CERTIFICATE OF ANALYSIS

(Certificate No. KMM020014-01)

Release Date: 22/01/2025 **Re-test Date:** 21/01/2028

Mirtazapine EP Impurity B

Identification

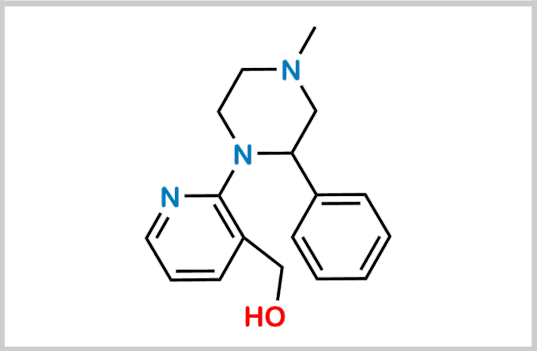
Chemical Name :
[2-[(2RS)-4-methyl-2-phenylpiperazin-1-yl]pyridin-3-yl]methanol (as per EP)

CAT No. : KMM020014

CAS No. : 61337-89-1

Molecular Formula : C17H21N3O

Molecular Weight : 283.4



Analytical Information

Batch No.	: M020014-091-144	**Solubility**	: Methanol
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.94 %	**IR**	: Confirm
Weight Loss By TGA	: 0.01 %	**1H NMR**	: Confirm
% Potency	: 99.93 %		

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 - 0.01(Weight Loss By TGA)] x [99.94(HPLC Purity)]/100 = 99.93 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		28/01/2025

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