CERTIFICATE OF ANALYSIS

(Certificate No. KML024013-01)

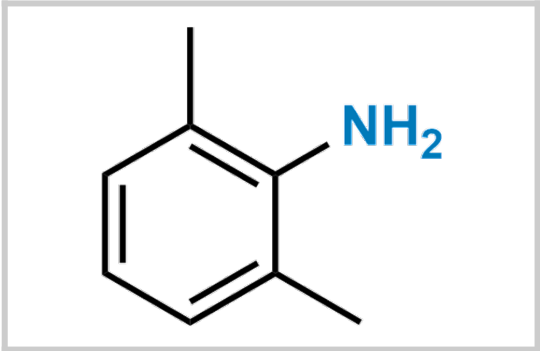
Release Date: 01/05/2025 **Re-test Date:** 30/04/2028

Lidocaine EP Impurity A

Identification

Chemical Name :
2,6-Dimethylaniline (as per EP)

Alt. Name	: Bupivacaine EP Impurity F ; Lidocaine USP Impurity A
CAT No.	: KML024013
CAS No.	: 87-62-7
Molecular Formula	: C8H11N
Molecular Weight	: 121.2



Analytical Information

Batch No.	: L024013-102-003	**Solubility**	: Acetonitrile
Description	: Light Brown Liquid	**Mass**	: Confirm
HPLC Purity	: 99.95 %	**IR**	: Confirm
Weight Loss By TGA	: 3.18 %	**1H NMR**	: Confirm
% Potency	: 96.77 %		

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 - 3.18(Weight Loss By TGA)] x [99.95(HPLC Purity)]/100 = 96.77 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		03/05/2025
Reviewed & Approved By	Quality Control	Jatin Patel		03/05/2025

Attachments : COA, HPLC, MASS, 1HNMR, IR and TGA