*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Cabotegravir**

**May 2023**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

---

**Active Ingredient:** Cabotegravir

**Dosage Form; Route:** Suspension, extended release; Intramuscular

**Strength:** 600 mg/3 mL

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

1. Type of study: In vivo bioequivalence study with pharmacokinetic endpoints
   Design: Single-dose, parallel, in vivo
   Strength: 600 mg/3 mL
   Subjects: Male and non-pregnant, non-lactating females, general population.
   Additional comments: Prior to injection of cabotegravir extended-release injectable suspension, an optional oral lead-in dosing followed by a washout period may be considered to assess the tolerability of cabotegravir as described in the product label.

**Analyte to measure:** Cabotegravir in plasma

**Bioequivalence based on (90% CI):** Cabotegravir

**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 (ANDA).

**Additional information:**

Device:
The reference listed drug (RLD) is presented as a kit that consists of one vial of cabotegravir suspension, one vial adapter, one syringe, and one injection needle. The vial adapter, syringe, and injection needle with needle guard are the device constituent parts.

FDA recommends that prospective applicants examine the size and shape, the external critical design attributes, and the external operating principles of the RLD devices when designing the Test (T) devices including:

- Vial adapter
- Needle gauge and length
- Needle guard system

User interface assessment:
An ANDA for this product should include complete comparative analyses so FDA can determine whether any differences in design for the user interface of the proposed generic product, as compared to the RLD, are acceptable and whether the product can be expected to have the same clinical effect and safety profile as the RLD when administered to patients under the conditions specified in the labeling. For additional information, refer to the most recent version of the FDA guidance for industry on *Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA*.[a]

---

**Unique Agency Identifier:** PSG_215499

[a] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.