

CERTIFICATE OF ANALYSIS

(Certificate No. KMR004002-01)

Release Date: 17/06/2024

Re-test Date: 16/06/2027

RK-I Impurity of Risperidone

Identification

Chemical Name :

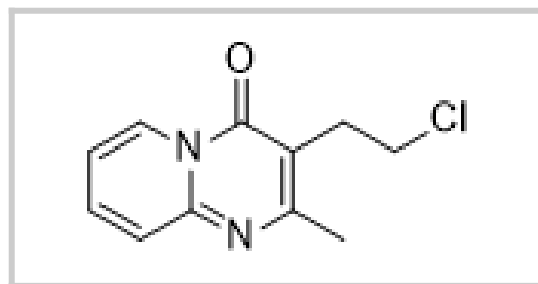
3-(2-chloroethyl)-2-methyl-4H-pyrido[1,2-a]pyrimidin-4-one

CAT No. : KMR004002

CAS No. : 41078-70-0

Molecular Formula : C₁₁H₁₁ClN₂O

Molecular Weight : 222.67



Analytical Information

Batch No. : RIS-IMP-4-073-266

Description : White Solid

HPLC Purity : 99.75 %

Weight Loss By TGA : 0.12 %

% Potency : 99.63 %

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 - 0.12(Weight Loss By TGA)] x [99.75(HPLC Purity)]/100 = 99.63 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 18/06/2024 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 18/06/2024 |

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