Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Meloxicam; Rizatriptan Benzoate

February 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strength: 20 mg; EQ 10 mg Base

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: 20 mg; EQ 10 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with a history of peptic ulcer disease and/or gastrointestinal bleeding or with risk factors for cardiovascular disease. Exclude geriatric subjects or CYP2C9 poor metabolizers due to increased risk of adverse reactions.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 20 mg; EQ 10 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See above comments.

Analytes to measure: Meloxicam and rizatriptan in plasma

Bioequivalence based on (90% CI): Meloxicam and rizatriptan

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution test method and sampling times: Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

For additional information, refer to the most recent version of the guidance for industry *Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances.*[a]

Document History: Recommended February 2026

Unique Agency Identifier: PSG_215431

[a] For the most recent version of a guidance, refer to the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm