*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

# Draft Guidance on Baricitinib

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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**Active Ingredient:** Baricitinib

**Dosage Form:** Tablet

**Route:** Oral

**Strengths:** 1 mg, 2 mg, 4 mg

**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: 4 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with latent tuberculosis, abnormal liver function tests or blood counts, or at an increased risk for thrombosis. Do not use live attenuated vaccines immediately prior to or during the study.

**Analyte to measure:** Baricitinib in plasma

**Bioequivalence based on (90% CI):** Baricitinib

**Waiver request of in vivo testing:** 1 mg and 2 mg strengths based on (i) acceptable bioequivalence study on the 4 mg 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 product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

**Product-specific testing conditions for in vitro feeding tube studies:** Since the approved labeling for the RLD states that the product may be administered via a feeding tube, in vitro nasogastric (NG) tube/orogastric (OG) tube and gastrostomy (G) tube studies are recommended which include comparative recovery, sedimentation volume, and re- dispersibility.

Testing tubes: NG/OG tube (8 French) and G tube (12 French) with different tube materials (e.g., polyvinyl chloride, silicone, polyurethane) and/or designs (e.g., various numbers of ports and/or eyes, retention balloons, open or closed distal end). At least one G tube should be tested with an inflated balloon design.

Testing strengths: 1 mg, 2 mg, and 4 mg

Dispersion and rinse medium: Dispersed a tablet with 30 mL of water for NG/OG tube or 15 mL of water for G tube. Flush remaining contents from NG/OG or G tubes with 15 mL of water. Report the pH value of the water.

Holding times: 0 and 15 minutes

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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.*