CERTIFICATE OF ANALYSIS

(Certificate No. KMN008010-)

Release Date: 28/10/2024 **Re-test Date:** 27/10/2027

Nateglinide EP Impurity F

Identification

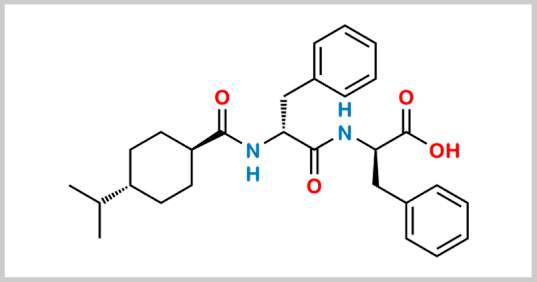
Chemical Name :
N-[[trans-4-(1-methylethyl)cyclohexyl]carbonyl]-D-phenylalanyl-D-phenylalanine

CAT No. : KMN008010

CAS No. : 944746-48-9

Molecular Formula : C28H36N2O4

Molecular Weight : 464.6



Analytical Information

Batch No.	: N008010-091-012	**Solubility**	: Methanol
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 99.90 %	**IR**	: Confirm
Weight Loss By TGA	: 0.75 %	**1H NMR**	: Confirm
% Potency	: 99.15 %		

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 - 0.75(Weight Loss By TGA)] x [99.90(HPLC Purity)]/100 = 99.15 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		28/10/2024

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