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Signature/Date: 25/10/10

Reviewed by: Francesca White
Signature/Date: 27/10/10

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1. **Scope**

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

2. **Objective**

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

3. **Definitions**

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

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 **Archive:** An indexed collection of historical records and out of date documentation.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. **Reference substance:** Any article that is used to provide a basis for comparison with the test substance.

3.5. **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. However, such a quality system can still be applied for laboratories in an academic setting.

3.6. **Personnel:** Refers to staff and student members making use of the laboratory.
3.7. **Protocol**: The method which has to be followed for a particular activity to be carried out.

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

3.9. **Test Substance**: The article that is the subject of the study or experiment.

4. **Responsibility**

   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. **Procedure**

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

   5.1.1. 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.

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

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

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

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

   5.1.6. 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.

   5.1.7 Collect, store and dispose of waste appropriately so as not to interfere with the integrity of an activity.
5.2. Personnel  
(Applicable to Laboratory Officer/s)

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

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

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

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

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

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

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

5.3.1. 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 carried out.

5.3.2. 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.

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

5.3.4. Label chemicals, reagents and solutions with:

5.3.4.1. Identity
5.3.4.2. Concentration and Purity (if applicable)
5.3.4.3. Hazard posed
5.3.4.4. Expiry date
5.3.4.5. Storage instructions
5.3.4.6. Source
5.3.4.7. Preparation date
5.3.4.8. Stability

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

5.4.1. Determine the identity, strength, purity and composition which define the test and reference substance and ensure that these are documented.
5.4.2. Label each storage container for the test and reference substance with name, code number, batch number, expiry date and storage conditions.
5.4.3. Be aware of the stability of the test and reference substance under storage conditions for all studies.

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

5.5.1. Ensure that the test facility has a set of approved and revised SOPs.
5.5.2. Review each SOP every 2 years from its date of approval or before if deemed necessary.
5.5.3. Ensure that the personnel have access to the appropriate SOPs for use during their activity and also to comply with the instructions given in these documents.
5.5.4. Ensure that SOPs, manuals, published text books, analytical methods and articles relative to the activities that are being undertaken are available.
5.5.5. Ensure that the latest authorised copy of each SOP is available in each laboratory.
5.5.6. Justify, document and acknowledge any deviations from an SOP.
5.6. Flow Chart

5.6.1 Facilities

Start

Ensure test facility is of suitable size and location to meet the requirements of the activities and to minimise disturbances

Ensure test facility has areas for isolation of substances / organisms which are suspected to be bio-hazardous

Ensure suitable storage areas are available for supplies and equipment

Storage areas provide protection against infestation, contamination and deterioration

Arrange storage areas to satisfy these criteria

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

Provisions to regulate environmental conditions present

Provide accordingly

Yes

No

Adequate archive facilities present

Set up an adequate archiving system

Yes

No

Collect, store and dispose of waste properly

End

Yes
5.6.2 Personnel

Start

Ensure each individual engaged in conduct or responsible for the supervision of an activity has educational background, training and experience

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

Ensure personnel take necessary personal health precautions to avoid contamination of test and reference substances

Ensure personnel engaged in an activity wear appropriate clothing for duties they are to perform

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

Personnel clearly understand functions they are to perform

Provide training

End
5.6.3 Equipment, Materials and Reagents

Start

Ensure equipment is suitably located, of appropriate design and adequate capacity to function according to the activities that are carried out

Periodically inspect, clean, maintain and calibrate equipment according to each equipment’s SOP

Records of such activities maintained in each respective equipment logbook

Yes

Ensure equipment and other materials do not interfere with test systems

Label chemicals, reagents and solutions with identity, concentration and purity, hazard posed, expiry date, storage instructions, source, preparation date and stability

End

No

Record accordingly
5.6.4 Test and Reference Substances

Start

Determine identity, strength, purity and composition of test and reference substance

These parameters documented

No

Document accordingly

Yes

Label each storage container with name, code and batch numbers, expiry date and storage conditions

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

End
5.6.5 Standard Operating Procedures

Start

Set of approved and revised SOPs present

Yes

Review each SOP every 2 years from its date of approval or before, if deemed necessary

No

Compile SOP set

Personnel have access to the SOPs during an activity

Yes

Provide access

No

Ensure personnel comply with the instructions given in SOPs

Yes

No

SOPs, manuals, published text books, analytical methods and articles, relative to an activity, present

Provide accordingly

No

Latest authorised copy of each SOP available in each laboratory

Make available

Yes

Yes

Justify, document and acknowledge any deviations from an SOP

End
6. Precautions

N/A

7. References


8. Appendices

N/A

9. Revision History

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