

# CERTIFICATE OF ANALYSIS

(Certificate No. KMT010007-01)

Release Date: 27/12/2024

Re-test Date: 26/12/2027

## Tramadol Impurity B

### Identification

**Chemical Name :**

[2-(3-methoxyphenyl)cyclohex-1-en-1-yl]-N,N-dimethylmethanamine hydrochloride(as per EP)

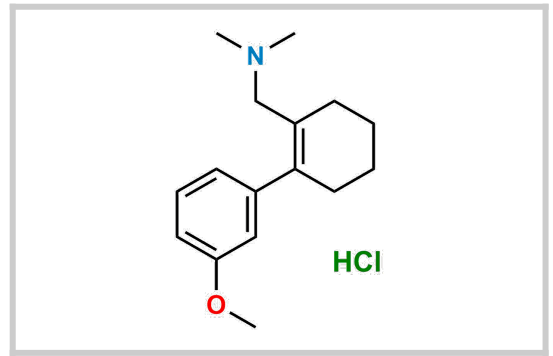
**Alt. Name** : Tramadol 1,2-Olefin Hydrochloride (USP)

**CAT No.** : KMT010007

**CAS No.** : 66170-32-9

**Molecular Formula** : C<sub>16</sub>H<sub>23</sub>NO : HCl

**Molecular Weight** : 245.4 : 36.5



### Analytical Information

**Batch No.** : T010007-091-110

**Description** : White Solid

**HPLC Purity** : 94.49 %

**Weight Loss By TGA** : 2.20 %

**% Potency** : 92.41 %

**Solubility** : Acetonitrile

**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 - 2.20(Weight Loss By TGA)] x [94.49(HPLC Purity)]/100 = 92.41 %

**Recommendation** : Released

	Department	Name	Signature	Date
<b>Prepared By</b>	Analytical	Jignesh Patel		01/01/2025
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		01/01/2025

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