

CERTIFICATE OF ANALYSIS

(Certificate No. KMS010001-04)

Release Date: 21/02/2026

Re-test Date: 20/02/2029

N-Nitroso Sitagliptin Impurity

Identification

Chemical Name :

7-nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine

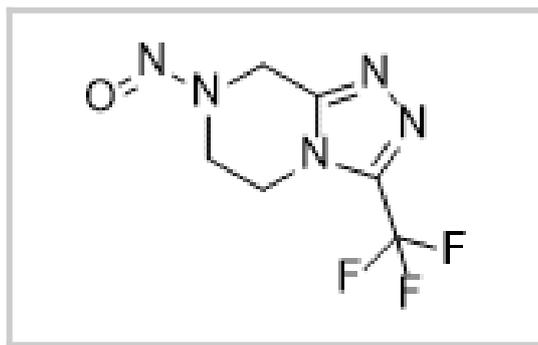
Alt. Name : Sitagliptin KSM Nitroso

CAT No. : KMS010001

CAS No. : 2892260-32-9

Molecular Formula : C₆H₆F₃N₅O

Molecular Weight : 221.14



Analytical Information

Batch No. : S010001-114-176

Solubility : ACN

Description : Light Yellow Solid

Mass : Confirm

HPLC Purity : 99.58 %

IR : Confirm

Weight Loss By TGA : 0.07 %

¹H NMR : Confirm

% Potency : 99.51 %

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 - 0.07(Weight Loss By TGA)] x [99.58(HPLC Purity)]/100 = 99.51 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		24/02/2026
Reviewed & Approved By	Quality Control	Jatin Patel		24/02/2026

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