

CERTIFICATE OF ANALYSIS

(Certificate No. KML006008-01)

Release Date: 14/08/2024

Re-test Date: 13/08/2027

Lurasidone LRSRC-11 Impurity

Identification

Chemical Name :

(3aR,4S,7R,7aS)-2-(((1S,2S)-2-((4-(benzo[d]isothiazol-3-yl)piperazin-1-yl)methyl)cyclohexyl)methyl)hexahydro-1H-4,7-methanoisoindole-1,3(2H)-dione

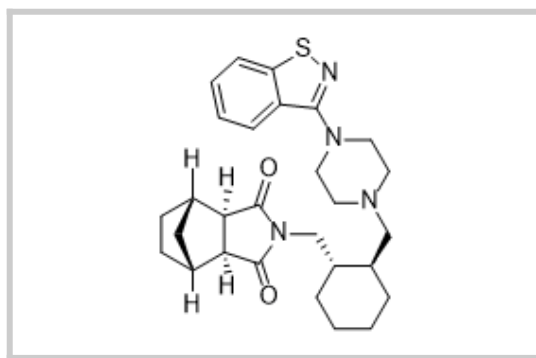
Alt. Name : Lurasidone 1S,2S-Isomer

CAT No. : KML006008

CAS No. : Not Available

Molecular Formula : C₂₈H₃₆N₄O₂S

Molecular Weight : 492.68



Analytical Information

Batch No. : LRSRC-11-073-335

Description : Off White Solid

HPLC Purity : 99.82 %

Weight Loss By TGA : 0.07 %

% Potency : 99.75 %

Solubility : ACN

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 - 0.07(Weight Loss By TGA)] x [99.82(HPLC Purity)]/100 = 99.75 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		14/08/2024
Reviewed & Approved By	Quality Control	Jatin Patel		14/08/2024

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