

CERTIFICATE OF ANALYSIS

(Certificate No. KML006028-01)

Release Date: 30/08/2025

Re-test Date: 29/08/2028

ENDO LURASIDONE IMPURITY

Identification

Chemical Name :

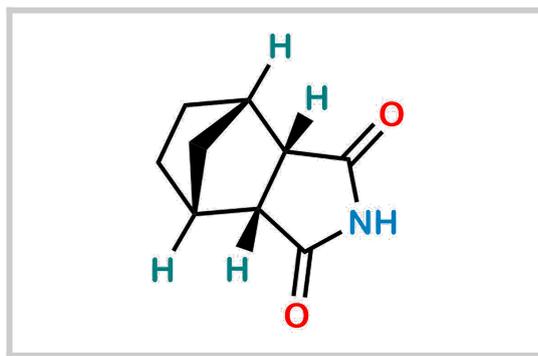
Lurasidone Endo KSM-III Impurity ; (3aR,4R,7S,7aS)-hexahydro-1H-4,7-methanoisoindole-1,3(2H)-dione

CAT No. : KML006028

CAS No. : 28871-95-6

Molecular Formula : C₉H₁₁NO₂

Molecular Weight : 165.2



Analytical Information

Batch No. : LUR-IMP-2-019-137

Description : White Solid

HPLC Purity : 97.51 %

Weight Loss By TGA : 1.99 %

% Potency : 95.57 %

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 = $[100 - 1.99(\text{Weight Loss By TGA})] \times [97.51(\text{HPLC Purity})]/100 = 95.57 \%$

-Re-tested on 30.08.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		29/01/2026
Reviewed & Approved By	Quality Control	Jatin Patel		29/01/2026

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA