Contains Nonbinding Recommendations

Draft Guidance on Azacitidine

Active ingredient: Azacitidine

Form/Route: Suspension/Injection

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way, crossover *in-vivo*
Strength: 100 mg/vial (25 mg/ ml)
Subjects: Males and females with confirmed diagnosis of myelodysplastic syndrome (MDS).
Additional Comments: Patients who are on a regimen of azacitidine therapy or have previously been determined to be candidates for azacitadine therapy. Females should not be pregnant, and if applicable, should practice abstention or contraception during the study. Please administer the drug subcutaneously (SC).

Submission of an Investigational New Drug Application (IND) is required prior to conducting a bioequivalence study for a cytotoxic drug product such as Azacitidine (See 21 C.F.R § 320.31).

As per 21 CFR § 314.94(a)(9)(iii) , the proposed parenteral drug product should be qualitatively (Q1) and quantitatively (Q2) the same as the corresponding reference listed drug.

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

Bioequivalence based on (90% CI): Azacitidine

Waiver request of in-vivo testing: Not applicable

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.fda.gov/cder/ogd/index.htm. 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.