

CERTIFICATE OF ANALYSIS

(Certificate No. KMM020002-01)

Release Date: 28/03/2024

Re-test Date: 27/03/2027

Mirtazapine EP Impurity F

Identification

Chemical Name :

2-methyl-1,3,4,14b-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-10(2H)-one

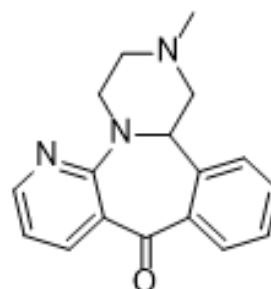
Alt. Name : Mirtazapine USP Related Compound
D ; Mirtazapine 10-Keto Impurity

CAT No. : KMM020002

CAS No. : 191546-97-1

Molecular Formula : C₁₇H₁₇N₃O

Molecular Weight : 279.34



Analytical Information

Batch No. : MIR-IMP-F-073-146

Description : Light Brown Solid

HPLC Purity : 99.75 %

Weight Loss By TGA : 0.04 %

% Potency : 99.71 %

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 - 0.04(Weight Loss By TGA)] x [99.75(HPLC Purity)]/100 = 99.71 %

Recommendation : Released

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

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