

CERTIFICATE OF ANALYSIS

(Certificate No. KME009007-01)

Release Date: 17/10/2024

Re-test Date: 16/10/2027

Enalapril EP Impurity B

Identification

Chemical Name :
((S)-1-Ethoxy-1-oxo-4-phenylbutan-2-yl)-L-alanine

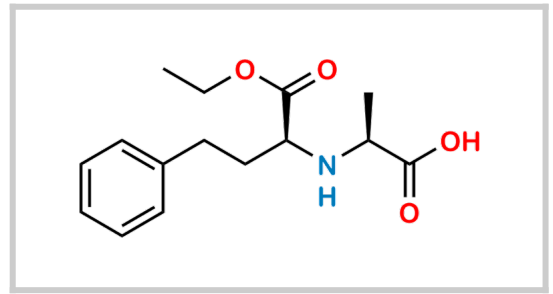
Alt. Name : Moexipril USP Related Compound F

CAT No. : KME009007

CAS No. : 82717-96-2

Molecular Formula : C₁₅H₂₁N₁O₄

Molecular Weight : 279.3



Analytical Information

Batch No. : RAM-IMP-2-019-307

Description : Off White Solid

HPLC Purity : 98.66 %

Weight Loss By TGA : 1.01 %

% Potency : 97.66 %

Solubility : Acetonitrile

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 - 1.01(Weight Loss By TGA)] x [98.66(HPLC Purity)]/100 = 97.66 %
-Re-tested on 17.10.2024

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 21/10/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 21/10/2024 |

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