Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy
Pharmacy Department
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Lecture 9

Laboratory Controls

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Outlines

- Laboratory Controls Requirements
- Laboratory Animals
- Stability Testing
- Container Materials Testing

Learning Outcomes

At the end of this chapter, you will be able to:

1. Explain GMP requirements for laboratory controls.
2. Describe the role and documentation requirements of laboratory animals in pharmaceutical testing and experimentation.
3. Differentiate between the three types of stability.
4. Evaluate testing requirements and limitations of pharmaceutical container materials, such as glass and plastics, in maintaining product quality.

Laboratory Controls Requirements

In the laboratory, **data integrity** starts with sampling, transporting the sample to the laboratory, and sample management in the laboratory. The lab control requirements:

1. Testing environment
2. Laboratory logistics
3. Method development and validation
4. Sampling plans and processes
5. Laboratory equipment qualification, calibration, and standardization
6. Laboratory errors, deviations, and investigations associated with methods, analysts, or instruments
7. Test performance and records

Laboratory Animals

Record requirements for animals are necessary to maintain control of their use in experimentation, testing, or assay procedures. Data fields for individual animals should include:

1. Identification number or letter assigned to each animal or group of animals
2. Characteristics and description of the animal
3. Source of animals (breeder, vendor)
4. Date of arrival
5. Age at arrival

Stability Testing

Stability studies can be classified into three types:

1. **Accelerated stability studies**. Performed under stress conditions (high temperature, humidity, light, oxygen, acidity) to predict shelf life quickly.
2. **Real-time stability studies**. Done under normal storage conditions to confirm shelf-life predictions. (Used for parameters like dissolution, fragility, and sterility where accelerated studies are less reliable).
3. **Ongoing production stability studies**. Continued commercial batches to ensure consistency and detect any hidden changes in materials or process.

Container Materials Testing

Test methodology for a range of container materials:

1. **Light transmission** test for glass and plastic containers
2. **Chemical resistance** test for glass containers
3. **Physicochemical** tests for plastic containers
4. **Biological** tests for plastics and other polymers
5. **Chemical** tests for polyethylene containers

Container Materials Testing

Glass limitations:

1. **Its alkaline surface** may raise the pH of the pharmaceutical formulation and induce a chemical reaction.
2. **Ionic radicals** present in the drug may precipitate insoluble crystals from the glass.
3. The **clarity** of the glass permits the transmission of high-energy wavelengths of light, which may accelerate physical or chemical reactions in the drug.

Container Materials Testing

Plastic limitations:

1. **Migration** of the drug through the plastic into the environment.
2. **Transfer** of environmental moisture, oxygen, and other elements into the pharmaceutical formulation.
3. **Leaching** of container ingredients into the drug.
4. **Adsorption** or **absorption** of the active drug or excipients by the plastic.

Students' Presentations

References

Bunn, G. P. (Ed.). (2015). *Good manufacturing practices for pharmaceuticals* (7th ed.). John Wiley & Sons.