

UCT FHS Pharmacy Manual template V1

[Study name and/or number]

Pharmacy Manual: Instructions for handling Investigational Medicinal Products (Version 1)

1. Abbreviations

CRC Clinical Research Centre
IMP Investigational medicinal product

2. Overview of IMP

2.1. The sponsor will provide the investigator with the following medication as bulk supplies:

Abbreviation	Full detail
IMP	IMP details as stated by the sponsor
Placebo for IMP	Placebo of IMP details as stated by the sponsor

2.2. Brief description of IMP handling and storage.

2.3. Brief description of placebo for IMP handling and storage.

3. Blinding

The trial is double blind; participants, sponsor, investigators and site staff responsible for performing assessments will remain blind from randomisation until database lock. The only un-blinded personnel (as indicated on the delegation log) will be:

- The study pharmacist(s)
- An un-blinded monitor
- The statistician who generates the randomization schedule.

The study pharmacist(s) will have no other clinical or regulatory responsibilities associated with the conduct of the study. The randomization schedule will be provided to the study pharmacist(s) in a sealed tamper-proof envelope by an un-blinded statistician not involved in analysis. Access to the randomization schedule during the study will be provided only to the study pharmacist(s) and the un-blinded monitor responsible for monitoring the study drug. The randomization schedule and all pharmacy source documents and dose preparation records that could link a

Pharmacy Manual Template

Ying-Ying Zheng



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