

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 :

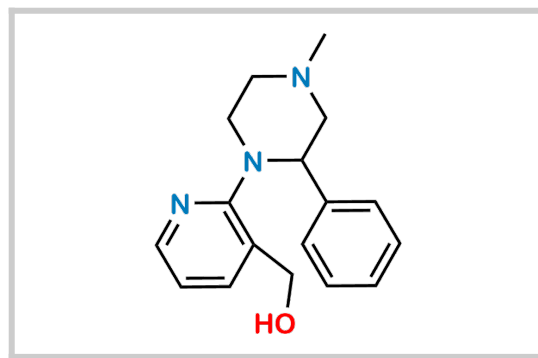
[2-[(2RS)-4-methyl-2-phenylpiperazin-1-yl]pyridin-3-yl]methanol (as per EP)

CAT No. : KMM020014

CAS No. : 61337-89-1

Molecular Formula : C₁₇H₂₁N₃O

Molecular Weight : 283.4



Analytical Information

Batch No. : M020014-091-144

Description : Off White Solid

HPLC Purity : 99.94 %

Weight Loss By TGA : 0.01 %

% Potency : 99.93 %

Solubility : Methanol

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

¹³C 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 - 0.01(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, ¹³CNMR IR and TGA