Good Laboratory Practices (GLP) for Pharmaceuticals

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Purpose of GLP principles

- To promote the development of quality test data
- Obtain reliable and reproducible data
- Obtain comparable data between countries
- Achieve international confidence in study data
- Avoid repition of studies
- Enable reconstruction of studies
- Optimise animal conditions
- Shorten the registration time of the drug

Good Laboratory Practices (GLP) for Pharmaceuticals and other Quality Control Laboratories.

Quality Control Laboratory Photo

- Good Laboratory Practices (GLP) was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978. It was followed a few years later by the Organization for Economic Co-operation and Development (OECD) Principles of GLP in 1992 & the OECD has since helped promote GLP to many countries.
- GLP is not only limited to chemicals but also it applies to medical devices, food additives, food packaging, colour additives and other non-pharmaceutical products or ingredients as well.

What is Good Laboratory Practice (GLP) :

- Good Laboratory Practice contains a set of principles that provides a framework within which laboratory studies (Activities) are planned, performed, monitored, recorded, reported and archived. GLP help assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be confidence upon when marking risk/safety assessment.

Why GLP is Important in Pharmaceuticals :

- Good Laboratory Practice contains different principles which are designed to ensure and promote consistency, quality, safety, reliability and integrity of chemicals during non-clinical and laboratory testing.
- **Basic Rules of GLP :**
- 1. Make sure to have the correct written instructions before starting a task.
  2. Do not carry out task for which you have not been trained.
  3. Keep records of information, results and actions taken. Make clear accurate records of what was done.
- 4.Check that the instrument/ equipment/material used are clean, calibrated and correct ones as per procedure.
- 5. Always notify if labels are seen either detached or appear to incorrect or are in wrong place.
  6. Never remove a label which has been incorrectly applied and never stick a new label over an old one of the same type. If label is incorrectly affixed strike it off, sign and paste new correct label adjacent to it
- 7. Clean the glassware drying oven, refrigerator, walk in chamber incubators, water bath of the instruments like dissolution tester, disintegration testers etc, used in the quality control laboratory as per the procedure.
- 8. Clean the work benches after completion of work or at the end of the day whichever is earlier and keep the respective specification, General test procedure (GTP), Standard test Procedure (SOP's) etc used back to the designated place.
  9. While closing the Quality Control Laboratory, ensure that all water taps, instruments (which are not running), equipments, computers are put 'OFF'. Put off the lights, AC's and closes the department.

Premises and Utilities :

1. Maintain the laboratory and its premises clean.
- 2. Keep work benches of laboratories clean and tidy all the time.
- 3. Keep the samples, standards, laboratory reagent, apparatus, accessories and records at adequate and suitable storage space.
- 4. For analytical preparation wherever water is to be used, use purified water for chromatographic analysis like HPLC, GC, etc. use HPLC grade water or water generated by Milli-Q system.
- 5. The utilities like compressed air, vaccum required for the functioning of laboratory should have identification mark.
- 6. Maintain temperature and humidity record as per respective procedure wherever applicable.
- 7. Follow the procedure in case access control system is to be followed where restricted entry is necessary .
- 8. In case of hazardous and poisonous materials, keep it at adequate storage area/facility with lock and key to avoid misuse. Also keep reserve sample, stability sample, laboratory standards in lock and key.
- 9. Use eye washer, water shower, first aid kit etc. in case of emergency which may arise during operation & Always identify the location of emergency exit in the laboratory for exit during emergency

Personnel :

- 1. All personnel prior to employment should be periodically re-examined for medical fitness. The Quality Control Manager should ensure that the personnel are medically fit to carry out the job.
  2. Personnel suffering from an infectious disease or having open lesion on the exposed surface of the body should not engage in activities that could results in compromising the quality of analysis.
  3. All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.
  4. The job responsibility should be assigned according to competency of the person and it should be timely revised for addition or deletion of responsibilities assigned previously.

  5. Smoking, eating, drinking,chilling or keeping plants, food,drinks and personnel medicine should not be permitted in laboratories area, where they might adversely influence the product quality.

Personnel :

- 6. Personnel should wear clean clothing (company uniform)suitable for activity with which they are involved and this clothing should be changed when appropriate. Personnel should strictly follow entry/exit and gowning procedure.
  7. While handling hazardous chemicals and while performing sterility, microbiological analysis, procedure of change of clothing and use of personnel protective equipment's and safety appliances should be strictly followed.

  8. Never handle any chemicals, raw materials intermediate & finished, unpacked product with bare hands. Always use the appropriate hand gloves while handling the same.

Training :

- 1. Training should be regularly conducted by qualified individuals and should cover, at a minimum, the particular operation that the employee performs. Training should be given on both the theory and practice of the work being undertaken in a particular area, as well as relevant ‘on-job’ training.
- 2. Records of training must be maintained. Training should be periodically accessed. All staff, including new staff and existing staff should be given basic training on Good Laboratory Practices during induction and at regular intervals subsequently. This training programme should be periodically updated.

Instruments / Equipments / Accessories :

- 1. The analytical instrument shall be house in dust free environment and whenever required, conditions of temperature and humidity shall be maintained at periodic checks of temperature and humidity be made and recorded.
- 2. All instruments / Equipments shall be qualified properly through IQ, OQ and PQ activities after receive in the laboratory.
- 3. Instruments requiring calibration shall be calibrated at regular intervals and records of such calibration or maintenance be maintained and there shall be written instruction in the form of Standard operating procedures for the operation.
- . Other equipment / accessory such as burette, pipette, volumetric flask, weight boxes, thermometers, etc, shall be thoroughly checked for accuracy of calibration before acceptance for use.
- 5. Computerized systems should have sufficient controls to prevent unauthorized access or changes to data. Software should not be left opened and unattended to avoid misuse. After use, save the data and close all operating system properly and then switch off the computer system.
- 6. Water from instrument / equipment (e.g. Dissolution, DT, Sonicators, etc.) should be changed regularly. When Instrument / equipment is not in use for longer period (e.g. breakdown) water should be removed and the instrument /equipment kept dry.

Validation / Verification of Analytical Methods :

- 1. A written protocol should be established that specifies how Validation /Verification will be conducted. The protocol should be reviewed, approved and authorized by the designated authorities.
- 2. A Validation / Verification report should be prepared, summarizing the results obtained, and drawing the appropriate conclusions, including recommendation for changes if any, based on the study.

Testing and Reporting :

- Sampling should be done in accordance with approved written procedure
- Sampling staff should trained for sampling activity and should have the knowledge of the nature of the samples to be handled and should refer respective specifications for the same
- Sampled containers should be adequately labelled and should have information for traceability

Testing and Reporting :

- There should be written procedure for testing materials and products at different stage of manufacture, describing the methods and instruments / equipments to be used
- There should be written procedure for testing materials and products at different stage of manufacture, describing the methods and instruments / equipments to be used & Specification should be available for every product / item .
- Testing should be done as per approved specification. The results obtained should be checked for compliance against specification. All calculations should be checked. The records of testing should be maintained.
- Use clean spatulas or butter papers for transferring and weighing samples .
- Attach all relevant analytical raw data obtained from instruments such as Analytical Balances, High Performance Liquid Chromatograph, Gas Chromatograph, UV-Spectrophotometer, IR-Spectrophotometer, Polarimeter, Refractometer, Potentiometer, Bulk Density Apparatus, to the record of analysis / calculation sheet.
- In case of analysis of temperature sensitive material stored at 2-8°C or in freezer (between -25°C to -10°C) .
- During analysis, if any abnormal or unexpected event or out of specification results occurs, address the same using a Incident Report or out of specification report & analysts shall report all Incidents and OOS to the Supervisor or Quality Control Manager as soon as possible.

Stability Studies :

- Stability studies should be carried out to obtain evidence on how the quality of a drug substance or drug product varies with time under the influence of factors such as temperature, humidity and light and enables establishment of recommended storage conditions, retest periods or shelf life for drug substances or drug products.
- A schedule should be designed to monitor the stability of each product .
- Out ofspecification or significant a typical trends should be investigated. Product failures should be promptly reported to technical head, regulatory affairs, R and D, quality assurance and customer, (if applicable), for necessary action. The possible impact on the batches distributed in the market should be considered.
- Asummary of data generated should be written and maintained. This summary should be subjected to periodic review.

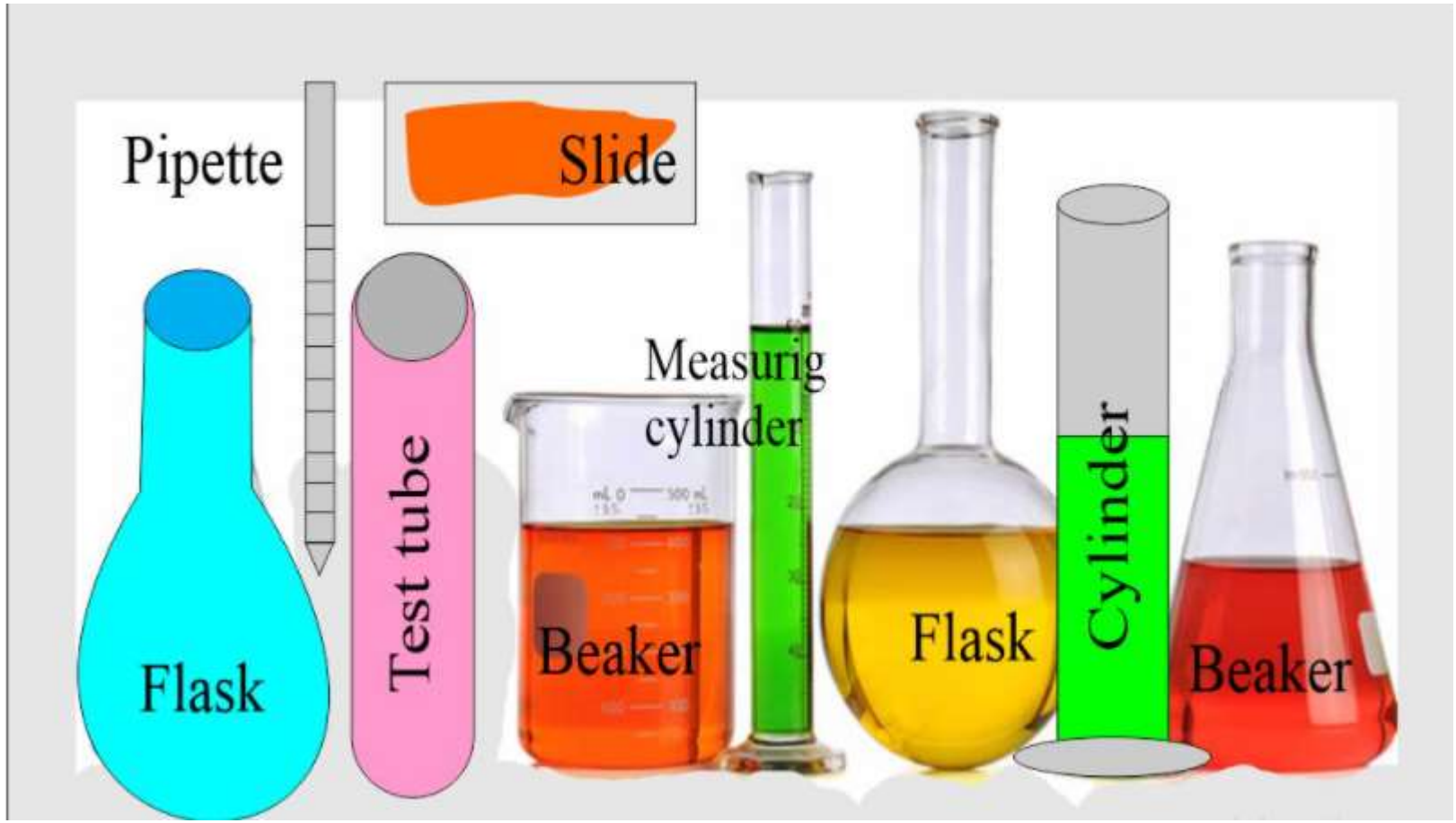
Stability Chember

Chemicals , Reagents, Glassware and Analytical Standards :

- ll reagents and solutions in the laboratory shall be properly identified with a label. Validity should be provided as appropriate for analytical reagents or standard solutions prepared and should be indicated on label together with specific storage conditions.
- Check the validity period of chemicals before use & standards and solutions should be labelled
- All the solutions, solvents dispensed and solvent waste collected in vessel / beaker should be covered entirely with appropriate cover.
- The glassware should be examined before use for cleanliness and damage; do not use cracked, chipped or any other defective glassware.

CHEMICALS & REAGENTS

VARIOUS TYPES OF LABORATORY GLASSWARE :



Documentation :

- Specifications, instructions, procedures and records must be free from errors and available in writing.
- Documents should be approved, sign and dated by appropriate and authorized persons.
- Records should be made or completed at the time each action is taken and in such a way that all significant activities are traceable.
- Good Documentation practices should be followed during entire documentation.

Results of Not following GLP in Laboratory

- Accident/Incident & Health Hazards
- Wrong/error in volume or weight measurement which may leads to wrong results.
- May leads to Instrument errors/Malfunctions
- Contamination of sample, reagent & solvent which may affect the product quality to be tested.
- Waste of time due to investigation of unexpected cause.
- Increase cost due to repetition & investigation
- Due to wrong result it may affect patient safety.
- Regulatory agency may take action results in warning letter, import alert etc.
- No evidence or documented proof of data generated

Conclusion :

- Everyone makes mistakes that's why GLP is needed. GLP principles are a good idea even if you are not required to follow the standards. There are some simple rules such as : Say What You Do (with written standard operating procedures), do what you say (follow the procedures), be able to prove it (with good record keeping).
- The principles of good laboratory practice (GLP) is to support the development of quality and validity of test data used for determining the safety of chemicals and chemicals product.
- Hence GLP aims to decrease the occurrence of mistakes or mix-ups through large and specific labelling requirements.
- So every analyst those who are working in Quality control or in other testing laboratory should follow GLP.


Certification of laboratory facilities
QA
Certificati on of analysts
Instrumen tation validation
Elements of GLP
Specimen/ sample-tracking
Statistical procedures
Documen tation & its record
Reagent/ materials certificatio n
Account ability.


Thank you