

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)

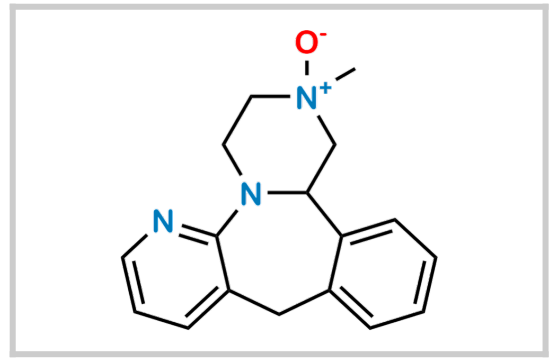
Alt. Name : Mirtazapine EP Impurity A ;
Mirtazapine USP Related Compound B
; Mirtazapine N-Oxide ;

CAT No. : KMM020013

CAS No. : 155172-12-6

Molecular Formula : C₁₇H₁₉N₃O

Molecular Weight : 281.4



Analytical Information

Batch No. : M020013-073-423

Description : White Solid

HPLC Purity : 95.17 %

Weight Loss By TGA : 1.78 %

% Potency : 93.48 %

Solubility : ACN : Water (1:1)

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 - 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