Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy
Pharmacy Department
Tishk International University

Lecture 7

Equipment

Dr. Louna Altrjman
Louna.altrjman@tiu.edu.iq

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Outlines

- Equipment Location
- Equipment Construction
- Equipment Cleaning
- Maintenance and Calibration Programs

Learning Outcomes

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

1. Explain GMP requirements for pharmaceutical equipment, including location, cleaning, maintenance, and calibration.
2. Identify key construction requirements for manufacturing equipment.

Equipment

Equipment used in manufacturing must be:

1. Suitable for its intended purpose.
2. Regularly cleaned.
3. Regularly maintained.
4. Regularly calibrated.

To ensure accurate and reliable performance

Equipment Location

The location of the equipment in the facility must be:

1. **Unidirectional** to enable an efficient flow of the manufacturing process. Backflow or crossflow within the process is to be minimized, as these incidents inherently have a high capability to cause mistakes.
2. Placed in an **easily accessible manner** to enable maintenance, instrumentation, and calibration. The key is easily accessible.

Equipment Construction

1. The **surfaces** into contact with components, in-process materials, or drug products shall not be reactive, additive, or absorptive**,** not to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. Stainless steel is used primarily for its inert nature and its ability to be cleaned and sterilized.

2. Any **substances required for operation**, such as lubricants or coolants, shall not be in contact with components, drug product containers, closures, in-process materials, or drug products, not to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

Equipment Cleaning

Written procedures shall be established and followed for cleaning and maintenance of equipment.

These procedures shall include, but are not necessarily limited to, the following:

1. Assignment of **responsibility** for cleaning and maintaining equipment.
2. Maintenance and cleaning **schedules**.
3. A **description** in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment.
4. **Protection** of clean equipment from contamination.
5. **Inspection** of equipment for cleanliness immediately before use.

Maintenance and Calibration Programs

Compliance programs need at least three components:

1. **Procedures** to provide instructions on what to do and how.
2. **Practices** that follow the approved procedures.
3. **Paperwork** that demonstrates that the practices were completed as per the procedures.

Students’ Presentations

References

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