

CERTIFICATE OF ANALYSIS

(Certificate No. KMD006083-01)

Release Date: 19/12/2024

Re-test Date: 18/12/2027

Darunavir DNV-II Impurity 1

Identification

Chemical Name :

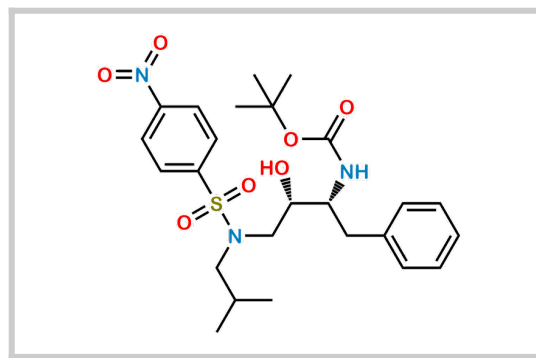
tert-butyl ((2R,3S)-3-hydroxy-4-(N-isobutyl-4-nitrophenylsulfonamido)-1-phenylbutan-2-yl)carbamate

CAT No. : KMD006083

CAS No. : 1005324-46-8

Molecular Formula : C₂₅H₃₅N₃O₇S

Molecular Weight : 521.6



Analytical Information

Batch No. : D006083-091-091

Description : White solid

HPLC Purity : 99.93 %

Weight Loss By TGA : 1.92 %

% Potency : 98.01 %

Solubility : DMSO

Mass : Confirm as Na adduct

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 - 1.92(Weight Loss By TGA)] x [99.93(HPLC Purity)]/100 = 98.01 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		19/12/2024
Reviewed & Approved By	Quality Control	Jatin Patel		19/12/2024

Attachments : COA, HPLC, MASS, ¹H NMR, TGA and IR