

CERTIFICATE OF ANALYSIS

(Certificate No. SZ-L024041-0435)

Analysis Date: 18/11/2020

Re-test Date: 11/03/2022

Linagliptin Impurity 27

Identification

Chemical Name : (R)-7-(but-2-yn-1-yl)-3-methyl-1-((4-methylquinazolin-2-yl)methyl)-8-(piperidin-3-ylamino)-3,7-dihydro-1H-purine-2,6-dione

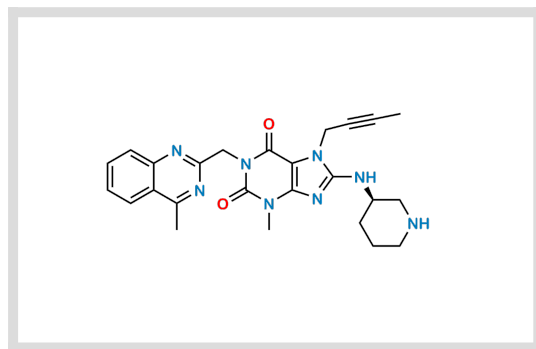
CAT No. : SZ-L024041

CAS No. : 1446263-38-2

Molecular Formula : C₂₅H₂₈N₈O₂

Molecular Weight : 472.55

Synonyms : Des-(R)-piperidin-3-amine 8-(R)-(Piperidin-3-ylamino) Linagliptin



Analytical Information

Batch Code	: SRL-116-75	HPLC Purity	: 97.49 %
Solubility	: ACN:Water (80:20)	Mass	: Confirm
Appearance of product	: Brown solid	IR Analysis	: Confirm
Long Term Storage	: 2-8 °C for long term storage	¹ H NMR	: Confirm
Weight Loss By TGA	: 1.45 %		

Additional Information

% Potency = [100 - 1.45 (Wt loss by TGA)] X [97.49 (HPLC Purity)] / 100 = 96.08 %

Recommendation : Released

	Department	Signature	Date
Prepared and Reviewed by	Analytical		
Approved By	Quality Control		

Attachments : HPLC, Mass, NMR, IR, TGA

Shipping Condition : All Products are stable to be shipped at room temperature, unless otherwise specified.