

Guidance on Nabumetone

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Active ingredient: Nabumetone

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 750 mg
Subjects: Normal healthy males and females, general population
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 750 mg
Subjects: Normal healthy males and females, general population
Additional comments:

Analytes to measure: 6-methoxy-2-naphthyl-acetic acid (6-MNA)

Bioequivalence based on (90% CI): 6-methoxy-2-naphthyl-acetic acid (6-MNA)

Waiver request of in-vivo testing: 500 mg based on (i) acceptable bioequivalence studies on the 750 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 conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the following USP method.