

Analysis Date: 08-10-2025

Re-test Date: 08-10-2028

## SAXAGLIPTIN IMPURITY 58

### Identification

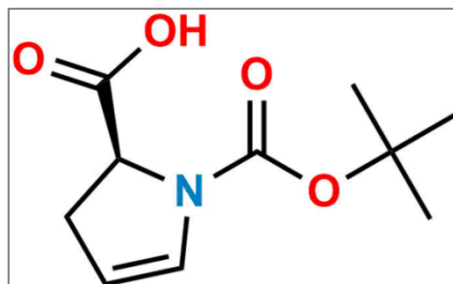
**Chemical Name** : (S)-1-(tert-butoxycarbonyl)-2,3-dihydro-1H-pyrrole-2-carboxylic acid

**CAT No** : ALL-SAX-99

**CAS No** : 90104-21-5

**Molecular Formula** : C<sub>10</sub>H<sub>15</sub>NO<sub>4</sub>

**Molecular Weight** : 213.2



### Analytical Information

|                              |                                   |                         |           |
|------------------------------|-----------------------------------|-------------------------|-----------|
| <b>Batch No.</b>             | : ALL-SAX-99                      | <b>HPLC Purity</b>      | : 98.00%  |
| <b>Solubility</b>            | : USP Diluent / EP Diluent (MEOH) | <b>Potency</b>          | : 95.55%  |
| <b>Appearance of Product</b> | : Off White Solid                 | <b>Mass</b>             | : Confirm |
| <b>Long Term Storage</b>     | : -20°C                           | <b>IR Analysis</b>      | : Confirm |
| <b>Weight Loss By TGA</b>    | : 1.453%                          | <b><sup>1</sup>HNMR</b> | : Confirm |
| <b>Residue Of Ignition</b>   | : 1.045%                          |                         |           |

### Additional Information

**%Potency** = [100 - (Weight Loss By TGA % + Residue Of Ignition %) × Chromatographic Purity%]/100 =  
 [100 - (1.453+1.045) × 98.00]/100 = 95.55%

**Recommendation** : Released

|                          | Department | Name                               | Signature |
|--------------------------|------------|------------------------------------|-----------|
| Prepared and Reviewed by | Analytical | Mr.Vipul khadase<br>Jr. Executive  |           |
| Approved By              | QA&QC      | Dr. Ashish Keche<br>Director QA&QC |           |

**Attachment** : HPLC, Mass, <sup>1</sup>H NMR, IR, TGA

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

#### Corporate Office