CERTIFICATE OF ANALYSIS

(Certificate No. KMR006030-01)

Release Date: 10/04/2025 **Re-test Date:** 09/04/2028

Ritonavir Impurity O

Identification

Chemical Name :
Thiazol-5-ylmethyl [(1S,2R,4S)-1-benzyl-2-hydroxy-4-[[(2S)-3-methyl-2-[[methyl[[2-(1-methylethyl)thiazol-4-yl]methyl]carbamoyl]amino]butanoyl]amino]-5-phenylpentyl]carbamate (as per EP); Thiazol-5-ylmethyl (2S,3R,5S)-3-hydroxy-5-[(S)-2-{3-[(2-isopropylthiazol-4-yl)methyl]-3-methylureido}-3-methylbutanamido]-1,6-diphenylhexan-2-ylcarbamate (as per USP)

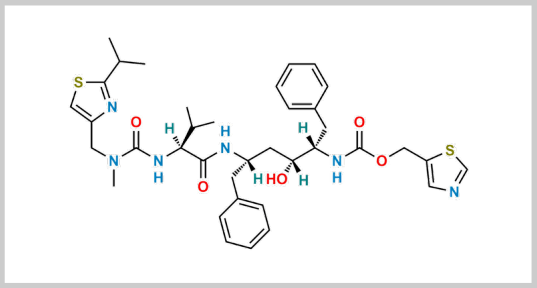
Alt. Name : 3R-Epimer Ritonavir (USP)

CAT No. : KMR006030

CAS No. : 1414933-81-5

Molecular Formula : C37H48N6O5S2

Molecular Weight : 720.9



Analytical Information

Batch No.	: RIT-EP-IMP-O-019-392	**Solubility**	: Acetonitrile
Description	: Off White solid	**Mass**	: Confirm
HPLC Purity	: 99.28 %	**IR**	: Confirm
Weight Loss By TGA	: 0.57 %	**1H NMR**	: Confirm
% Potency	: 98.71 %		

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 - 0.57(Weight Loss By TGA)] x [99.28(HPLC Purity)]/100 = 98.71 %
-Re-tested on 10.04.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/04/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/04/2025

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