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Risperidone 2 mg. An Open-Label, Single-
Dose, Fasting, Randomized-Sequence,
Two-Way Crossover Study in Healthy

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Male Chinese Volunteers. Yun Liu, Meng-qi Zhang, Jing-ying Jia, Yan-mei Liu, Gang-yi Liu, Shui-jun Li, Wei Wang, Li-ping Weng, and Chen Yu.

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A randomized, open-label, 2-period

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crossover study was performed to evaluate the pharmacokinetic properties and bioequivalence of 2 erlotinib hydrochloride tablets (a test formulation and a reference formulation) in healthy Chinese subjects. Subjects were randomized to receive a single oral dose of the erlotinib hydrochloride test or reference formulation (150 mg) under

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fasting conditions.

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**Pharmacokinetics and
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Pharmacokinetics and bioequivalence
evaluation of cyclobenzaprine tablets.

The purpose of this study was to
investigate cyclobenzaprine
pharmacokinetics and to evaluate

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bioequivalence between two different tablet formulations containing the drug. An open, randomized, crossover, single-dose, two-period, and two-sequence design was employed.

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evaluation of two branded formulations of aceclofenac 100 mg: a single-dose, randomized, open-label, two-period crossover comparison in healthy Korean adult volunteers. In these healthy Korean volunteers, results from the PK analysis suggested that the test and reference formulations of aceclofenac 100-mg tablets were bioequivalent,

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based on the regulatory definition.

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Bioequivalence and pharmacokinetic
evaluation of two branded formulations
of aceclofenac 100 mg: a single-dose,
randomized, open-label, two-period

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crossover comparison in healthy Korean
adult volunteers Si-YounRhimMD1 Jin-
HeeParkPhD2 Yoo-SinParkPhD2 Min-Ho
LeeMD3 Leslie M.ShawPhD4 Ju-
SeopKangMD, PhD2

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Evaluation of Two Formulations of
Risperidone 2 mg, *Drugs in R&D*, 2013,
pp. 29-36, Volume 13, Issue 1, DOI:
10.1007/s40268-012-0002-4 Home
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Bioequivalence and Pharmacokinetic Evaluation Study of Acetaminophen vs. Acetaminophen Plus Caffeine Tablets in Healthy Mexican Volunteers. Guzmán NA(1), Molina DR(2), Núñez BF(2), Soto-Sosa JC(2), Abarca JE(2).

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The aim of this trial was to explore the pharmacokinetics (PK) and safety with bioequivalence of orally administered Amlodipine provided by two sponsors in healthy volunteers (HVs). Methods Two separate randomized, open-label, single-dose, crossover-design studies

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were conducted: a fasting study (n = 24)
and a fed study (n = 24).

Evaluation of pharmacokinetics and safety with ...

This pharmacokinetic approach is one of the most accurate, sensitive, and reproducible ways to evaluate bioequivalence. It is also relatively

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efficient and has been used to establish
...

**Developing New Ways to Evaluate
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Guidance Issuing Office Center for Drug
Evaluation and Research The Food and
Drug Administration (FDA) is announcing
the availability of a draft guidance for

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industry entitled "Bioequivalence...

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**Bioequivalence Studies With
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Guideline on the pharmacokinetic and
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dosage forms . Draft Agreed by
Pharmacokinetics Working Party .

October 2012 bioequivalence studies

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that are not covered by the current guideline on the investigation of bioequivalence

(CPMP/EWP/QWP/1401/98). 3. Legal basis and relevant guidelines

Guideline on the pharmacokinetic and clinical evaluation ...

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evaluation of... both period of the study with no adverse effects were reported or observed. All volunteers continued to the end and were discharged in good health. The HPLC analytical method for Febuxostat plasma sample showed good specificity, sensitivity, linearity, precision and accuracy.

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Title: Bioequivalence and Pharmacokinetics Evaluation of ...

Abstract. The purpose of this study was to investigate cyclobenzaprine pharmacokinetics and to evaluate bioequivalence between two different tablet formulations containing the drug. An open, randomized, crossover, single-dose, two-period, and two-sequence

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design was employed. Tablets were administered to 23 healthy subjects after an overnight fasting and blood samples were collected up to 240 hours after drug administration.

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cts. Each subject received Epivir and

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Lamivir formulation separated by 7 days of drug-free washout period. Plasma concentrations of 3TC were used to estimate PK parameters such as maximum observed plasma concentration (C_{max}) and area under plasma concentration-time curve (AUC_{∞}). Geometric mean ratios (relative to Epivir) and resultant 90% CI of 3TC for

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Cmax and AUC ∞ were 1.00 (0.89-1.12 ...

**Pharmacokinetic Profiling and
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This document defines the studies necessary to investigate the efficacy, safety, biopharmaceutic and pharmacokinetic properties of modified release formulations following oral,

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intramuscular and subcutaneous administration and transdermal dosage forms in man. It aims to set out general principles for designing, conducting and evaluating such studies.

Pharmacokinetic and clinical evaluation of modified ...

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Evaluation of Two Formulations of
Armodafinil 250 mg Tablets in Healthy
Indian Adult Male Subjects Menon S1*,
Kandari K1, Mhatre M and Nair S
Institute for Advanced Training and
Research in Interdisciplinary Sciences
(Therapeutic Drug Monitoring
Laboratory), Mumbai- 400022, India

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**Journal of Bioequivalence &
Bioavailability**

Pharmacokinetics and bioequivalence evaluation of two losartan potassium 50-mg tablets: A single-dose, randomized-sequence, open-label, two-way crossover study in healthy Chinese male volunteers Author links open overlay panel Jing-Ying Jia MS 1 Meng-Qi

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Zhang MS 1 Yan-Mei Liu MD 1 Yun Liu

MD 1 Gang-Yi Liu MS 1 Shui-Jun Li PhD 1

Chuan Lu BPharm ...

**Pharmacokinetics and
bioequivalence evaluation of two ...**

Objective: To evaluate serum
pharmacokinetics of tapentadol
administered to healthy subjects as

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extended-release (ER) tablets. Design:

Seven single-dose studies (five randomized, crossover, bioequivalence studies; a study in Japanese men; and a randomized, crossover, effects-of-food study) and one repeated-dose study.

Setting: Clinical research settings in the United States and The Netherlands.

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Pharmacokinetic evaluation of tapentadol extended-release ...

This is a summary report of the conference on "Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies." The conference was held from December 3 to 5, 1990, in the Washington, D.C., area and was

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Food and Drug Administration,

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