Active ingredient: Lenalidomide
Form/Route: Capsules/Oral
Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 25 mg
   Subjects: Healthy adult males, general population. Female subjects should be excluded from the bioequivalence studies.
   Additional comments: All subjects should adhere to the REVLIMID REMSTM program guidelines and warnings for lenalidomide.

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 25 mg
   Subjects: Healthy adult males, general population. Female subjects should be excluded from the bioequivalence studies.
   Additional comments: Please see comments above.

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

Bioequivalence based on (90% CI): Lenalidomide

Waiver request of in vivo testing: 2.5 mg, 5 mg, 10 mg, 15 mg and 20 mg based on (i) acceptable fasting and fed bioequivalence studies on the 25 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:
Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.