

# CERTIFICATE OF ANALYSIS

(Certificate No. KME009007-01)

Release Date: 17/10/2024

Re-test Date: 16/10/2027

## Enalapril EP Impurity B

### Identification

**Chemical Name :**  
((S)-1-Ethoxy-1-oxo-4-phenylbutan-2-yl)-L-alanine

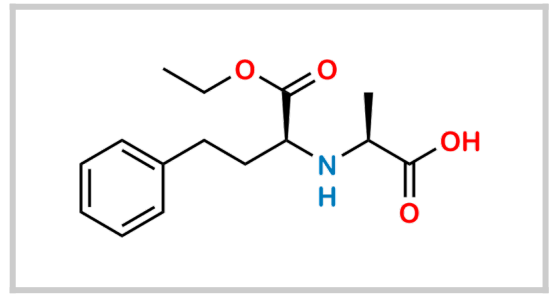
**Alt. Name** : Moexipril USP Related Compound F

**CAT No.** : KME009007

**CAS No.** : 82717-96-2

**Molecular Formula** : C<sub>15</sub>H<sub>21</sub>N<sub>1</sub>O<sub>4</sub>

**Molecular Weight** : 279.3



### Analytical Information

**Batch No.** : RAM-IMP-2-019-307

**Description** : Off White Solid

**HPLC Purity** : 98.66 %

**Weight Loss By TGA** : 1.01 %

**% Potency** : 97.66 %

**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 - 1.01(Weight Loss By TGA)] x [98.66(HPLC Purity)]/100 = 97.66 %

-Re-tested on 17.10.2024

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		21/10/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		21/10/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA