Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Tolmetin Sodium

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet

Route: Oral

Strengths: EQ 200 mg Base, EQ 400 mg Base[1], EQ 600 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 600 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with a history of peptic ulcer disease or gastrointestinal bleeding. Exclude subjects with cardiovascular risk factors.

Analyte to measure: Tolmetin in plasma

Bioequivalence based on (90% CI): Tolmetin

Waiver request of in vivo testing of additional strengths: Justification based on (i) an acceptable bioequivalence study on the EQ 600 mg Base strength, (ii) acceptable comparative in vitro dissolution studies between the additional strengths and the EQ 600 mg Base strength using 12 units per strength, and (iii) proportional similarity of the formulations across all strengths

[1] The strength identified is the subject of an approved suitability petition (FDA-1990-P-0044).

Dissolution: Dissolution test(s) should be included for quality control and to support a waiver request of in vivo testing of additional strengths.

Dissolution test method and sampling times: Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[2] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

For drug products containing high solubility drug substances that meet the rapidly dissolving criteria, demonstration of discriminating ability may not be needed. 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]

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Unique Agency Identifier: PSG_017628

[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.

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