

Pharmaceutical
Research Centre

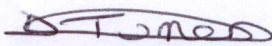
STANDARD OPERATING PROCEDURE

8 RECEIPT AND LOGGING OF TEST MATERIAL

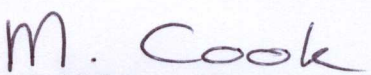
VERSION 2

REASON FOR REVISION: Updated Procedure

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DATE: 15.07.2006

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HEAD OF DISPENSARY

DATE: 2/8/06

1 SUMMARY

This SOP details the procedure to be used for receipt and logging in of test materials from sponsors.

2 RESPONSIBILITIES

- 2.1 Receipt of test materials at the front desk may be undertaken by any trained member of the Administration or Security staff.
- 2.2 Receipt of test materials in the dispensary may be undertaken by any trained member of the Dispensary staff.

3 PROCEDURES FOR RECEIPT OF TEST MATERIALS

- 3.1 On receipt of the test material at the front desk, check the package details against the courier's delivery document to ensure correct package received, before signing for acceptance and informing the addressee of the arrival of the package.
- 3.2 On receipt of the test material into the dispensary, open the package and check the container labels against the sample shipment document to ensure correct test material received.
- 3.3 Check the physical appearance (e.g. yellow powder), the test material identification number and the batch number(s) against the sample shipment document. If any of these do not match with the documentation, contact the Head of Dispensary to clarify the situation.
- 3.4 Complete a test material record of use form (Appendix 1) to include the test material identification, batch number, physical appearance, storage conditions, expiry date, date of receipt and amount received.
- 3.5 Prepare a Pharmaceutical Research Centre test material label for each primary container using the PRCLabel program including: test material identification (name and number), batch number, storage conditions, expiry date, date of receipt, gross weight, net weight and hazard category. Affix label(s) to primary container(s), without obscuring

the original label. Store the test material under the required conditions.

- 3.6 Inform the Study Director and the Sponsor contact that the material has arrived safely.
- 3.7 File the record of use form and the accompanying documentation in the relevant test material file.

APPENDIX 1 TEST MATERIAL RECORD OF USE



TEST MATERIAL USAGE RECORD

TEST MATERIAL:

SERIAL NUMBER:

DATE RECEIVED:

EXPIRY DATE:

STORAGE CONDITIONS (please circle):

AMBIENT

+ 4°C

- 20°C

SILICA GEL

DARK

N₂

BATCH NUMBER:

HAZARD CATEGORY:

GROSS WEIGHT (g):

NET WEIGHT (g):

Please check all the above information to verify the correct test material details

APPEARANCE OF TEST MATERIAL & CONTAINER

APPEARANCE OF TEST MATERIAL:

DESCRIPTION OF THE CONTAINER:

DATE	INITIAL WEIGHT(g)	SIGNED	FINAL WEIGHT(g)	SIGNED	USED FOR