

# 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)

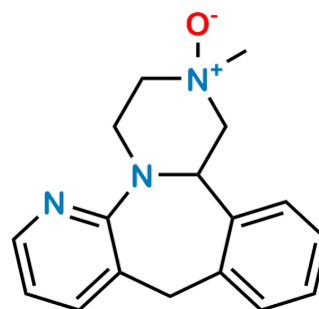
**Alt. Name** : Mirtazapine EP Impurity A ;  
Mirtazapine USP Related Compound B  
; Mirtazapine N-Oxide ;

**CAT No.** : KMM020013

**CAS No.** : 155172-12-6

**Molecular Formula** : C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O

**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

**<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 - 1.78(Weight Loss By TGA)] x [95.17(HPLC Purity)]/100 = 93.48 %  
-<sup>13</sup>CNMR 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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA