

# 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

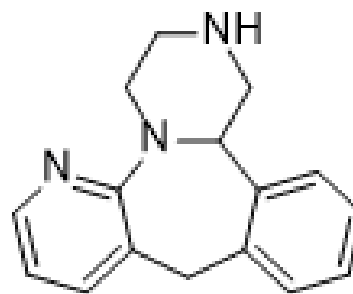
**Alt. Name** : Mirtazapine USP Related Compound  
A ; N-Desmethyl Mirtazapine

**CAT No.** : KMM020004

**CAS No.** : 61337-68-6

**Molecular Formula** : C<sub>16</sub>H<sub>17</sub>N<sub>3</sub>

**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

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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 %  
-<sup>13</sup>CNMR 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA