

## Draft Guidance on Tiagabine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active Ingredient:** Tiagabine hydrochloride

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two options: BCS waiver or in vivo studies

### I. BCS waiver option:

It may be possible to request a waiver of in vivo testing for all the strengths of this product, provided that the appropriate documentation regarding high solubility, high permeability, and rapid dissolution—as detailed in the guidance for industry *Waiver of In Vivo Bioavailability and Bioequivalence for Immediate-Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System*—is submitted in the application. If the applicant decides to request the Biopharmaceutics Classification System (BCS) waiver, the applicant should use information contained in the approved labeling of the reference product. The decision on whether the waiver is acceptable will be made upon review of the data submitted in the abbreviated new drug application (ANDA).

### II. In vivo studies option:

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in vivo  
Strength: 4 mg at a dose of 4 mg (1x4 mg)  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: None
  
2. Type of study: Fed  
Design: Single-dose, two-way crossover in vivo  
Strength: 4 mg at a dose of 4 mg (1x4 mg)  
Subjects: Healthy males and nonpregnant females, general population  
Additional comments: None

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**Analytes to measure (in appropriate biological fluid):** Tiagabine in plasma

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

**Waiver request of in vivo testing:** 2 mg, 12 mg, and 16 mg based on (i) acceptable BE studies on the 4 mg strength, (ii) proportionally similar formulation across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site available to the public at the following location:

<http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products.

Specifications will be determined upon review of the ANDA.