Contains Nonbinding Recommendations

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Draft Guidance on Etrasimod Arginine

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strength: EQ 2 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 2 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with abnormal complete blood counts or liver function tests, or electrocardiogram abnormalities (e.g., bradycardia, conduction abnormalities). Monitor for signs and symptoms of bradycardia with pulse and blood pressure measurements. Subjects should be informed not to use live attenuated vaccines at least four weeks prior to, during, and for five weeks after the study. Females of reproductive potential should use effective contraception during the study and for ten days after the last dose. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of etrasimod. Alternatively, a parallel study design may be considered.

Analyte to measure: Etrasimod in plasma

Bioequivalence based on (90% CI): Etrasimod

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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Unique Agency Identifier: PSG_216956

[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*.