

Good Bio-Medical Laboratory Practice

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Editorial

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Editorial

In 1972, New Zealand formally introduced Good Laboratory Practice (GLP) as the Testing Laboratory Registration Act. Good Laboratory Practice is a quality management system; it is not a scientific management system. GLP based on fundamentals of scientific principles and practices are indispensable for providing scientific confidence in studies conducted for Pharmacological safety & testing [1].

Good Laboratory Practice is a set of principles intended to assure the quality and integrity of non-clinical laboratory testing that are intended to support research & marketing permits for products regulated by government agencies. GLP or good laboratory practices are accepted methods to carry out procedures or operations in a laboratory. The laboratory management say that these practices help ensure safety, accuracy, consistency, high quality, reliability and reproducibility. They have a positive influence on the quality of the results [2].

Good Laboratory Practice applies to non-clinical studies conducted for the assessment of the credibility and traceability of data, safety or potency of chemicals (including pharmaceuticals) to man, animals and the environment [3]. Good Laboratory Practice, a data quality system, should not be confused with standards for laboratory safety - appropriate gloves, glasses & clothing to handle lab materials safely. The principles of Good Laboratory Practice aim to ensure and promote safety, consistency, high quality, and reliability of chemicals in the process of non-clinical and laboratory testing. Good Bio-Medical Laboratory Practice is not limited to Chemicals & Pharmaceuticals also applies to medical devices, food additives, food packaging, additives,

ingredients and other non-pharmaceutical products or active pharmaceutical ingredients (API).

Learning Objectives of Practical

Aims

To provide opportunities for lab workers (new comers; students) to learn, develop and practice in laboratory:

- The complication of the scientific method and experimental design.
- Improve problem-solving skills.
- Generic biological practical skills (e.g. weighing, preparing solutions, Pipetting).
- Skills in observation, measurement, appreciation of variability, concern for precision, data handling skills: analysis, presentation and interpretation.
- Oral and written communication skills: report writing and presentations.
- An appreciation of safety in the laboratory.
- Pharmaco-chemical specific practical skills.
- Concept of Methodology – re-enforcing existing and gaining new knowledge.

Objectives

- To be able to follow a written schedule in a laboratory setting over a range of methodologies and to know and able to observe appropriate safety measures to ensure safe working.
- To be able to prepare accurately appropriate solution of drugs, to administer required doses and to achieve required concentrations in in vivo and in vitro situations.
- To have prepare the apparatus and solutions for the set up at least two different isolated preparations.

- To have determine responses to agonist and antagonist drug administration.
- To have determined the relationship between concentration and response for an agonist.
- To have demonstrated and measured drug selectively.
- To have experience methods of data gatherings, data validation, data analysis and data interpretation.
- To understand and able to demonstrate principles of good experimental design.

Precautions for Laboratory Personnel

Following are Laboratory Practices

- Access the laboratory must be restricted to authorized person only.
- Staff and students must wear laboratory coat and remove it before leaving the laboratory.
- Keep laboratory clean and tidy and retain only necessary items.
- Do not store food and personal items in the laboratory, especially in the refrigerator.
- Eating, drinking, smoking and applying cosmetics are prohibited in the laboratory.
- Wear gloves while collecting and handling specimens and remove before leaving the work place.
- Do not touch your own skin, mucus membrane, electric switch door knobs, registers etc. with gloved hand.
- Wash hand with soap and water, before leaving the laboratory.
- Use plastic wear instead of glass wear, if possible.
- Use containers with secured lids for transportation and storage.
- Never pipette by mouth.
- Prevent formation of aerosols or splashing of materials.
- Autoclave contaminated laboratory coats, before sending them to the laundry.
- All accidental exposure must be reported immediately to supervisor.
- Consider all specimens as potentially infectious (blood and body fluids may be infectious)
- Put used tips, tubes, vials etc. in a glass beaker containing bleach solution for few hours or overnight before disposal.
- Any spillage of contaminated waste or reusable materials must be appropriately decontaminated by bleach solution before disposal or reuse.

- All work surfaces must be appropriately decontaminated with bleach solution, at the end of working day.
- Most widely used chlorine releasing disinfectants are:
 - a. Calcium Hypochlorite (Bleaching powder or Chlorinated lime)
 - b. Sodium Hypochlorite (Liquid Bleach)
 - c. Sodium Dichloroisocyanurate (NaDCC Tablet)
- Chlorine solution must be prepared fresh (At least daily) and protected.
- Autoclaves contaminated materials and then bury it in a land fill site or send for incineration.

Precautions

- Avoid needle stick injuries.
- Take care when collecting blood.
- Do not recap, bend, break or remove needles from disposable syringes.
- Dispose all needles & lancets in secured (Puncture-proof) Containers, located as close as possible to where they are to be used and then handle as infected materials.

Last but not the least, Good laboratory practices are guidelines; they have not the force of law. We also refer to good laboratory practice is part of the quality management that ensures that concern consistently produce goods and control to a high quality test results and the Importance of Standard Operating Procedures [4].

References

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