CERTIFICATE OF ANALYSIS

(Certificate No. KMS007048-01)

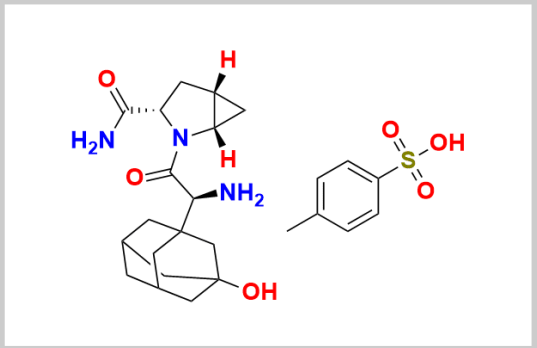
Release Date: 13/04/2026 **Re-test Date:** 12/04/2029

Saxagliptin Stage-IIA (Saxa-Amide)

Identification

Chemical Name :
(1S,3S,5S)-2-((2S)-2-amino-2-(3-hydroxyadamantan-1-yl)acetyl)-2-azabicyclo[3.1.0]hexane-3-carboxamide P-Toluene Sulphonate Salt

Alt. Name	: 3-Descarbonitrile 3-Acetamido Saxagliptin
CAT No.	: KMS007048
CAS No.	: Not Available ; 1496712-39-0(Free base)
Molecular Formula	: C18H27N3O3 : C7H8O3S
Molecular Weight	: 333.4 : 172.2



Analytical Information

Batch No.	: SAX-STAGE-IIA-045-018	**Solubility**	: ACN
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 95.80 %	**IR**	: Confirm
Weight Loss By TGA	: 1.25 %	**1H NMR**	: Confirm
% Potency	: 94.6 %		

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 - 1.25(Weight Loss By TGA)] x [95.80(HPLC Purity)]/100 = 94.6 %
-Re-tested on 13.04.2026

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		13/04/2026
Reviewed & Approved By	Quality Control	Parag Vekariya		13/04/2026

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