

# 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

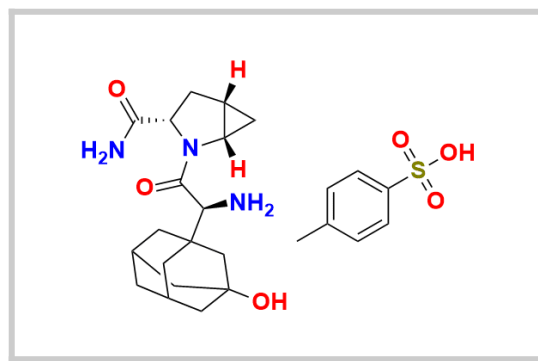
**Alt. Name** : 3-Descarbonitrile 3-Acetamido  
Saxagliptin

**CAT No.** : KMS007048

**CAS No.** : Not Available ; 1496712-39-0(Free base)

**Molecular Formula** : C<sub>18</sub>H<sub>27</sub>N<sub>3</sub>O<sub>3</sub> : C<sub>7</sub>H<sub>8</sub>O<sub>3</sub>S

**Molecular Weight** : 333.4 : 172.2



### Analytical Information

**Batch No.** : SAX-STAGE-IIA-045-018

**Description** : Off White Solid

**HPLC Purity** : 95.80 %

**Weight Loss By TGA** : 1.25 %

**% Potency** : 94.6 %

**Solubility** : ACN

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 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
<b>Prepared By</b>	Analytical	Jignesh Patel		13/04/2026
<b>Reviewed &amp; Approved By</b>	Quality Control	Parag Vekariya		13/04/2026

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, IR and TGA