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Revision History

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1. **Scope**

This Standard Operating Procedure (SOP) provides the Good Laboratory Practice (GLP) guidelines to be followed in the laboratories of the Pharmacy Department, University of Malta.

2. **Objective**

To ensure that GLP guidelines are followed by the laboratories personnel and students using of the laboratory.

3. **Definitions**

3.1 **Good Laboratory Practice**: Embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users can be assessed for pharmaceuticals.

3.2 **Batch**: A specific quantity or lot of a test, control or reference substance.

3.3 **Control substance**: Any chemical substance or mixture or any other material other than a test substance feed or water that is administered to the test system in the course of a study. It is used to establish a basis for comparison with the test substance for chemical or biological measurements.

3.4 **Reference substance**: Any chemical substance or mixture, analytical standard or material other than a test substance feed or water that is administered to or used in analysing the test system. It is used to establish a basis for comparison with the test substance for known chemical or biological measurements.

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

3.6 **Activity**: This could be a study, experiment, practical, calibration of an instrument, or preparation of standard solutions.
4. Responsibility

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

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

5. Procedure

5.1 Facilities
(Applicable to the Laboratory Officer)

5.1.1 Ensure that the test facility is of suitable size and location to meet the requirements of your activity and to minimise any disturbances that could interfere with the validity of the activity.

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

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

5.1.4 Provide separate laboratory space and other space for the performance of the routine and specialised procedures required by an activity.

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

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

5.1.7 Allow an authorised employee to inspect facility and records of all specimen required to be maintained for the activity.

5.1.8 Inspect, clean and maintain equipment adequately.
5.2 Personnel  
(Applicable to the Laboratory Officer)

5.2.1 Ensure that each individual engaged in the conduct of or responsible for the supervision of an activity has education, 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 the activity as stated by the protocol.

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

5.2.4 Ensure that personnel engaged in the activity wear clothing appropriate for the duties they perform.

5.2.5 Report any health or medical conditions that may be considered to have an adverse effect on the activity.

5.2.6 Ensure that personnel clearly understand the functions they are to perform.

5.3 Apparatus, Materials and Reagents  
(Applicable to the Laboratory Officer)

5.3.1 Ensure that apparatus and materials do not interfere with test systems.

5.3.2 Label chemicals, reagents and solutions with:
   5.3.2.1 Identity
   5.3.2.2 Concentration
   5.3.2.3 Expiry date
   5.3.2.4 Storage instructions
   5.3.2.5 Source
   5.3.2.6 Preparation date
   5.3.2.7 Stability

5.4 Equipment  
(Applicable to Demonstrators and Students)

5.4.1 Ensure that the equipment used in the generation, measurement or assessment of data is of appropriate design and adequate capacity to function according to the study protocol.

5.4.2 Test, calibrate and standardise equipment used for the generation, measurement or assessment of date.
5.4.3 Always follow the SOP for each equipment present in the laboratory before initiating a study.

5.5 Test, Control and Reference Substances  
(Applicable to the Demonstrator and Students)

5.5.1 Determine the identity, strength, purity and composition which define the test, control or reference substance. Ensure they are documented.
5.5.2 Label each storage container for test, control, or reference substance by name, code number, batch number, expiry date and storage conditions.
5.5.3 Know the stability of test, control and reference substances under storage conditions for all studies.

5.6 Standard Operating Procedures  
(Applicable to the Laboratory Officer)

5.6.1 Ensure that the test facility has a set of approved and revised SOPs, so that the data generated is of good quality and integrity.
5.6.2 Ensure that manuals and SOPs relative to the laboratory or study being undertaken are available.
5.6.3 Ensure that the latest version of authorised copy of the SOP is available in the appropriate laboratory.
5.6.4 Justify, document and acknowledge any deviations from SOPs.

6 Precautions

Not applicable.

7 References
