

Guidance on Temazepam

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Active ingredient: Temazepam

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 30 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in vivo*
Strength: 30 mg
Subjects: Healthy males and nonpregnant females, general population.
Additional Comments:

Analytes to measure (in appropriate biological fluid): Temazepam in plasma

Bioequivalence based on (90% CI): Temazepam

Waiver request of *in-vivo* testing: 7.5 mg, 15 mg, 22.5 mg based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable *in vitro* dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.