CERTIFICATE OF ANALYSIS

(Certificate No. KMM020013-01)

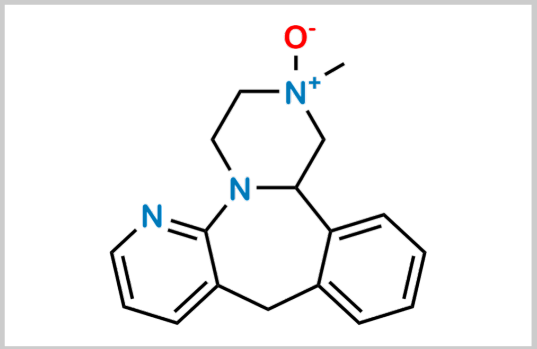
Release Date: 22/10/2024 **Re-test Date:** 21/10/2027

Mirtazapine EP Impurity A

Identification

Chemical Name :
(14bRS)-2-methyl-1,2,3,4,10,14b-hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine 2-oxide (as per EP)

Alt. Name	: Mirtazapine EP Impurity A ; Mirtazapine USP Related Compound B ; Mirtazapine N-Oxide ;
CAT No.	: KMM020013
CAS No.	: 155172-12-6
Molecular Formula	: C17H19N3O
Molecular Weight	: 281.4



Analytical Information

Batch No.	: M020013-073-423	**Solubility**	: ACN : Water (1:1)
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 95.17 %	**IR**	: Confirm
Weight Loss By TGA	: 1.78 %	**1H NMR**	: Confirm
% Potency	: 93.48 %	**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 - 1.78(Weight Loss By TGA)] x [95.17(HPLC Purity)]/100 = 93.48 %
-13CNMR added on 05.02.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/02/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/02/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA