

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

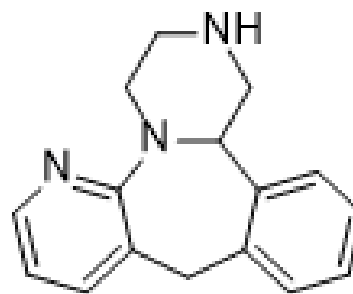
Alt. Name : Mirtazapine USP Related Compound
A ; N-Desmethyl Mirtazapine

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

Description : Light Brown Solid

HPLC Purity : 98.02 %

Weight Loss By TGA : 4.83 %

% Potency : 93.29 %

Solubility : Methanol

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 - 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