date:** 02/08/2025

Pantoprazole N-Oxide Impurity

Identification

Chemical Name:

2-(((6-(Difluoromethoxy)-1H-benzo[d]imidazol-2-yl)sulfinyl)methyl)-3,4-dimethoxypyridine 1-oxide

CAT No. : KMP012073

CAS No. : 953787-60-5

Molecular Formula : C16H15F2N3O5S

Molecular Weight : 399.4



Analytical Information

Batch No. : PEN-N-OXIDE-030-248 **Solubility** : Acetonitrile **Description** : Off White Solid : Confirm **Mass HPLC Purity** : 99.05 % IR : Confirm Weight Loss By TGA : 0.29 % 1H NMR : Confirm % Potency : 98.76 % **13C 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 - 0.29(Weight Loss By TGA)] x [99.05(HPLC Purity)]/100 = 98.76 %

Remarks: COA Re-generated on 19.11.2024

-13CNMR added on 10.12.2024

Recommendation: Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 13/12/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 13/12/2024 |

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA