Good Bio-Medical Laboratory Practice

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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 Pharmaco-chemical 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 gathering, 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 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