

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM020002-01)

Release Date: 28/03/2024

Re-test Date: 27/03/2027

## Mirtazapine Impurity F

### Identification

**Chemical Name :**

2-methyl-1,3,4,14b-tetrahydrobenzo[c]pyrazino[1,2-a]pyrido[3,2-f]azepin-10(2H)-one

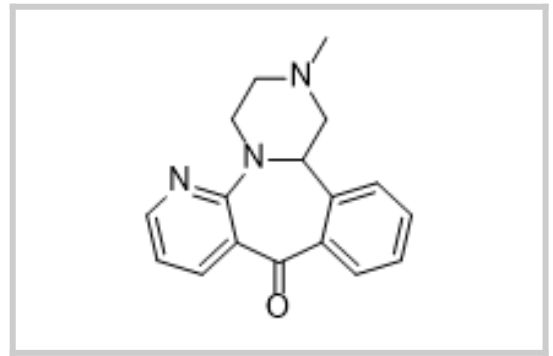
**Alt. Name** : Mirtazapine USP Related Compound D ; Mirtazapine 10-Keto Impurity

**CAT No.** : KMM020002

**CAS No.** : 191546-97-1

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

**Molecular Weight** : 279.34



### Analytical Information

**Batch No.** : MIR-IMP-F-073-146

**Solubility** : ACN

**Description** : Light Brown Solid

**Mass** : Confirm

**HPLC Purity** : 99.75 %

**IR** : Confirm

**Weight Loss By TGA** : 0.04 %

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

**% Potency** : 99.71 %

### 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 - 0.04(Weight Loss By TGA)] x [99.75(HPLC Purity)]/100 = 99.71 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		04/04/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		04/04/2024

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA