

# 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)

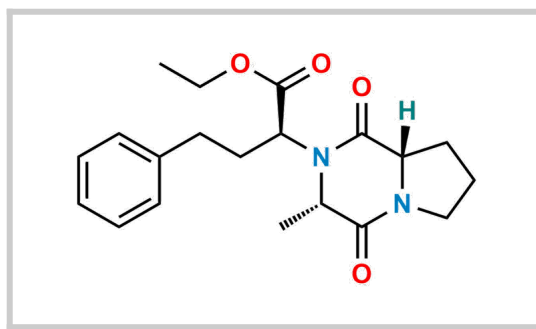
**Alt. Name** : Enalapril USP Related Compound D ;  
Enalapril Diketopiperazine

**CAT No.** : KME009009

**CAS No.** : 115729-52-7

**Molecular Formula** : C<sub>20</sub>H<sub>26</sub>N<sub>2</sub>O<sub>4</sub>

**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

**<sup>1</sup>H 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, <sup>1</sup>H NMR, IR and TGA