Guidance on Clonidine Hydrochloride

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Active ingredient: Clonidine Hydrochloride
Form/Route: Tablets/Oral
Recommended studies: 1 study

1. Type of study: fasting
   Design: single-dose, two-way crossover in-vivo
   Strength: 0.3 mg
   Subjects: Normal healthy males and females, general population.
   Additional Comments:

Analytes to measure: Clonidine in plasma

Bioequivalence based on (90% CI): Clonidine

Waiver request of in-vivo testing: 0.1 mg and 0.2 mg based on (i) acceptable bioequivalence study on the 0.3 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.

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