

CERTIFICATE OF ANALYSIS

(Certificate No. KMT023012-01)

Release Date: 28/10/2025

Re-test Date: 27/10/2028

Terbinafine Impurity E

Identification

Chemical Name :

(2E,4E)-4-(4,4-dimethylpent-2-yn-1-ylidene)-N,N'-dimethyl-N,N'-bis(naphthalen-1-ylmethyl)pent-2-ene-1,5-diamine Dihydrochloride (as per EP)

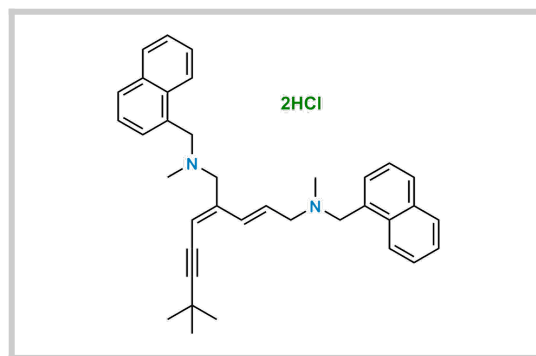
Alt. Name : Terbinafine Dimer Impurity

CAT No. : KMT023012

CAS No. : Not Available (HCl Salt); 934365-23-8 (Freebase)

Molecular Formula : C₃₆H₄₀N₂ : 2HCl

Molecular Weight : 500.7 : 2(36.5)



Analytical Information

Batch No. : SL-AVV-339-092

Description : Off White Solid

HPLC Purity : 99.18 %

Weight Loss By TGA : 2.13 %

% Potency : 97.07 %

Solubility : ACN : Water (50 : 50)

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 - 2.13(Weight Loss By TGA)] x [99.18(HPLC Purity)]/100 = 97.07 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		28/10/2025

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