

CERTIFICATE OF ANALYSIS

(Certificate No. KME009009-01)

Release Date: 01/12/2022

Re-test Date: 30/11/2025

Enalapril EP Impurity D

Identification

Chemical Name :

Ethyl (2S)-2-[(3S,8aS)-3-methyl-1,4-dioxohexahydropyrrolo[1,2-a]pyrazin-2(1H)-yl]-4-phenylbutanoate (as per EP)

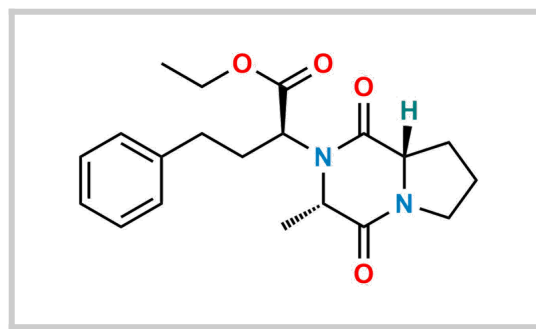
Alt. Name : Enalapril USP Related Compound D ;
Enalapril Diketopiperazine

CAT No. : KME009009

CAS No. : 115729-52-7

Molecular Formula : C₂₀H₂₆N₂O₄

Molecular Weight : 358.4



Analytical Information

Batch No. : ENA-EPD-030-359

Description : Off White Solid

HPLC Purity : 99.82 %

Weight Loss By TGA : 0.60 %

% Potency : 99.22 %

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 - 0.60(Weight Loss By TGA)] x [99.82(HPLC Purity)]/100 = 99.22 %

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