# CERTIFICATE OF ANALYSIS

(Certificate No. KMR004028-01)

**Release Date:** 01/12/2025 **Re-test Date:** 30/11/2028

## Risperidone EP Impurity D

## Identification

**Chemical Name** :
3-[2-[4-(5-Fluoro-1,2-benzisoxazol-3-yl)piperidin-1-yl]ethyl]-2-methyl-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-4-one

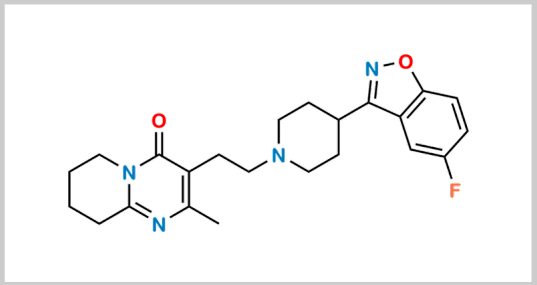
**Alt. Name** : 5-Fluoro Risperidone (USP)

**CAT No.** : KMR004028

**CAS No.** : 1199589-74-6

**Molecular Formula** : C23H27FN4O2

**Molecular Weight** : 410.5




## Analytical Information

**Batch No.** : R004028-114-023

**Description** : Light Yellow Solid

**HPLC Purity** : 99.45 %

**Weight Loss By TGA** : 1.68 %

**% Potency** : 97.78 %

**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 - 1.68(Weight Loss By TGA)] x [99.45(HPLC Purity)]/100 = 97.78 %

**Recommendation** : Released

| | Department | Name | Signature | Date |
|---|---|---|---|---|
| **Prepared By** | Analytical | Jignesh Patel | | 01/12/2025 |
| **Reviewed & Approved By** | Quality Control | Jatin Patel | | 01/12/2025 |

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