CERTIFICATE OF ANALYSIS

(Certificate No. KMM020002-01)

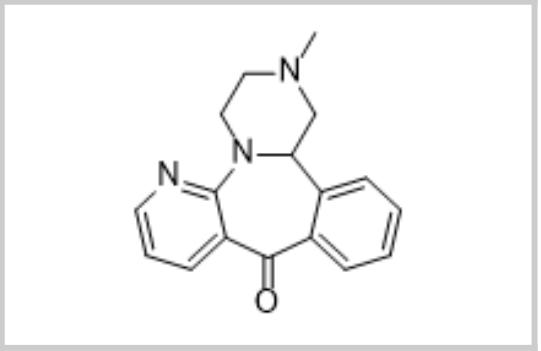
Release Date: 28/03/2024 **Re-test Date:** 27/03/2027

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	**Solubility**	: Acetonitrile
Description	: Light Brown Solid	**Mass**	: Confirm
HPLC Purity	: 99.75 %	**IR**	: Confirm
Weight Loss By TGA	: 0.04 %	**1H NMR**	: Confirm
% Potency	: 99.71 %		

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