

# **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

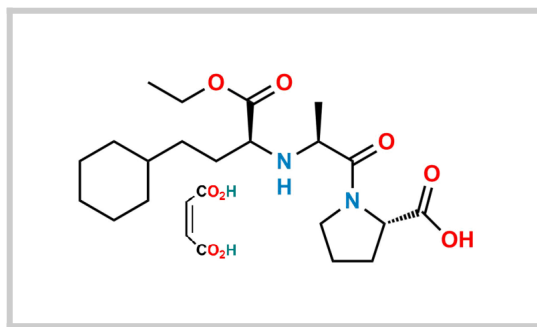
**Alt. Name** : Enalapril Cyclohexyl Analog

**CAT No.** : KME009013

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

**Molecular Formula** : C<sub>20</sub>H<sub>34</sub>N<sub>2</sub>O<sub>5</sub> : C<sub>4</sub>H<sub>4</sub>O<sub>4</sub>

**Molecular Weight** : 382.5 : 116.1



### **Analytical Information**

**Batch No.** : E009013-102-230

**Description** : White Solid

**HPLC Purity** : 99.54 %

**Weight Loss By TGA** : 0.73 %

**% Potency** : 98.81 %

**Solubility** : ACN : WATER  
(85:15)

**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 - 0.73(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, <sup>1</sup>HNMR, IR and TGA