

CERTIFICATE OF ANALYSIS

(Certificate No. KMN008010-)

Release Date: 28/10/2024

Re-test Date: 27/10/2027

Nateglinide EP Impurity F

Identification

Chemical Name :

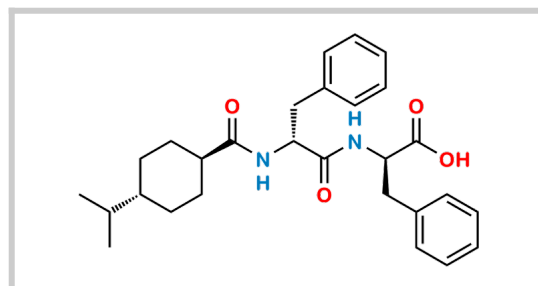
N-[[trans-4-(1-methylethyl)cyclohexyl]carbonyl]-D-phenylalanyl-D-phenylalanine

CAT No. : KMN008010

CAS No. : 944746-48-9

Molecular Formula : C₂₈H₃₆N₂O₄

Molecular Weight : 464.6



Analytical Information

Batch No. : N008010-091-012

Description : Off White Solid

HPLC Purity : 99.90 %

Weight Loss By TGA : 0.75 %

% Potency : 99.15 %

Solubility : 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 - 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