

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)

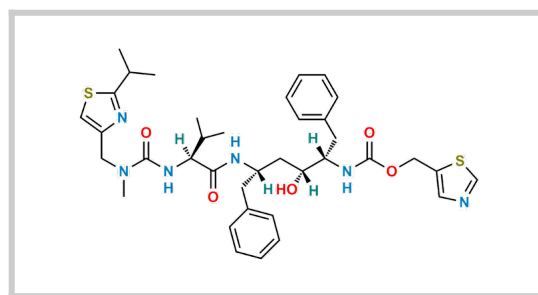
Alt. Name : 3R-Epimer Ritonavir (USP)

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

Description : Off White solid

HPLC Purity : 99.28 %

Weight Loss By TGA : 0.57 %

% Potency : 98.71 %

Solubility : Acetonitrile

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 - 0.57(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