

CERTIFICATE OF ANALYSIS

(Certificate No. KMM020004-01)

Release Date: 24/04/2024

Re-test Date: 23/04/2027

Mirtazapine EP Impurity D

Identification

Chemical Name :
1,2,3,4,10,14b-hexahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepine

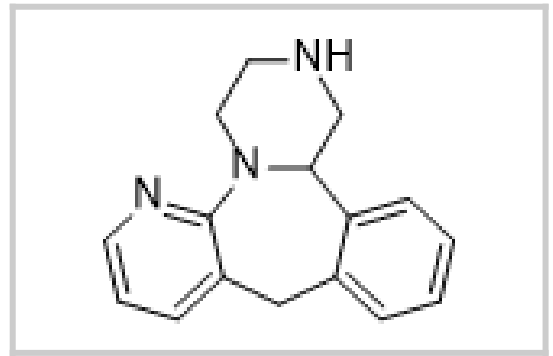
Alt. Name : Mirtazapine USP Related Compound
A ; N-Desmethyl Mirtazapine

CAT No. : KMM020004

CAS No. : 61337-68-6

Molecular Formula : C₁₆H₁₇N₃

Molecular Weight : 251.33



Analytical Information

Batch No.	: MIR-EP-IMP-D-073-182	Solubility	: Methanol
Description	: Light Brown Solid	Mass	: Confirm
HPLC Purity	: 98.02 %	IR	: Confirm
Weight Loss By TGA	: 4.83 %	¹H NMR	: Confirm
% Potency	: 93.29 %	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 - 4.83(Weight Loss By TGA)] x [98.02(HPLC Purity)]/100 = 93.29 %
-¹³CNMR added on 06.02.2025

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