

# CERTIFICATE OF ANALYSIS

(Certificate No. KMM020003-01)

Release Date: 19/04/2024

Re-test Date: 18/04/2027

## Mirtazapine EP Impurity E

### Identification

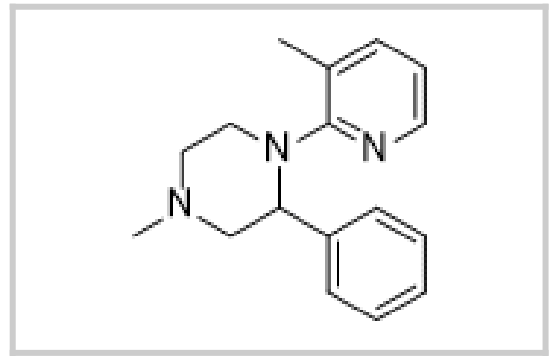
**Chemical Name :**  
4-methyl-1-(3-methylpyridin-2-yl)-2-phenylpiperazine

**CAT No. :** KMM020003

**CAS No. :** 191546-94-8

**Molecular Formula :** C<sub>17</sub>H<sub>21</sub>N<sub>3</sub>

**Molecular Weight :** 267.37



### Analytical Information

**Batch No. :** MIR-EPE-073-098

**Description :** Off White Solid

**HPLC Purity :** 99.39 %

**Weight Loss By TGA :** 0.14 %

**% Potency :** 99.25 %

**Solubility :** ACN

**Mass :** Confirm

**IR :** Confirm

**<sup>1</sup>H 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 =**  $[100 - 0.14(\text{Weight Loss By TGA})] \times [99.39(\text{HPLC Purity})]/100 = 99.25 \%$

**Recommendation :** Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		26/04/2024
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		26/04/2024

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