Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Dexmethylphenidate Hydrochloride; Serdexmethylphenidate Chloride

February 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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 Ingredients: Dexmethylphenidate hydrochloride; Serdexmethylphenidate chloride

Dosage Form; Route: Capsule; oral

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 10.4 mg Base; EQ 52.3 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 10.4 mg Base; EQ 52.3 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analytes to measure: Dexmethylphenidate and serdexmethylphenidate in plasma

Bioequivalence based on (90% CI): Dexmethylphenidate

Submit serdexmethylphenidate data as supportive evidence of comparable therapeutic outcome. For serdexmethylphenidate, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

Waiver request of in vivo testing: EQ 5.2 mg Base; EQ 26.1 mg Base and EQ 7.8 mg Base; EQ 39.2 mg Base strengths based on (i) acceptable bioequivalence studies on the EQ 10.4 mg Base; EQ 52.3 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

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 for each of all strengths of the test and reference products. Specifications will be determined upon review of the Abbreviated New Drug Application (ANDA).

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