

CERTIFICATE OF ANALYSIS

(Certificate No. KMR006021-01)

Release Date: 12/10/2023

Re-test Date: 11/10/2026

Ritonavir Impurity F

Identification

Chemical Name :

Thiazol-5-yl-methyl [(1S,2S,4S)-1-benzyl-4-[[[(2S)-1-benzyl-2-hydroxy-4-[(4S)-4-(1-methylethyl)-2,5-dioxoimidazolidin-1-yl]-5-phenylpentyl]carbamate (as per EP); Thiazol-5-ylmethyl (2S,3S,5S)-3-hydroxy-5-[(S)-4-isopropyl-2,5-dioxoimidazolidin-1-yl]-1,6-diphenylhexan-2-ylcarbamate (as per USP)

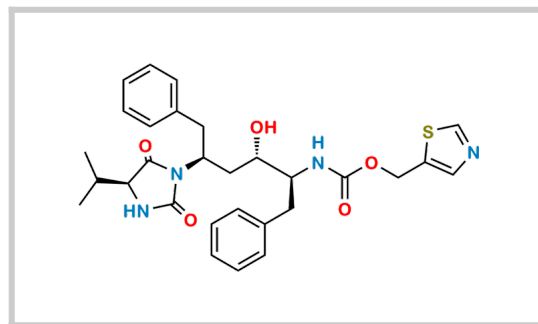
Alt. Name : Hydantoin Amino Alcohol Ritonavir (USP)

CAT No. : KMR006021

CAS No. : 1010809-61-6

Molecular Formula : C₂₉H₃₄N₄O₅S

Molecular Weight : 550.7



Analytical Information

Batch No. : RIT-EP-IMP-F-045-297

Description : Off White Solid

HPLC Purity : 94.27 %

Weight Loss By TGA : 0.84 %

% Potency : 93.48 %

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 - 0.84(Weight Loss By TGA)] x [94.27(HPLC Purity)]/100 = 93.48 %

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