## 1. COMPILATION AND AUTHORISATION

| Action | Designated Person | Signature | Date |
|---|---|---|---|
| Author | L. Scholtz | | 20-02-2017 |
| Peer Reviewed | Antoinette Fick | | 20-02-2017 |
| QA review | L. Scholtz | | 20-02-2017 |
| Approved | R. Hayeshi | | 28-02-2017 |

## 2. DISTRIBUTION

| Designation |
|---|
| QA Manager |
| Head: Vivarium |
| Bio analytical Facility Co-ordinator |
| Laser Based Facility Co-ordinator |
| Formulation Facility Co-ordinator |
| Study Director(s) |


Controlled Document
Cancelled 21-02-2017
Uncontrolled copy
Superceded on 21-02-207

## 3. POLICY ANN OBJECTIVE

According to the OECD guidelines, GLP stipulate that all documents generated within the GLP Quality Management System are consistently accurate, legible, correct and complete.
The objective of this procedure is to define standard practices for completing Quality Management System documents.

## 4. SCOPE

All documents created as part of the Quality Management System of the PCDDP. This includes, but not exclusive to SOPs, Forms, GLP Study Plans, Laboratory books, Log sheets, etc.

Uncontrolled copy
Superceded on 21-02-2017

## 5. REFERENCE DOCUMENTS

OECD series on Principles of GLP

SOP_All_Prep 1: Preparation and labelling of materials, reagent and solutions

## 6. ABBREVIATIONS AND/OR DEFINITIONS

| Abbreviation | Description |
|---|---|
| DST | Department of Science and Technology |
| GLP | Good Laboratory Practices |
| N/A | Not applicable |
| NWU | North-West University |
| OECD | Organisation for Economic Co-operation and Development |
| QA | Quality Assurance |
| SOP | Standard Operating Procedure |
| PCDDP | Preclinical Drug Development Platform |

## 7. RESPONSIBILITIES

Responsible for this SOP : QA Manager

7.1. Technologists, Laboratory assistants, Study personnel, students and Animal care takers:

- Comply with this procedure

7.2. Facility Heads and Co-ordinators, Study Director

- Comply with this procedure, and ensure compliance with this procedure by other staff in the facility.

7.3. QA Unit

- Ensure compliance with this procedure

## 8. TEST PRINCIPLE

N/A

## 9. MATERIALS AND EQUIPMENT

N/A

Uncontrolled copy
Superceded on 21-02-2017

## 10. SAFETY

N/A

## 11. PROCEDURES

### 11.1. Numbering and sequence

- When a document has a unique number, as stipulated by an SOP, the number must be on the document itself and all relating documents.
- Ensure that all parts of the document are traceable to the unique document number by indicating the number on all pages and by listing attachments/ addendums and number of pages per attachment.

### 11.2. Attachments

- Attachments to documents should be numbered with an unique consecutive number as stipulated by the document related SOP.
- Attachments to documents must cross-reference the document number.
- Documents must cross-reference attachment and attachment number.
- All pages of the attachment must be traceable through page numbering of the attachment (written in, initials and dated if necessary). and numbering with Page X of Y

### 11.3. Authorisation by signature

- Ensure that the document and all attachments are signed off and dated by the appropriate authorities before implementation, use and archiving.

### 11.4. Initials and signatures

- Initials or signatures may be used on documents, defined by the relevant SOP.
- Both initials and signature of an individual must remain consistent throughout documents.

- Only those authorized to sign particular documents may do so
- If official delegation is officially documented in personnel documents, a delegate may sign 'pp' for the signatory, provided they have been trained in the procedure and that this training is documented.
- Pre- or post-dating signatures is unacceptable.

Uncontrolled copy
Superceded on 21-02-2017

### 11.5. Cancellation of incomplete documents

- Cancelled documents may not be destroyed.
- Cancelled documents should be marked through with a line (top left to bottom right), marked "Cancelled", annotate with reasons, sign and dated and file as usual in the document system.
- Cancelled documents are retained along with valid documents.

### 11.6. Unique GLP study numbers

11.6.1. Documents

- All documents, forms, log sheets used in or related to a GLP study, must be labelled with the unique GLP study number.

11.6.2. Test and reference samples

- All test and reference samples used in a GLP study will be in addition to the information stipulated by the SOP_All_Prep 1: Preparation and labelling of materials, reagent and solutions, be labelled with the unique study number.

11.6.2. Animal cages

- All animal cages containing animals used in a GLP study, must be labelled with the unique GLP study number.

### 11.7. Copies of documents

- Unless specified otherwise by an SOP, photocopied documents should be stamped as "Copy" and signed and dated by the person making the copy.

### 11.8. Ink colour of pens

- On filled-in documents use only black ballpoint to ensure sufficient resolution and resistance to water. Pencil or erasable ink in not acceptable. Tip-ex not allowed.
- On labels, permanent black felt-tipped markers may be used.

### 11.9. Date and Time format

- Date format is DD/MM/YYYY or DD-MM-YYYY. There must be two digits for both day and month.
- Time is entered in 24h format, e.g. 14h45.

Uncontrolled copy
Superceded on 21-02-2017

### 11.10. Units of Measure

- SI units are used: m, cm, kg, g, L, ml, not ounces, inches, feet or gallons.
- Use a space between the number and the unit of measure.

### 11.11. Significant figures and rounding

- Specifications and Test methods will indicate the number of significant digits required.
- Unless otherwise specified, the first non-significant digit is rounded up if greater than or equal to 0.5.
- If significant digits are not stipulated, two decimal digits are the norm.

### 11.12. Timing of entries

- Entries, signatures and dates should be made at the time each action is taken, not retrospectively.
- Entries must be made directly into the required book, document or form. They may not be made on scraps of paper or post-it notes and transferred onto official documentation later.

### 11.13. Fields

- Stay within the boundary of the field for entries. Do not use margins (except in the case of annotations or corrections).
- Fields on completed standard forms must not be left blank. If data is not required in a particular field, the field must be marked "N/A" (not applicable) or crossed through, signed and dated. Cross through from top left to bottom right to prevent the possibility of retrospective addition of writing on the top left corner of the crossed-out area.
- Do not use ditto marks.
- If the space in a field is not enough, an annotation may be given and entry continued in the margin, bottom of page or back of the page.

### 11.14. Calculations

- All calculations performed must be shown in the document.
- All calculations must be checked by a second person.
- Both compiler and checker must sign and date the calculation form.

Uncontrolled copy
Superceded on 21-02-2017

### 11.15. Corrections

- If an error is made while filling in a document, draw a single straight line through the error, enter the correction, provide a reason, initial and date the change. Ensure that the original entry remains legible. Overwriting and tippex are not acceptable; nor is pre-dating of corrections.
- If corrections are required on an already-signed-off document, complete the change as outlined above, and, in addition, obtain countersignatures from the final document signatories.

## 12. DOCUMENTS and ARCHIVES

None

## 13. ADDENDUM

None

## 14. DOCUMENT HISTORY

| Date | Issue no | Reason for revision |
|---|---|---|
| 02-07-2013 | Draft 1 | First issue of SOP based on initial process |
| 04-10-2013 | 1 | First SOP issued |
| 20-02-2014 | 2 | Addition of Test Procedure |
| 23-06-2014 | 3 | Training Removed |
| 27-02-2017 | 4 | SOP review and new template |