PAPER- 9

PHARMA REGULATORY AFFAIRS

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UNIT-I.

Long Essay Questions:

Write an Essay on GLP: Good laboratory Practices

→ It is defined as the set of rules, Procedures and practices given in an organisation / Industry / laboratory in order to ensure the Quality, Safety, purity & Efficacy

- It was given by USFDA on Nov 19, 1976.

Purpose of GLP Guidelines:

1) To promote the development of Quality
2) To Avoid repetition of studies
3) Obtain reliable & reproducible Data
4) Ensure each & every step is valid (or) not
5) Assure the Quality & integrity

Objectives:

1) Adopt good & safe Operating procedures
2) prevent Errors of Humans & equipments
3) prevent unsafe & Hazadrous acts
4) Improve Efficiency of the Job
5) Ensure the data submitted is its digital form

GLP Principles

(1) Test Facility organization and personnel.

- The individual person should have knowledge on the GLP.
- They must follow the study plan and appropriate SOPs
- They must have more knowledge and they are responsible for the Quality of their data
- They must exercise Healthy precacations & minimize risks, to ensure the integrity of study

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2) Quality Assurance programme
The QA personnal must have the following responsibilities
1) Accessthe updated study plans and SOP's
2) Documented verification for the study plan
3) Inspection of the plan
4) Repost the inspection reports

3) Facilities
1) Suitable size, Construction & location
2) Adequate separation of different types of activities performed in the lab
3) Isolation of test systems to prevent the Biological Hazards
4) Separate storage rooms
5) Separate washing areas & ancillary areas.

4) Apparatus, Materials and Reagents:
1) Apparatus of appropriate design and adequate Capacity must be selected
2) Calibration, cleaning and maintaince of Equipment must be documented
3) chemicals, reagents and solutions should be labelled to indicate identity, Expiry date and storage conditions

5) Test systems:
1) proper identification of Test syetems
2) Maintaing records for source, date of arrival of the test systems
3) proper cleaning & sanitization

6) Test & Reference Items:
1) Test and reference items should be characterized and stored separately
2) performance of reference items must be tested to check its stability

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7) SOP's:

1) SOP is the written procedure for laboratory programme

2) They define how to carry out the activity as per the Guideliner

3) They are written in chronological oder with simple & understandable manner

8) Performance of the Study:

1) The study is Conducted and the performance is checked by testing aganist reference sample

2) All the test procedures must be recorded

9) Reporting of study results:

1) After performing the tests, the results are submitted to QA personnel

2) The report must include description of materials, test methods & results.

10) Storage & retention of records & Materials:

1) All the study plans, raw data, Sampling data, Inspection data, SOP's, master formula records must be maintained

2) If any material is disposed before the expiry, the reason should be Justified and documented.

2) Why are reserve samples maintained?

Reserve Sample:

Reserve sample is said to be a representation of the lot of the drug product.

The reserve sample must be atleast two times of the necessary quantity required to perform all the tests to determine whether the API (or) drug product meets its specifications

- The reserve samples can be also called as retention samples.
- They must be stored in the same container in which it is marketed.

Reserve samples are maintained in the pharmaceutical industry for several important reasons

1) Regulatory requirements

Regulatory bodies such as FDA require pharmaceutical manufacturers to retain reserve samples as a part of GMP these samples serves as evidence of the quality and composition of the product at the time of its release

2) Quality control and Analysis

Reserve samples acts as a reference (or) control for future use in case of product quality (or) stability issues. these can be used for additional testing (or) analysis to investigate any complaints (or) deviations (or) unexpected results that may arise during product life-cycle

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3) Stability studies: Reserve samples are crucial for conducting stability studies to determine the long-term quality and shelf-life of pharmaceutical products.
The samples are stored under controlled conditions, & monitored various physical, chemical and microbiological properties to ensure its safety & efficacy

4) Post-Market surveillance: During product recall (or) adverse reactions, reserve samples provides an opportunity for analysis & investigation these samples were examined to determine any quality related issues and also helps to identify solutions and preventive measures

5) Analytical Method validation: Reserve samples serve as a reference standard for validation of Analytical methods used in quality control testing. By comparing the results obtained from testing new batches with the reserve samples, the accuracy, precision can be determined.

6) Intellectual Property protection:
In some cases, where the pharmaceutical product is patented, reserve samples can serve as a evidence of the product's formula, composition and quality. This Helps to protect the Intellectual property rights of the manufacturer and provides legal support

in case of any infringement (copying)

7) Records: Reserve samples serves as a record of product's manufacturing and quality control process. They act as a reference for future audits, inspections and evaluations.

It is essential to store the reserve samples as per the guidelines given by the regulatory authorities

The Guidelines include

- ✓ Sample size
- ✓ Storage Conditions
- ✓ Labelling
- ✓ Documentation
- ✓ Retention period.

State the contents of SOP on Handling the rejected materials:

SOP: standard operating procedure

It is the written procedure for any process that is followed during the operation of any system (or) Equipment

SOP is the Heart of Quality system.

- It ensures product quality and patient safety
- The main importance of SOP is to maintain pharmaceutical Quality management system (PQMS).

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The SOP's on Handling the rejected materials that are proved to be unsuitable for Consumer use due to various reasons may vary from Industry to Industry.

The common contents Include

1) Purpose / Objective: clearly state the purpose for the SOP to establish a standardized set of Guidelines for proper handling of the rejected materials with respect to the regulatory requirements in a Efficient Manner

2) Scope: Define the scope of the SOP by mentioning the rejected materials,

- The rejected materials may include damaged goods, defective products, Expired products etc

3) Responsibilities:

Mention the role and responsibilities of the personnel involved in Handling the rejected materials

- It may include Quality Control team, production team and ware Housing Team

4) Reason for Rejection

- Define the reason, why that product is considered rejected.
- It should include quality standards, regulatory requirements, safety precautions and other relevant factors.

Segregation

5) Material Identification and segregation:
- This involves identification of the rejected materials and segregate them based on their specific characteristics to avoid unintentional mixing and cross-contamination.
- This involves labelling, tagging (or) physically seperating the rejected materials

6) Documentation:
- proper documentation is essential for record-keeping purposes.
- The SOP should specify the information, that is required to be recorded, such as rejection, quantity, Batch/lot Number, date and any relevant observations
- It should also define appropriate forms that are used for documentation.

7) Disposal:
- It must include the appropriate process for disposal of the rejected materials.
- This may include return to supplier, recycling, scrap (or) any other approved methods
- It should also specify who has the authority to make decision regarding the disposal.

8) Corrective and preventive Actions: (CAPA)
- It should include the steps to be taken to investigate the root cause for the rejection and Implement corrective and preventive actions (CAPA) to avoid the occurence in the future.

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9) Training:

- Proper training should be given to the employees regarding the handling of these rejected materials.
- SOP must include any specified training requirements and methods for documenting the training activities.
- The SOP should include the roles and responsibilities of the personnel involved in handling the rejected materials.

10) Review & Approval:

- The SOP should include a section detailing the review and approval process
- It should provide a list of relavant references such as Industrial standards, regulatory requirements, that are applicable during handling of the rejected materials.
- These may include Quality control procedures, inspections, rejection forms (or) any other relavant materials.

Short #1

SHORT QUESTIONS.

Write about certificate of Analysis (COA)

The certificate of analysis is a document that provides detailed information about the purity, quality and characteristics of a specified products.

- It serves as a tool for Quality assurance and commonly used in various industries including pharmaceuticals, food, cosmetics etc
- COA contains results obtained by testing done in Quality control of an individual batch.

purpose:

1) the primary purpose of CoA is to provide accurate data about the product's characteristics and test results of:
   - ✓ Raw materials
   - ✓ API
   - ✓ Finished products

2) It assures the consumers, that the product meets established standards and is safe to use

Contents: COA includes:

a) product Details: Name, batch/lot Number, manufacturing date, expiration data and product description.

b) manufacturer Information: Name, address, Contact details of the Company that manufactured that product

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c) Test Methods: It includes list of the tests performed on the products.
d) Results: All the test results and the acceptance criteria is mentioned
e) Reference standards: It includes information of the reference materials that are used in the testing process.
f) Analytical Equipment: Includes details of the equipment utilized for the analysis
g) Date of Analysis: The date when the tests are conducted is mentioned
h) Signature: Signature of the authorized personnel who is responsible for conducting the tests should be done for approving the CoA

Key Elements:

a) Identity: Confirms products identity, including its name batch/lot Number and description
b) Purity and Composition: Specifies the purity levels and Composition of product, including the presence of impurities & Contaminants
c) Strength & potency: Determines the products strength (or) potency of the pharmaceutical products.
d) Physical characterstics: Describes physical properties such as appearance, odor, colour and solubility
e) Microbiological Testing: Indicates the absence/ presence of Harmful micro-organisms, especially

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in food, beverages and pharmaceuticals.

t) Stability: Evaluates the product stability, including its resistance to degradation (or) changes under specific conditions.

write about Generating STP:

STP: Standard Testing procedure

STP plays a critical role in the pharmaceutical Industry by ensuring the quality, safety, and efficacy of the pharmaceutical products.

- STP provides a systematic and standardized approach for testing various aspects of the pharmaceutical products, including raw materials, in-process products and Finished products.

The steps involved in generating STP's are as follows:

① Identifying Testing Requirement:

The 1st step in generating STP is to identify the specific testing requirements for the pharmaceutical product.

- Factors such as Identity, purity, potency, safety, stability and characteristics of the products are considered for defining a specific testing procedure.

② Test parameters & Acceptance criteria:

The next step is to identify & define the test parameters and establish appropriate acceptance criteria.

- the test parameters should include physical, chemical, biological and microbiological tests.

- Acceptance criteria for the above tests should be based on the pharmacopoeial standards / monographs and regulatory specifications.

③ Develop testing procedure:

- The development of testing procedure should include step-by-step detailed description of the test to be performed.
- The description should include materials, equipments, reagents, sampling methods, analytical techniques etc

④ Method validation:

Before implementing the STP, it is essential to validate the testing methods to ensure the accuracy, precision, specificity.

- Method validation includes conducting a series of experiments to demonstrate that the method is suitable for the purpose
- Validation parameters include linearity, accuracy, precision, limit of detection, limit of quantification etc

⑤ Documentation:

- All the generated STP's should be documented in a clear, consize and comprehensive manner
- The documentation should include purpose of the test, step-by-step instructions, safety precautions, calculations and reference standards

⑥ Review & Approval:

The generated STP's should undergo a thorough review by experts such as scientists, quality assurance and regulatory affairs professionals.

- The review ensures that the STPs meet the regulatory requirements and then approved and Implemented.

⑦ Training:

After approval, training should be given for the laboratory personnel to understand the procedures, techniques and safety precautions of STP's.

Write about the principles of GLP.

(1st Essay)