Contains Nonbinding Recommendations

Draft Guidance on Prednisolone Sodium Phosphate

Active ingredient: Prednisolone Sodium Phosphate

Form/Route: Orally Disintegrating Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 30 mg prednisolone base
Subjects: Normal healthy males and females, general population.
Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.
The whole tablet should be placed on the tongue and allowed to disintegrate for 30 seconds. After 30 seconds, all subjects should consume 240 mL of water.

Analytes to measure (in appropriate biological fluid): Prednisolone in plasma.

Bioequivalence based on (90% CI): Prednisolone

Waiver request of *in-vivo* testing: 10 mg and 15 mg (base) based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.fda.gov/cder/ogd/index.htm. 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.