CERTIFICATE OF ANALYSIS

(Certificate No. KML075011-01)

Release Date: 21/03/2024 **Re-test Date:** 20/03/2027

LIFITEGRAST IMPURITY B

Identification

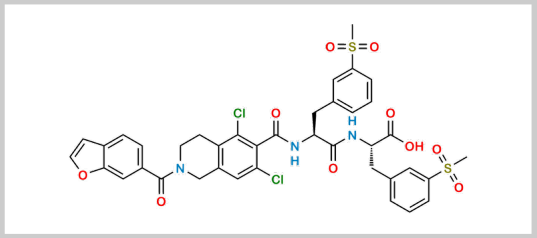
Chemical Name :
(S)-2-((S)-2-(2-(Benzofuran-6-carbonyl)-5,7-dichloro-1,2,3,4-tetrahydroisoquinoline-6-carboxamido)-3-(3-(methylsulfonyl)phenyl)propanamido)-3-(3-(methylsulfonyl)phenyl)propanoic acid

CAT No. : KML075011

CAS No. : Not Available

Molecular Formula : C39H35Cl2N3O10S2

Molecular Weight : 840.7



Analytical Information

Batch No. : SL-KVS-288-156

Description : Off White Solid

HPLC Purity : 96.57 %

Weight Loss By TGA : 1.73 %

% Potency : 94.9 %

Solubility : DMSO and Methanol

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 - 1.73(Weight Loss By TGA)] x [96.57(HPLC Purity)]/100 = 94.9 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		21/03/2024
Reviewed & Approved By	Quality Control	Jatin Patel		21/03/2024

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