

Document 1

Excerpts from Study Plan

**Pharmaceutical
Research Centre**

STUDY PLAN

SPONSOR: Pharmaceutical Research LTD
Huddersfield,
West Yorkshire
HD1 3AA

CRO: Pharmaceutical Research Centre
Nottingham Science Park,
Nottingham
NG1 2AA

STUDY TITLE: 5 Day Pharmacokinetic Study

STUDY NUMBER: PRL/099

TEST MATERIAL: PRL-7963

STUDY DIRECTOR: S Taylor

PROJECTED TIMINGS:

Start of Experimental Work:	18 April 2007
Completion of Experimental Work:	23 April 2007
Draft Report:	June 2007

Study Director Appointment: _____ Date: _____
Pharmaceutical Research Centre Management

Study Plan Approval: _____ Date: _____
Study Director

5 DAY PHARMACOKINETIC STUDY

STANDARD OPERATING PROCEDURES

All routine activities conducted during the course of this study at the Pharmaceutical Research Centre facility are detailed in Standard Operating Procedures.

TEST MATERIAL

The test material, PRL-7963, Batch Number 1 will be supplied by the Sponsor. A certificate of Analysis will be provided prior to start of the study.

The test material is a white crystalline powder with a purity of 99.7% and molecular weight of 575. It will be stored at ambient temperature in the dark. The solubility of the test material is >10g/L.

Dose levels

The following dose levels were selected:

Group number	Group description	Dose level (mg/kg)
1	Control	0
2	Low	25
3	Intermediate	50
4	High	100

TEST MATERIAL FORMULATION

The test material will be prepared as solutions in distilled water, at concentration of 2.5 mg/ml (Group 2 - Low), 5.0 mg/ml (Intermediate) and 10mg/ml (Group 4 - High). The test material should be weighed out in milligrammes to 1 decimal place and match the requested amount +/- 0.5mg. Group 1 (Control) will receive distilled water.

5x10ml aliquots will be taken from the stock solutions prepared for each group into vials for dosing. The dosing solutions will be stored at approximately +4°C prior to use. The actual storage temperature will be recorded in the study data. Each formulation container will be labelled with Serial Number, Study Number and concentration.

All details pertaining to the test material preparation must be recorded on the appropriate Preparation Record.

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Formulation Request

Pharmaceutical Research Centre

FORMULATION REQUEST

Test Material	PRL-7963
Serial Number	111895
Study Number	PRL/099
Vehicle	Distilled water
Date of request	18 th April 2007
Date required	18 th April 2007

Group number	Group Description	Dose Level (mg/kg bodyweight)	Dose Concentration (mg/ml)	Test Material (mg)	Tolerance (mg)	Made up to (ml)	Aliquots (n x ml)	Dose Volume (ml/kg bodyweight)
1	Control	0	0	0		100	5 x 10	10
2	Low	25	2.5	250.0	± 0.5	100	5 x 10	10
3	Intermediate	50	5	500.0	± 0.5	100	5 x 10	10
4	High	100	10	1000.0	± 0.5	100	5 x 10	10

Storage: Store at approximately +4°C prior to dosing.

Requested by: STaylor Signature 18/4/07 Date

Checked by: ~~DKompson~~ Signature 18/04/07 Date

Completed by: LS Signature 18/4/07 Date

Document 3

Determination of Drug Accountability Data Record

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Research Centre

DETERMINATION OF DRUG ACCOUNTABILITY
DATA RECORD

TEST MATERIAL: PRL-7963
PROJECT IDENTIFICATION: PRL/099

SERIAL NUMBER: 111895
PAGE: 1

SERIAL NUMBER	MASS OF TEST MATERIAL	VOLUME OF WATER	SIGNED & DATED
111895	1001.1 mg	100 mL	LS 18/04/2007

Please record all equipment identifiers

ADDITIONAL COMMENTS:

SIGNED: L Stafford.

DATE: