Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy
Pharmacy Department
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Lecture 4

Production and Process Controls

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Outlines

- Important Definitions
- Charge-in of Components
- Calculation of Yield
- Sampling and Testing of In-process Materials and Drug Products

Learning Outcomes

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

1. Define key GMP terms related to production, including batch, lot, drug product, active ingredient, and strength.
2. Explain GMP requirements for charge-in of components, including weighing, identification, documentation, and verification procedures.
3. Calculate the percentage of theoretical yield.
4. Describe the role of in-process sampling and testing in ensuring batch uniformity, quality, and compliance during manufacturing.

Important Definitions

- **Batch:** a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- **Lot:** a batch, or a specific identified portion of a batch, that is assigned a unique identification number for traceability.
- **Lot number**, **control number**, or **batch number:** any unique combination of letters, numbers, or symbols, which shows the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

Important Definitions

- **Active ingredient** means any component that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals.

- **Drug product** means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a **placebo**.

Important Definitions

Strength means:

1. The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis).
2. The potency, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

Charge-in of Components

A. The **batch** shall be formulated with the intent to provide not less than 100% of the labeled or established amount of active ingredient.

This does **not** mean that it is required to calculate by assay the exact amount of active ingredient, per batch.

Some manufacturers may have thought that formulating a product at 98% would save them 2% on the active pharmaceutical ingredient while still producing a product that met the specification of 97% to 101% of the stated amount.

A financial incentive, not a quality focus.

Charge-in of Components

B. **Components** for drug product manufacturing shall be weighed, measured, or subdivided as appropriate.

If a component is removed from the original container to another, the new container shall be identified with the following information:

1. Component name or item code.
2. Receiving or control number.
3. Weight or measure in a new container.

Charge-in of Components

C. **Weighing**, measuring, or subdividing operations for components shall be adequately supervised.

Each container of component dispensed to manufacturing shall be examined by a second person to ensure that:

1. The component was released by the quality control unit.
2. The weight or measure is correct as stated in the batch production records.
3. The containers are properly identified.

Charge-in of Components

D. Each **component** shall be added to the batch by one person and verified by a second person.

This verification by a second person is required when the dispensing process is manual. In the case where the use of a validated, automated dispensing system is in place, a second operator check is not required.

Calculation of Yield

Theoretical yield: the maximum quantity that could be produced, based on the quantities of components assigned to a batch, assuming no loss or error in production.

As required by the **GMP regulations**, yield calculations involve reporting the following data at each appropriate phase:

1. Actual yield (kg)
2. % yield = (actual yield/theoretical starting quantity) × 100

$$\%\,\text{Yield} = \frac{\text{Actual Yield}}{\text{Theoretical Yield}} \times 100\%$$

Sampling and Testing of In-process Materials and Drug Products

To ensure batch uniformity and the integrity of drug products, **written procedures** shall be established and followed that describe the **in-process controls and tests** to be conducted on appropriate samples of in-process materials for each batch.

Such **control procedures** shall include the following, where appropriate:

1. Tablet or capsule weight variation
2. Disintegration time
3. Adequacy of mixing to assure uniformity and homogeneity
4. Dissolution time and rate
5. Clarity, completeness, or pH of solutions

Sampling and Testing of In-process Materials and Drug Products

In-process materials shall be tested for identity, strength, quality, and purity as appropriate and approved or rejected by the quality control unit during the production process.

For example, after significant phases or after storage for long periods.

References

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