

# CERTIFICATE OF ANALYSIS

(Certificate No. KML024021-01)

Release Date: 22/01/2025

Re-test Date: 21/01/2028

## RANOLAZINE ZEN-II IMPURITY

### Identification

**Chemical Name :**

2-Chloro-N-(2,6-dimethylphenyl)acetamide (as per EP)

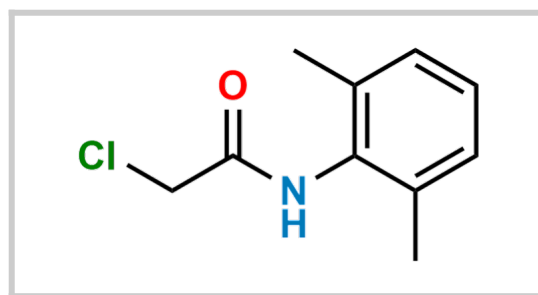
**Alt. Name** : Lidocaine USP Related Compound H

**CAT No.** : KML024021

**CAS No.** : 1131-01-7

**Molecular Formula** : C<sub>10</sub>H<sub>12</sub>ClNO

**Molecular Weight** : 197.7



### Analytical Information

**Batch No.** : L024021-091-172

**Description** : Off White Solid

**HPLC Purity** : 99.98 %

**Weight Loss By TGA** : 0.15 %

**% Potency** : 99.83 %

**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 - 0.15(Weight Loss By TGA)] x [99.98(HPLC Purity)]/100 = 99.83 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		22/01/2025
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		22/01/2025

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