

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA011003-01)

Release Date: 24/08/2022

Re-test Date: 23/08/2025

## Amlodipine Related Compound A

### Identification

**Chemical Name :**

3-Ethyl 5-methyl 2-((2-aminoethoxy)methyl)-4-(2-chlorophenyl)-6-methylpyridine-3,5-dicarboxylate fumarate

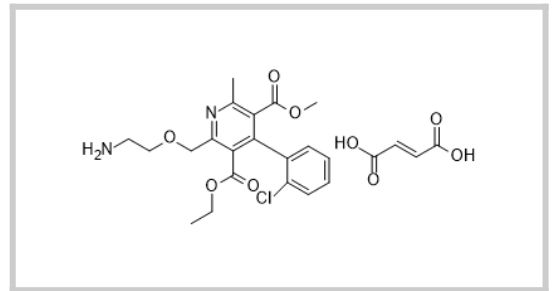
**Alt. Name** : Amlodipine USP Related Compound A

**CAT No.** : KMA011003

**CAS No.** : 2138811-33-1

**Molecular Formula** : C<sub>20</sub>H<sub>23</sub>ClN<sub>2</sub>O<sub>5</sub> : C<sub>4</sub>H<sub>4</sub>O<sub>4</sub>

**Molecular Weight** : 406.86 : 116.07



### Analytical Information

**Batch No.** : AML-RC-A-030-262

**Description** : White Solid

**HPLC Purity** : 95.34 %

**Weight Loss By TGA** : 2.05 %

**% Potency** : 93.39 %

**Solubility** : ACN : Water (1:1)

**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** =  $[100 - 2.05(\text{Weight Loss By TGA})] \times [95.34(\text{HPLC Purity})]/100 = 93.39 \%$

Remarks : COA Re-generated on 12.06.2024

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		12/06/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		12/06/2024

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