

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Avacopan

August 2023

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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: Avacopan

Dosage Form: Capsule

Route: Oral

Strength: 10 mg

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: 10 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Exclude subjects with abnormal complete blood counts or liver function tests. Monitor for signs and symptoms of infection during and after the study. Exclude subjects with evidence of current or prior hepatitis B or C virus infection. Ensure an adequate washout period between treatments in crossover study due to long elimination half-life of avacopan. Alternatively, a parallel study design may be considered.
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 10 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: See comments above.

Analyte to measure: Avacopan in plasma

Bioequivalence based on (90% CI): Avacopan

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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