

CERTIFICATE OF ANALYSIS

(Certificate No. KME009013-01)

Release Date: 02/01/2023

Re-test Date: 01/01/2026

Enalapril EP Impurity H

Identification

Chemical Name :
(S)-4-Cyclohexyl-1-ethoxy-1-oxobutan-2-yl-L-alanyl-L-proline

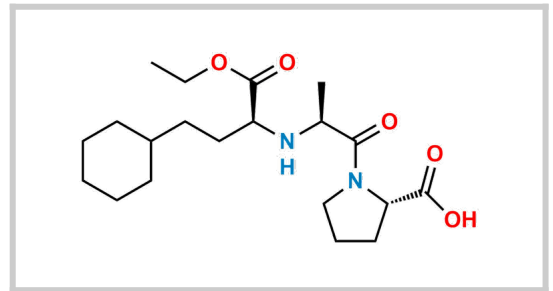
Alt. Name : Enalapril Cyclohexyl Analog

CAT No. : KME009013

CAS No. : 2055735-10-7

Molecular Formula : C₂₀H₃₄N₂O₅

Molecular Weight : 382.5



Analytical Information

Batch No. : ENA-EPH-030-370

Description : Colorless Semi Solid

HPLC Purity : 95.94 %

Weight Loss By TGA : 1.47 %

% Potency : 94.53 %

Solubility : ACN : Water (1:1)

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 - 1.47(Weight Loss By TGA)] x [95.94(HPLC Purity)]/100 = 94.53 %

Remarks : COA Re-generated on 21.10.2024

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, ¹H NMR, IR and TGA