

Guidance on Tiagabine Hydrochloride

This guidance represents 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.

Active Ingredient: Tiagabine hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two options: Biopharmaceutics Classification System (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 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

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 abbreviated new drug application (ANDA).