

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)

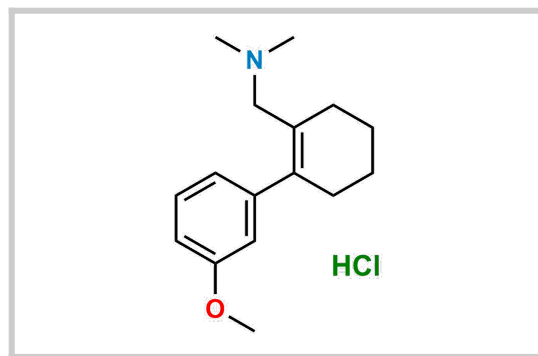
Alt. Name : Tramadol 1,2-Olefin Hydrochloride (USP)

CAT No. : KMT010007

CAS No. : 66170-32-9

Molecular Formula : C₁₆H₂₃NO : 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

¹H 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
Prepared By	Analytical	Jignesh Patel		01/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		01/01/2025

Attachments : COA, HPLC, MASS, ¹HNMR, IR and TGA