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*Draft - Not for Implementation*

## **Draft Guidance on Cedazuridine; Decitabine**

**May 2022**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

This guidance, which interprets the Agency's regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic cedazuridine; decitabine.

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**Active Ingredients:** Cedazuridine; Decitabine

**Dosage Form; Route:** Tablet; oral

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 100 mg; 35 mg  
Subjects: Patients with myelodysplastic syndromes or chronic myelomonocytic leukemia who are already on established regimen of 100 mg; 35 mg once daily  
Additional comments: On Day 1 of the treatment cycle, patients should receive either the test or the reference product. After the Day 1 treatment, the patients should resume taking the therapeutic medication in the remaining cycle in their established dosing regimen. Blood sampling for bioequivalence should consist of appropriate sampling times following the dose on Day 1. Monitor complete blood count as recommended in the labeling. Exclude patients with expected changes in concomitant medications that can potentially affect the pharmacokinetics of cedazuridine and decitabine. Female patients

of reproductive potential should use effective contraception during treatment with cedazuridine and decitabine and for 6 months after the last dose. Male patients with female partners of reproductive potential should use effective contraception during treatment with cedazuridine and decitabine and for 3 months after the last dose. Submission of an Investigational New Drug Application is required prior to the conduct of a bioequivalence study for a cytotoxic drug product pursuant to 21 CFR § 320.31(3).

**Analytes to measure:** Cedazuridine and decitabine

**Bioequivalence based on (90% CI):** Cedazuridine and decitabine

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <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.

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