

CERTIFICATE OF ANALYSIS

(Certificate No. KMM020003-01)

Release Date: 19/04/2024

Re-test Date: 18/04/2027

Mirtazapine EP Impurity E

Identification

Chemical Name :

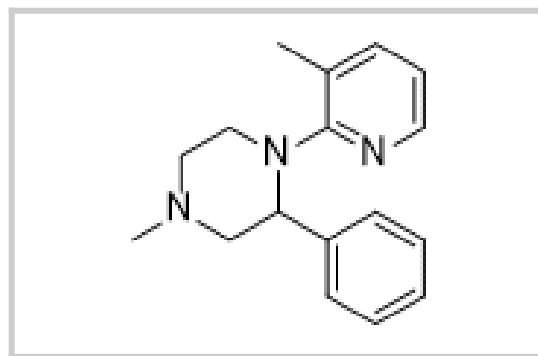
4-methyl-1-(3-methylpyridin-2-yl)-2-phenylpiperazine

CAT No. : KMM020003

CAS No. : 191546-94-8

Molecular Formula : C₁₇H₂₁N₃

Molecular Weight : 267.37



Analytical Information

Batch No. : MIR-EPE-073-098

Description : Off White Solid

HPLC Purity : 99.39 %

Weight Loss By TGA : 0.14 %

% Potency : 99.25 %

Solubility : ACN

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 - 0.14(Weight Loss By TGA)] x [99.39(HPLC Purity)]/100 = 99.25 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		26/04/2024
Reviewed & Approved By	Quality Control	Jatin Patel		26/04/2024

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