

CERTIFICATE OF ANALYSIS

(Certificate No. KML006001-01)

Release Date: 05/03/2024

Re-test Date: 04/03/2027

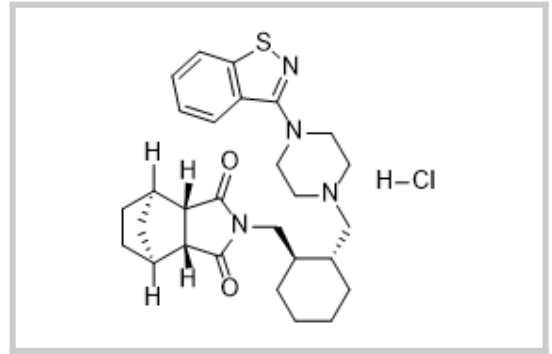
Lurasidone Hydrochloride PRS

Identification

Chemical Name :

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

CAT No. : KML006001
CAS No. : 367514-88-3
Molecular Formula : C₂₈H₃₆N₄O₂S : HCl
Molecular Weight : 492.68 : 36.5



Analytical Information

| | | | |
|--------------------|-------------------|--------------------|-----------|
| Batch No. | : LUR-WRS-045-215 | Solubility | : ACN |
| Description | : White Solid | Mass | : Confirm |
| HPLC Purity | : 99.91 % | IR | : Confirm |
| Weight Loss By TGA | : 0.04 % | ¹ H NMR | : Confirm |
| % Potency | : 99.87 % | | |

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 = $[100 - 0.04(\text{Weight Loss By TGA})] \times [99.91(\text{HPLC Purity})]/100 = 99.87 \%$
Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|-------------|-----------|------------|
| Prepared By | Analytical | Parag Patel | | 05/03/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 05/03/2024 |

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