

CERTIFICATE OF ANALYSIS

(Certificate No. KMR004036-01)

Release Date: 16/10/2026

Re-test Date: 15/10/2029

Risperidone EP Impurity M

Identification

Chemical Name :

6-Fluoro-3-(4-piperidinyl)-1,2-benzisoxazole hydrochloride

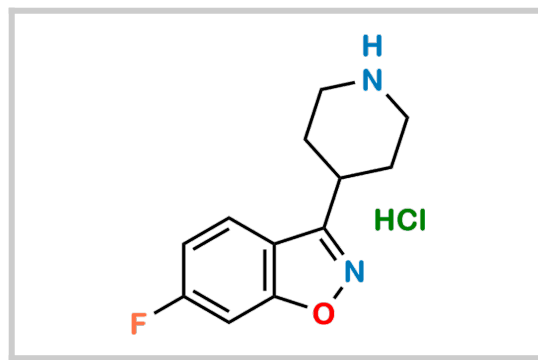
Alt. Name : Risperidone Amine Impurity (HCl Salt) ; Paliperidone USP Related Compound B

CAT No. : KMR004036

CAS No. : 84163-13-3

Molecular Formula : C₁₂H₁₃FN₂O : HCl

Molecular Weight : 220.2 : 36.5



Analytical Information

Batch No. : PAL-RC-B-030-330

Description : White Soild

HPLC Purity : 99.26 %

Weight Loss By TGA : 2.82 %

% Potency : 96.46 %

Solubility : Water

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 - 2.82(Weight Loss By TGA)] x [99.26(HPLC Purity)]/100 = 96.46 %

-Re-tested on 16.10.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		16/10/2026
Reviewed & Approved By	Quality Control	Jatin Patel		16/10/2026

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