

CERTIFICATE OF ANALYSIS

(Certificate No. KME009013-02)

Release Date: 25/08/2025

Re-test Date: 24/08/2028

Enalapril EP impurity H

Identification

Chemical Name :

((S)-4-Cyclohexyl-1-ethoxy-1-oxobutan-2-yl)-L-alanyl-L-proline maleate

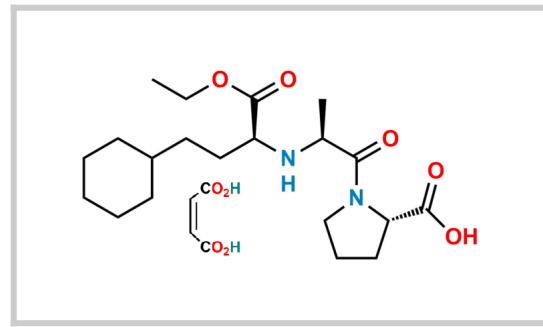
Alt. Name : Enalapril Cyclohexyl Analog

CAT No. : KME009013

CAS No. : Not Available ; 2055735-10-7 (free base)

Molecular Formula : C20H34N2O5 : C4H4O4

Molecular Weight : 382.5 : 116.1



Analytical Information

Batch No. : E009013-102-230

Solubility : ACN : WATER (85:15)

Description : White Solid

Mass : Confirm

HPLC Purity : 99.54 %

IR : Confirm

Weight Loss By TGA : 0.73 %

1H NMR : Confirm

% Potency : 98.81 %

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 - 0.73(Weight Loss By TGA)] x [99.54(HPLC Purity)]/100 = 98.81 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/01/2026
Reviewed & Approved By	Quality Control	Jatin Patel		21/01/2026

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