

*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*Draft – Not for Implementation*

**Draft Guidance on Tolmetin Sodium**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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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**Active Ingredient:** Tolmetin sodium

**Dosage Form:** Capsule

**Route:** Oral

**Strength:** EQ 400 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 400 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 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<sup>1</sup> 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*.<sup>a</sup>

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**Document History:** Recommended February 2026

**Unique Agency Identifier:** PSG\_018084

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<sup>a</sup> 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>.

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