L-Università ta' Malta

STANDARD OPERATING PROCEDURE

SOP NUMBER	SOP TITLE
PHR-002-01	**GOOD LABORATORY PRACTICE**

PART 1

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PART 2

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Approver **Mr Pierre Micallef** Lab Manager - Research Support Services Directorate	

PART 3

Authorizer **Mr Simon Sammut** University Secretary - Office of the Secretary Rectorate	**Date of Issue:** **Date of next revision:**

PART 4 (To be filled in by OOS, QSU or RSSD)

☐ This procedure has been revised and is no longer valid as from: (Write date)	☐ Date of NEXT REVISION is extended until: (Max. 4 years)	☐ SOP rendered obsolete on: (Write date)

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1. Reason for revision

1.1. Change of SOP/PD/102-03 to the current harmonised University template.

2. Purpose and scope

2.1. This Standard Operating Procedure (SOP) applies to the staff and students of the Department of Pharmacy to follow the Good Laboratory Practice (GLP) guidelines implemented for the laboratories of the Department of Pharmacy, University of Malta.

2.2. To define the Good Laboratory Practice guidelines adopted for the laboratories of the Department of Pharmacy, University of Malta.

3. Definitions

3.1. **Activity:** One of the many different procedures that can be carried out within the laboratories of the Department of Pharmacy for example: particular study, experiment, practical session or calibration of an instrument.

3.2. **Archive:** An indexed collection of historical records and out of date documentation.

3.3. **Bio-hazardous:** Substances that may cause disease in other living organisms or cause significant impact to the environment or community. Includes certain types of recombinant DNA, bacteria and viruses infectious to humans, animals and plants and also biologically active agents such as toxins, allergens and venom.

3.4. **Good Laboratory Practice (GLP):** A quality system originally concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. Such a quality system can still be applied for laboratories in an academic setting.

3.5. **Personnel:** Refers to staff and student members making use of the laboratory.

3.6. **Protocol:** The method which has to be followed for a particular activity to be carried out.

3.7. **Reference substance:** Any article that is used to provide a basis for comparison with a test substance.

3.8. **Standard Operating Procedure (SOP):** A set of written instructions that document an activity.

3.9. **Test Substance:** A subject of a study or experiment.

4. Responsibilities

4.1. The student, demonstrator and laboratory officer as appropriate, are responsible for following this SOP.

4.2. The Laboratory Officer is responsible for ensuring that this SOP is followed.

5. Health and Safety Requirements

5.1. Refer to SOP PHR-001-01 (Health and Safety in the Laboratory).

5.2. No specific precautions needed.

6. Procedure

6.1. **Facilities**
(Applicable to Laboratory Officer/s)

6.1.1. Ensure that test facility is of suitable size and location to meet the requirements of the activities that are carried out and to minimise any disturbances.

6.1.2. Ensure that test facility has areas for the isolation of substances or organisms which are suspected to be bio-hazardous.

6.1.3. Ensure that suitable storage areas are available for supplies and equipment and that these areas provide protection against infestation, contamination and deterioration.

6.1.4. Ensure that separate laboratory space is available for the performance of routine and specialised procedures that may be required by an activity.

6.1.5. Ensure that the facility has provisions to regulate environmental conditions such as temperature and humidity.

6.1.6. Ensure that adequate archive facilities are present to provide secure storage and retrieval of out of date documentation and to protect contents from untimely deterioration.

6.1.7. Collect, store and dispose of waste appropriately so as not to interfere with the integrity of an activity.

6.2. **Personnel**
(Applicable to Laboratory Officer/s)

6.2.1. Ensure that each individual engaged in the conduct of or if responsible for the supervision of an activity has an educational background, training and experience to enable each individual to perform the assigned functions.

6.2.2. Ensure that there is a sufficient number of personnel for the proper conduct of each activity as stated by its protocol.

6.2.3. Ensure that personnel take necessary personal health precautions designed to avoid contamination of test and reference substances.

6.2.4. Ensure that individuals engaged in an activity wear appropriate clothing for the duties they are to perform.

6.2.5. Report any medical condition/s that may be considered to have an adverse effect on an activity.

6.2.6. Ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions.

6.3. **Equipment, Materials and Reagents**
(Applicable to Laboratory Officer/s)

6.3.1. Ensure that the equipment used in the generation, measurement or assessment of data is suitably located, of appropriate design and of adequate capacity to function according to the activities that are being carried out.

6.3.2. Periodically inspect, clean, maintain and calibrate the equipment according to each equipment's SOP and ensure that records of such activities are maintained in each respective equipment logbook.

6.3.3. Ensure that the equipment and other materials present do not interfere with test systems.

6.3.4. Label chemicals, reagents and solutions with:

- Identity
- Concentration and Purity (if applicable)
- Hazard posed
- Expiry date
- Storage instructions
- Source
- Preparation date
- Stability

6.4. **Test and Reference Substances**
(Applicable to Demonstrator/s and/or student/s)

6.4.1. Determine the identity, strength, purity and composition which define the test and reference substance and ensure that these are documented.

6.4.2. Label each storage container for the test and reference substance with name, code number, batch number, expiry date and storage conditions.

6.4.3. Be aware of the stability of the test and reference substance under storage conditions for all studies.

6.5. **Standard Operating Procedures**
(Applicable to Laboratory Officer/s)

6.5.1. Ensure that the test facility has a set of approved and revised SOPs.

6.5.2. Review each SOP every 4 years from its date of approval or before if deemed necessary.

6.5.3. Ensure that personnel have access to the appropriate SOPs for use during their activity and also comply with the instructions given in these documents.

6.5.4. Ensure that SOPs, manuals, published text books, analytical methods and articles relative to the activities that are being undertaken are available.

6.5.5. Ensure that the latest authorised copy of each SOP is available in each laboratory.

6.5.6. Justify, document and acknowledge any deviations from an SOP.

7. References

7.1. Organisation for Economic Co-operation and Development. OECD Principles of Good Laboratory Practice. Paris: OECD Publications; 1998.

7.2. Seiler JP. Good Laboratory Practice – the Why and the How, 2nd edn. EU: Springer-Verlag Berlin Heidelberg; 2005.

7.3. Special Programme for Research and Training in Tropical Diseases. Handbook: Good Laboratory Practice (GLP): Quality Practices for Regulated Non-clinical Research and Development. 2nd Edn. Geneva: World Health Organization; 2010.

7.4. Akyar I. GLP: Good Laboratory Practice. In: Eldin AB (ed.) *Modern Approaches to Quality Control.* London: InTech; 2011.

7.5. Zhou M. Introduction, Objectives, and Key Requirements for GLP Regulations. *Regulated Bioanalytical Laboratories.* New Jersey: Wiley; 2011.

7.6. Bornstein-Forst S. Establishing Good Laboratory Practice at Small Colleges and Universities. *J Microbiol Biol Educ.* 2017; 18(1).

8. List of Appendices/Worksheets

8.1. Appendix 1: Flow Chart - Facilities
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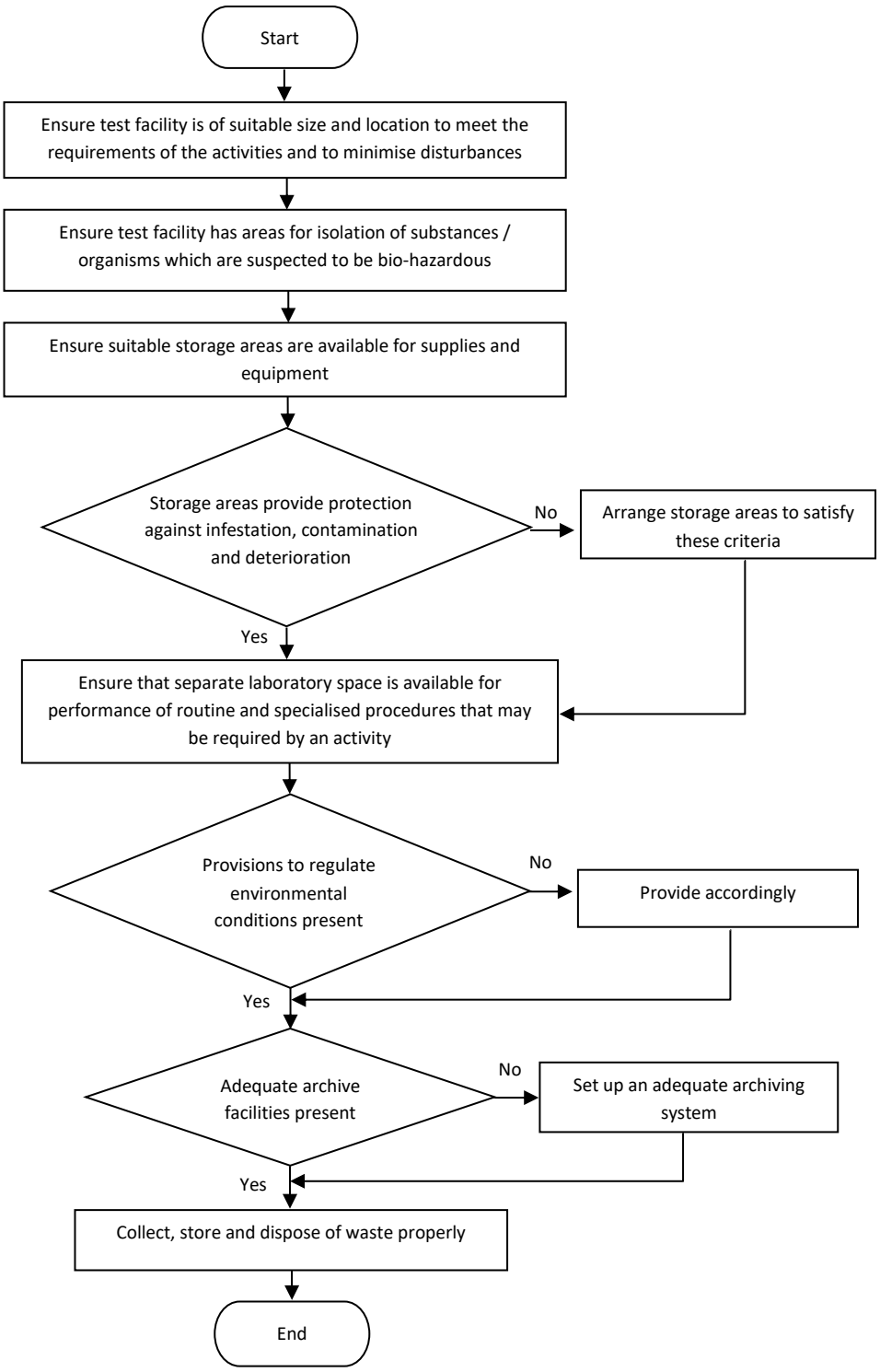
APPENDIX 1

FLOW CHART - FACILITIES



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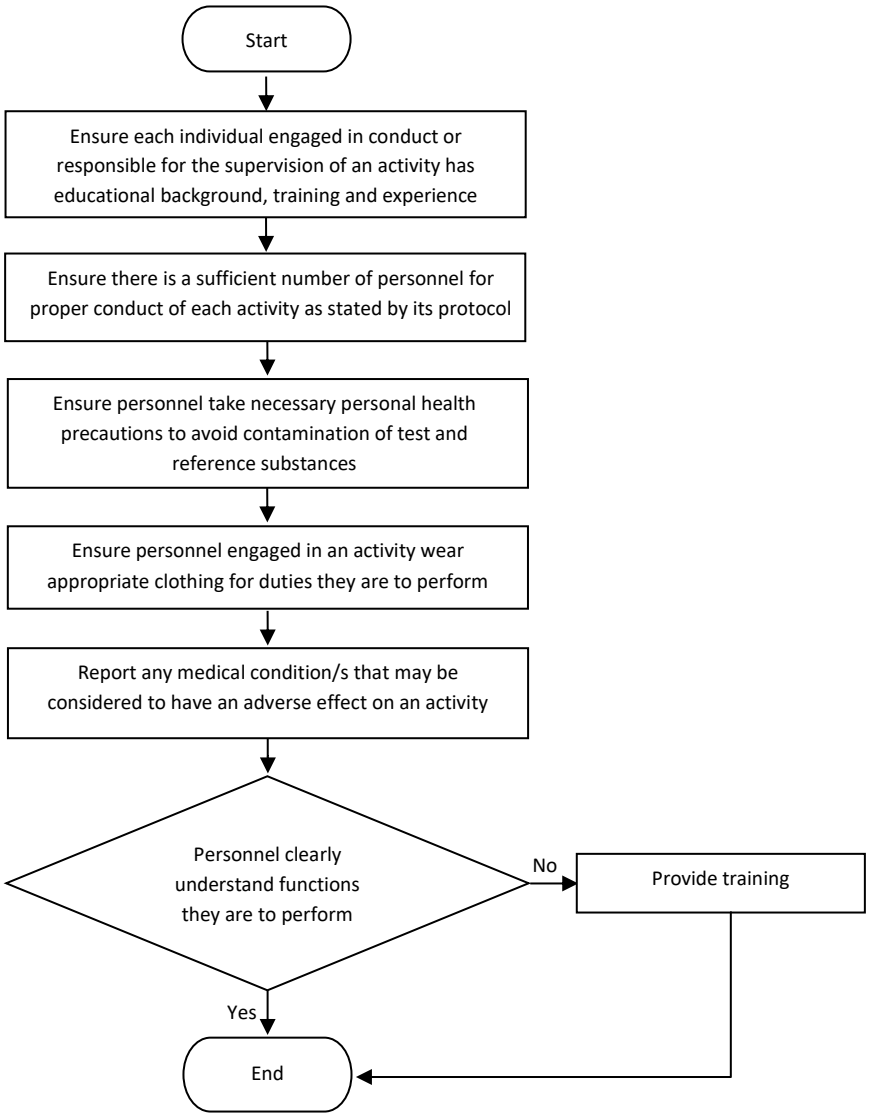
APPENDIX 2

FLOW CHART - PERSONNEL



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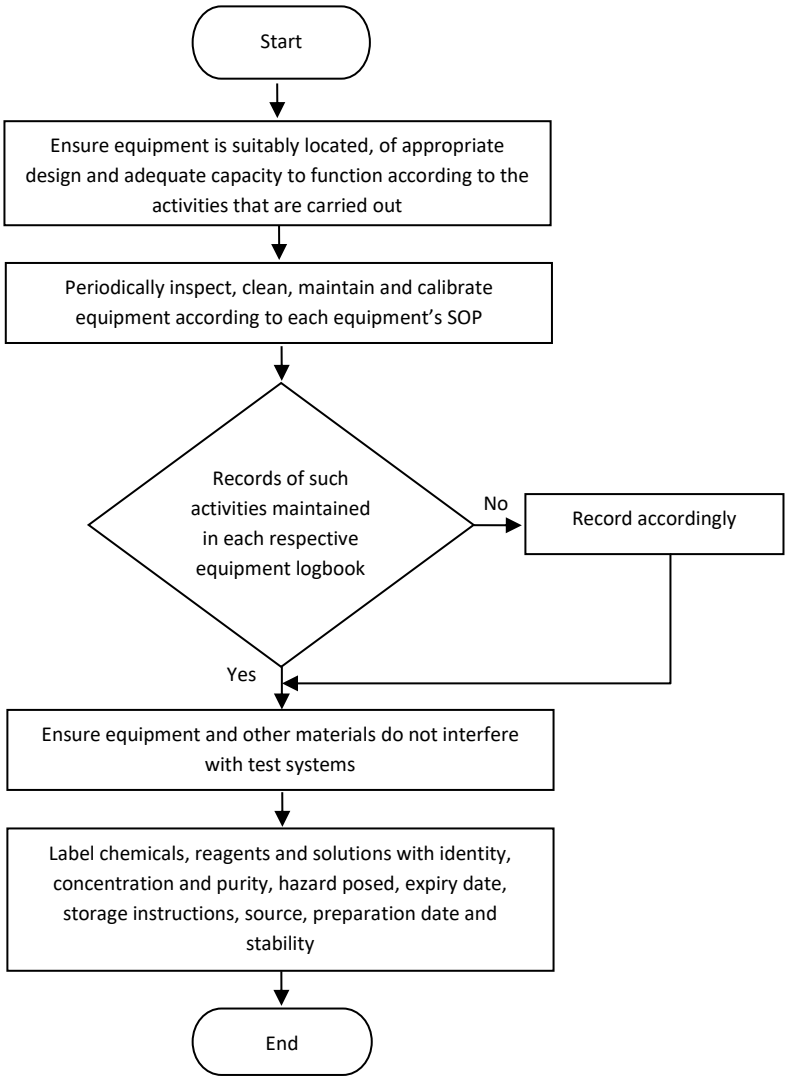
APPENDIX 3

FLOW CHART - EQUIPMENT, MATERIALS AND REAGENTS



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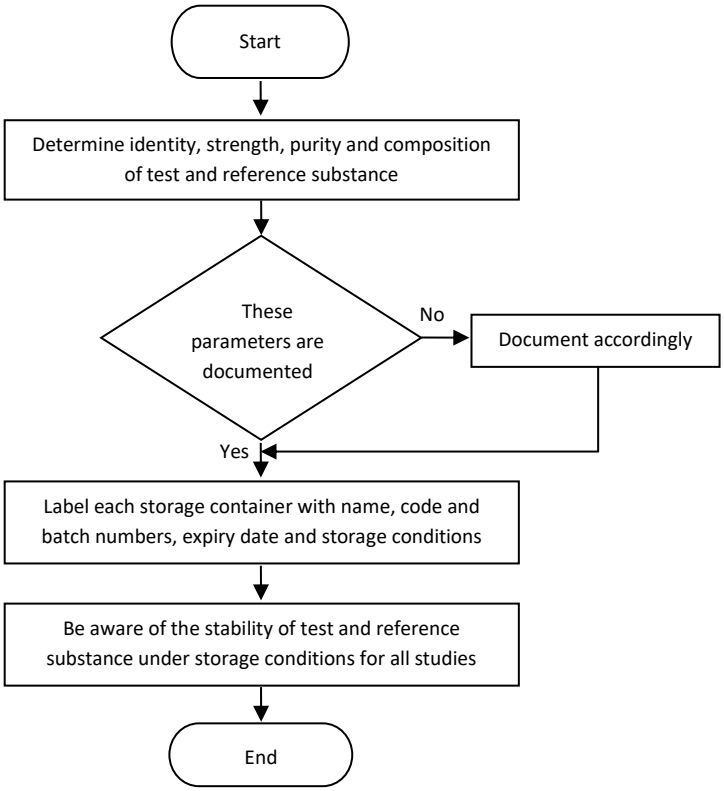
APPENDIX 4

FLOW CHART - TEST AND REFERENCE SUBSTANCES



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APPENDIX 5

FLOW CHART - STANDARD OPERATING PROCEDURES