

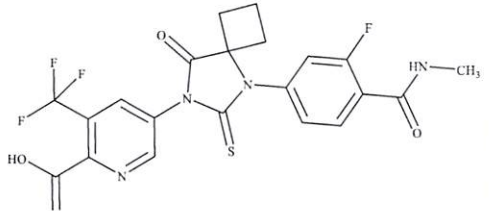


## Certificate of Analysis



Certificate No.: 20250815503

Date: August 15, 2025

Retest date: August 13, 2028

|                              |   |  |
|------------------------------|---|--|
| <b>Compound Name:</b>        | <b>Apalutamide Impurity 12</b>  |  |
| <b>Synonyms:</b>             | 5-(5-(3-fluoro-4-(methylcarbamoyl)phenyl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]octan-7-yl)-3-(trifluoromethyl)picolinic acid |  |
| <b>TLC Catalogue Number:</b> | A-284015  |  |
| <b>CAS Number:</b>           | N/A   |  |
| <b>Alternate CAS Number:</b> | N/A   |  |
| <b>Molecular Weight:</b>     | 496.44  |  |
| <b>Molecular Formula:</b>    | C <sub>21</sub> H <sub>16</sub> F <sub>4</sub> N <sub>4</sub> O <sub>4</sub> S  |  |
| <b>Source:</b>               | TLC Pharmaceutical Standards  |  |
| <b>Source Lot No.:</b>       | C0233-056A15  |  |
| <b>Storage Conditions:</b>   | Store at 2-8 °C   |  |
| <b>Solubility:</b>           | Methanol, DMSO  |  |

| Test Description               | Specifications                  | Results         |
|--------------------------------|---------------------------------|-----------------|
| <b>Visual Description</b>      | Off-white solid                 | <b>Conforms</b> |
| <b>Identification</b>          |                                 |                 |
| <b>IR</b>                      | Conforms to structure           | <b>Conforms</b> |
| <b>MS</b>                      | Conforms to structure           | <b>Conforms</b> |
| <b><sup>1</sup>H NMR</b>       | Conforms to structure           | <b>Conforms</b> |
| <b>Purity (HPLC)</b>           | Not less than 95.0%             | <b>99.3%</b>    |
| <b>Impurity (HPLC)</b>         | RT 8.17, 0.26%; RT 12.33, 0.40% |                 |
| <b>Residual Solvents (NMR)</b> | 0.7% acetonitrile               |                 |
| <b>Assay (qNMR)</b>            | Not less than 90.0%             | <b>95.9%</b>    |
| <b>Recommendation:</b>         | <b>Release.</b>                 |                 |

| Name                      | Department        | Signature  | Date       |
|---------------------------|-------------------|--|------------|
| Reviewed and approved by: | Quality Control   |  | 08/15/2025 |
| Approved by:              | Quality Assurance |  | 08/15/2025 |

**Attachments:** Peak Attribution Table, HPLC, IR, MS and NMR spectra.