

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)

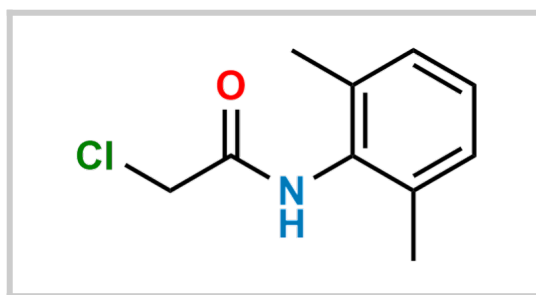
Alt. Name : Lidocaine USP Related Compound H

CAT No. : KML024021

CAS No. : 1131-01-7

Molecular Formula : C₁₀H₁₂ClNO

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

¹H 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
Prepared By	Analytical	Jignesh Patel		22/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/01/2025

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA