CERTIFICATE OF ANALYSIS

(Certificate No. KMR004031-01)

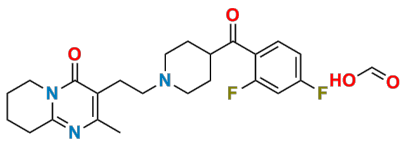
Release Date: 10/07/2026 **Re-test Date:** 09/07/2029

Risperidone EP Impurity H

Identification

Chemical Name :
3-(2-(4-(2,4-difluorobenzoyl)piperidin-1-yl)ethyl)-2-methyl-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-4-one Formate Salt

Alt. Name	: Risperidone Difluoroketone (USP)
CAT No.	: KMR004031
CAS No.	: Not Available ; 158697-67-7 (Free Base)
Molecular Formula	: C23H27F2N3O2 : CH2O2
Molecular Weight	: 415.5 : 46.03



Analytical Information

Batch No.	: R004031-136-093	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.82 %	**IR**	: Confirm
Weight Loss By TGA	: 1.40 %	**1H NMR**	: Confirm
% Potency	: 98.42 %		

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 - 1.40(Weight Loss By TGA)] x [99.82(HPLC Purity)]/100 = 98.42 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/07/2026
Reviewed & Approved By	Quality Control	Jatin Patel		10/07/2026

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