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Draft Guidance on Dronedarone Hydrochloride

October 2024

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Active Ingredient: Dronedarone hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 400 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 400 mg Base
   Subjects: Healthy males
   Additional comments: Exclude subjects who have abnormal electrocardiogram or risk factors for cardiac arrhythmias (e.g., bradycardia and prolonged QT interval).

Analytes to measure: Dronedarone and its active metabolite, N-debutyl dronedarone in plasma

Bioequivalence based on (90% CI): Dronedarone

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, 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 C_{max}.

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 for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] 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.*