

Guidance on Dipyridamole

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Active ingredient: Dipyridamole

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover *in-vivo*

Strength: 75 mg

Subjects: Normal healthy males and females, general population

Additional Comments:

Analytes to measure: Dipyridamole in plasma

Bioequivalence based on (90% CI): Dipyridamole

Waiver request of in-vivo testing: 25 mg and 50 mg based on (i) acceptable bioequivalence study on the 75 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.