

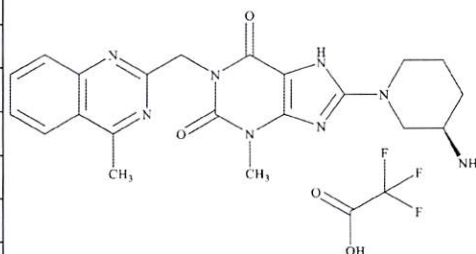
Certificate of Analysis

Certificate No.: **20230619014**



Date: June 19, 2023

Retest date: June 12, 2026

| | |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Compound Name: Linagliptin Impurity 103 Trifluoroacetate | |
| Synonyms: | (R)-8-(3-aminopiperidin-1-yl)-3-methyl-1-((4-methylquinazolin-2-yl)methyl)-3,7-dihydro-1H-purine-2,6-dione, 2,2,2-trifluoroacetic acid (1:1) |
| TLC Catalogue Number: | L-44116 |
| CAS Number: | N/A |
| Molecular Weight: | 420.48 114.02 |
| Molecular Formula: | C ₂₁ H ₂₄ N ₈ O ₂ · C ₂ HF ₃ O ₂ |
| Source: | TLC Pharmaceutical Standards |
| Source Lot No.: | 5707-008A3 |
| Storage Conditions: | Store at 2-8 °C |
| Solubility: | Methanol, DMSO |



| Test Description | Specifications | Results |
|--------------------------------|--------------------------------------------------|----------------------------------------------------------------|
| Visual Description | Pale yellow solid | Conforms |
| Identification | | |
| IR | Conforms to structure | Conforms |
| MS | Conforms to structure | Conforms |
| ¹ H NMR | Conforms to structure | Conforms |
| ¹⁹ F NMR | Conforms to structure | Conforms |
| Purity (HPLC) | Not less than 95.0% | 98.5% |
| Impurity (HPLC) | RT 6.80, 0.23%; RT 10.78, 0.27%; RT 16.03, 0.25% | |
| Optical Rotation | N/A | [α] _D ^{25.0} (c=0.31, DMSO): -20.2° |
| Residual Solvents (NMR) | 1.5% methanol | |
| Assay (qNMR) | Not less than 90.0% | 93.3% |
| Recommendation: | Release. | |

| Name | Department | Signature | Date |
|---------------------------|-------------------|--------------------------------------------------------------------------------------|------------|
| Reviewed and approved by: | Quality Control |  | 06/20/2023 |
| Approved by: | Quality Assurance |  | 06/20/2023 |

Attachments: HPLC, IR, MS and NMR spectra.