Active Ingredient: Apalutamide
Dosage Form; Route: Tablet; oral
Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 60 mg
   Subjects: Males, general population
   Additional Comments: Apalutamide can cause fetal harm and potential loss of pregnancy. Male study subjects with female partners of reproductive potential should use effective contraception (e.g. practice abstention or contraception) during and 3 months after in vivo bioequivalence studies.

   Apalutamide has a long terminal elimination half-life. Ensure adequate washout periods between treatments in a crossover study or consider using a parallel study design. For long half-life drug products with low intra-subject variability in distribution and clearance, an AUC truncated to 72 hours may be used in place of AUC_{0-t} or AUC_{0-inf}. For either a crossover or parallel study, sample collection time should be adequate to ensure completion of gastrointestinal transit of the drug product and absorption of the drug substance. Collect sufficient blood samples in the bioequivalence studies to adequately characterize the peak concentration (C_{max}) and time to reach peak concentration (T_{max}).

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 60 mg
   Subjects: Males, general population
   Additional Comments: See comments above.

Analytes to measure (in appropriate biological fluid): Apalutamide in plasma

Bioequivalence based on (90% CI): Apalutamide

Waiver request of in-vivo testing: Not Applicable

Recommended May 2019
Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website, available to the public at the following location: [http://www.accessdata.fda.gov/scripts/cder/dissolution/](http://www.accessdata.fda.gov/scripts/cder/dissolution/). Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).