BIOAVAILABILITY STUDY AND COLONIC RESIDENCE TIME EVALUATION BY X-RAY OF ORNIDAZOLE FROM COATED TABLETS IN HEALTHY HUMAN VOLUNTEERS

Pharmaceutics M Pharmacy Project Title – Example Summary Aim – B pharm Projects

BIOAVAILABILITY STUDY AND COLONIC RESIDENCE TIME EVALUATION BY X-RAY OF ORNIDAZOLE FROM COATED TABLETS USING APPROVED PHARMACEUTICAL EXCIPIENTS IN HEALTHY HUMAN VOLUNTEERS

Summary

Aim	:	1) To carry bioavailability study of Ornidazole from coated tablets by using pharmaceutical excipients and compare with marketed product. 2) To carry colonic residence time evaluation by X-ray study of Ornidazole from coated tablets.
Drugs used	:	Ornidazole 400 mg.
Subjects	:	Eight healthy human male volunteers
Study design	:	Crossover design
Institution	:	
Principal Investigator:		

Study Procedure: Eight human healthy male subjects in the age group of 25-30 will be enrolled in the study after physical examination by a physician and standard laboratory tests.

Inclusion Criteria:

i. Non-allergic to drug
ii. Healthy as per the physical examination and laboratory tests
iii. Non-participation in any study/blood donation during preceding three months
iv. Written informed consent

Study design: Simple randomized crossover design

The subject will be treated with single oral dose of Ornidazole after overnight fasting. In the crossover study, subjects will be given coated tablets of Ornidazole. Blood samples will be collected at 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 24 and 30 hours.

The subject will be treated with single oral dose of placebo tablets after overnight fasting. In the crossover study, subjects will be given placebo tablets of Ornidazole. X-Rays will be taken at 2, 5, 8,12 and 24 hours.

Treatments: Eight male volunteers shall be distributed in to two groups. A 2x2 cross over design shall be used in the study. Each volunteer in the two groups will receive the floating matrix tablets and commercial dosage form as .

The study consists of two treatments (Ornidazole coated, commercial). Ornidazole 400 mg will be given by oral route in the form of coated tablets and blood samples will be collected at 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 24 and 30 hours.

A drug free interval of at least two weeks will be kept between the two treatments. A standard breakfast will be served 2 hours after drug administration followed by standard lunch after 4 hours.

ORNIDAZOLE

Ornidazole is an anti infective / antibacterial and antiprotozaol drug available as 400mg, 500 mg and 1000 mg tablets for oral administration. Its chemical name is 1-(3-chloro-2-hydroxypropyl)-2-methyl-5-nitroimidazole.

The half-life of the drug is approximately 7.4 hours in plasma. Ornidazole is metabolised in liver through biotranformation reactions while excretion is mainly by Urine.

ContraIndications: Hypersensitivity to ornidazole or to other nitroimidazole derivatives

Adverse Reactions: Somnolence, headache, nausea, vomiting, dizziness, tremor, rigidity, poor coordination, seizures, tiredness, vertigo, temporary loss of consciousness and signs of sensory or mixed peripheral neuropathy, taste disturbances, abnormal LFTs, skin reaction.

Physical properties:

Solubility	:	It is slightly soluble in water, and soluble in chloroform.
Pka	:	2.4 ± 0.1
Category	:	It is a anti-infective and anti-protozoal agent

Pharmacokinetics

Bioavailability	:	>90 % by oral route
Absorption	:	Absorbed from entire GIT.
Protein Binding	:	<15 %
Half life	:	14.67 $\pm$ 1.0 hrs
Dosage	:	400 to 1000 mg daily.

APPROVAL OF THE ETHICAL COMMITTEE

The study entitled “Bioavailability study and colonic residence time evaluation by x-ray of Ornidazole from coated tablets in healthy human volunteers” has been approved / not approved for conducting in the healthy human volunteers.