Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Carisoprodol

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strengths: 250 mg, 350 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Randomized, single-dose, two-way crossover, in vivo
   Strength: 250 mg
   Subjects: Healthy males and non-pregnant non-lactating females
   Additional comments: None

Analyte to measure: Carisoprodol in plasma

Bioequivalence based on (90% CI): Carisoprodol

Waiver request of in vivo testing: 350 mg based on (i) acceptable bioequivalence study on the 250 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of formulations between both strengths

Carisoprodol 350 mg tablet is a DESI[1]- effective drug for which there are no known or suspected bioequivalence problems, and as such is rated "AA" in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

[1] Drug Efficacy Study Implementation

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 both strengths of the test product and reference listed drug (RLD).[2] Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended March 2010; Revised October 2024

Unique Agency Identifier: PSG_011792

[2] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*