CERTIFICATE OF ANALYSIS

(Certificate No. KMR004036-01)

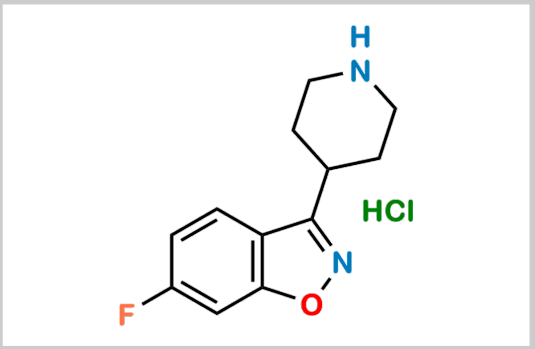
Release Date: 16/10/2026 **Re-test Date:** 15/10/2029

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	**Solubility**	: Water
Description	: White Soild	**Mass**	: Confirm
HPLC Purity	: 99.26 %	**IR**	: Confirm
Weight Loss By TGA	: 2.82 %	**1H NMR**	: Confirm
% Potency	: 96.46 %		

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