Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Cannabidiol

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Cannabidiol

Dosage Form; Route: Solution; oral

Strength: 100 mg/mL

Recommended Studies: Request for waiver of in vivo bioequivalence study

Waiver option: To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of cannabidiol oral solution (100 mg/mL) must contain the same active drug ingredient in the same concentration and dosage form as the reference listed drug (RLD) and contain no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic availability.

Additional Comments: Tetrahydrocannabidiol (THC) is controlled in the drug substance with a limit of no more than 0.10% w/w.

The following two criteria should be assessed to ensure botanical raw material (BRM) identity:

1. The same plant species: the BRM (cannabis) used to manufacture the proposed Cannabidiol should be collected from the same plant species, *Cannabis sativa* L. The species *Cannabis sativa* L. should be correctly identified and authenticated using appropriate analytical methods (e.g., macroscopic/microscopic and/or DNA bar-coding methods). Due to the many cultivars within this species, identification and authentication of plant species should be conducted at the cultivar(s) level if the potential cultivar(s) will be used as a natural source of the BRM.
2. BRM assessment: the plant parts (e.g., leaves and flowers) used as the BRM should be defined. The BRM should be collected following established good agricultural and collection practices (GACP) procedures to minimize variations in BRM and eventually ensure the batch-to-batch consistency of the drug substance. Refer to the Botanical Drug Development Guidance for Industry for the Agency's current thinking on BRM quality control[1]and refer to the draft guidance titled Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research for additional information.[2]

[1] Botanical Drug Development Guidance for Industry. https://www.fda.gov/media/93113/download

[2] Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research Guidance for Industry (Draft). https://www.fda.gov/media/140319/download