CERTIFICATE OF ANALYSIS

(Certificate No. KMT010011-01)

Release Date: 20/03/2025 **Re-test Date:** 19/03/2028

TRAMADOL IMPURITY E

Identification

Chemical Name :
(2RS)-2-[(dimethylamino)methyl]cyclohexan-1-one hydrochloride (as per EP) ; 2-[(Dimethylamino)methyl]cyclohexanone hydrochloride (as per USP)

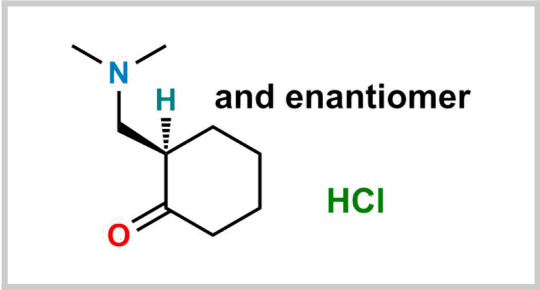
Alt. Name : Tramadol USP Related Compound B

CAT No. : KMT010011

CAS No. : 42036-65-7

Molecular Formula : C9H17NO : HCl

Molecular Weight : 155.2 : 36.5



Analytical Information

Batch No. : T010011-091-279

Description : Off White Solid

HPLC Purity : 94.16 %

Weight Loss By TGA : 0.30 %

% Potency : 93.88 %

Solubility : Water

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 - 0.30(Weight Loss By TGA)] x [94.16(HPLC Purity)]/100 = 93.88 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/03/2025
Reviewed & Approved By	Quality Control	Jatin Patel		21/03/2025

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