

CERTIFICATE OF ANALYSIS

(Certificate No. KMR001002-01)

Release Date: 25/08/2022

Re-test Date: 24/08/2025

N-Nitroso Ramipril Impurity

Identification

Chemical Name :

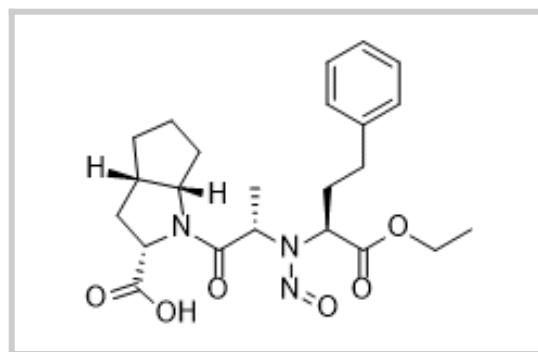
(2S,3aS,6aS)-1-(((S)-2-(((S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl)(nitroso)amino)propanoyl)octahydrocyclopenta[b]pyrrole-2-carboxylic acid (Mixture of E/Z Isomer)

CAT No. : KMR001002

CAS No. : Not Available

Molecular Formula : C₂₃H₃₁N₃O₆

Molecular Weight : 445.51



Analytical Information

Batch No. : RAM-N-NO-030-264

Solubility : ACN

Description : Yellow Thik Syrup

Mass : Confirm

HPLC Purity : 94.54 %

IR : Confirm

Weight Loss By TGA : 2.43 %

¹H NMR : Confirm

% Potency : 92.24 %

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 - 2.43(Weight Loss By TGA)] x [94.54(HPLC Purity)]/100 = 92.24 %

Remarks : COA Re-generated on 22.03.2024

-Mixture of Isomers

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 22/03/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 22/03/2024 |

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