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Case Control Study

Bioequivalence of two esomeprazole magnesium enteric-coated formulations in healthy Chinese subjects

Liu ZZ et al. Bioequivalence of esomeprazole magnesium enteric-coated preparations.

Abstract

BACKGROUND

At present, the pharmacokinetics and bioequivalence of esomeprazole in healthy Chinese subjects and the effects of food on the pharmacokinetics have not been well studied.

AIM

The objective is to evaluate the pharmacokinetic characteristics of esomeprazole magnesium enteric coated capsule in the healthy subjects in China and to assess the bioequivalence of the two formulations.

METHODS

Clinical procedures were conducted in the Phase I Clinical Trial Unit of The Affiliated Hospital to Changchun University of Chinese Medicine. A total of 64 healthy subjects were enrolled into the study. 32 subjects in fasting and fed, respectively, took the test or

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Bioequivalence study of two esomeprazole 20 mg capsule formulations namely **Esolok®20 (Test product)** and **Nexium20** (Reference product) was carried out in the present **study**. 24 healthy male volunteers were enrolled into this randomized, **single-dose**, **two-period**, crossover, **open-label pharmacokinetic study** with one week washout period.

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This has led to development of **enteric coated formulations** of **esomeprazole**, to protect the active ingredient from degradation by gastric acid, though this also delays absorption. ... **two**-treatment, **two**-period, **two**-sequence, single-dose, crossover, **bioequivalence study** with eighteen (18) male **subjects** of Asian origin, in the age range of 18-45 ...

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the predetermined FDA **bioequivalence** range of 80% – 125%. In conclusion, the test and reference **formulations** of **esomeprazole** meet the regulatory criteria for **bioequivalence** both in terms of rate and extent of absorption. **Bioequivalence** Evaluation **of Two Esomeprazole** 20 mg Capsule **Formulations in Healthy** Male Bangladeshi Volunteers

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