CERTIFICATE OF ANALYSIS

(Certificate No. KMT010007-01)

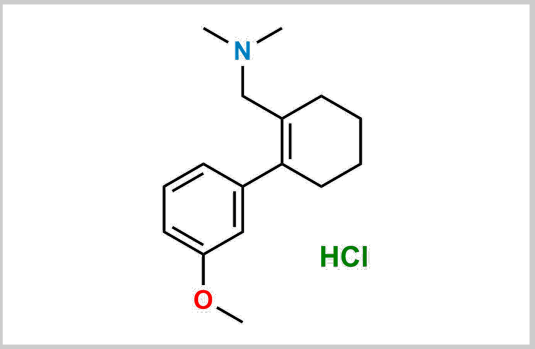
Release Date: 27/12/2024 **Re-test Date:** 26/12/2027

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	**Solubility**	: Acetonitrile
Description	: White Solid	**Mass**	: Confirm
HPLC Purity	: 94.49 %	**IR**	: Confirm
Weight Loss By TGA	: 2.20 %	**1H NMR**	: Confirm
% Potency	: 92.41 %		

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