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In-Process and Finished-Product Quality Control

Practical 12 - QC record practical

Aim

To prepare and interpret an in-process and finished-product quality-control panel.

Principle

In-process tests support manufacturing control; release tests assess the finished product against approved specifications. The required panel depends on dosage form, route, product and current monograph or dossier.

Materials and Requirements

- Model tablet, capsule, oral liquid and sterile-product specifications
- Supplied manufacturing and laboratory results
- Controlled sampling, test and release templates
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Map each quality attribute to its manufacturing stage, sampling plan, method and limit.
3. For tablets and capsules review mass, content, uniformity and applicable disintegration or dissolution evidence.
4. For oral liquids review identity, content, pH, delivered volume, physical uniformity and microbial controls; for sterile products add the relevant sterility, endotoxin, particulate and integrity requirements.
5. Reconcile individual results, deviations and analytical suitability before preparing a quality disposition recommendation.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Dosage form / stage	Attribute / method	Result and limit	Decision / follow-up
Tablet / capsule	Specify panel	Enter	Evaluate
Oral liquid	Specify panel	Enter	Evaluate
Sterile product	Specify panel	Enter	Evaluate

Calculations

- Percentage deviation = (observed - target)/target x 100
- A numerical average cannot substitute for a required individual-unit criterion.

Worked Example

Illustrative target tablet mass 400 mg and observed mean 404 mg differ by +1.0%.

The mass calculation does not establish content uniformity or a passing release decision; apply the separate product tests.

Result and Interpretation

• Present the full quality panel and identify any missing or unacceptable evidence.

Precautions

• Use current product-specific criteria.
• Do not infer sterility from appearance.
• Keep sampling and batch traceability.

Viva Questions and Answers

Is mass uniformity the same as content uniformity?

No; drug distribution and composition also matter.

Why test during processing?

It can identify variation before the batch is finished.

Who releases a batch?

The authorised quality function under the applicable system.

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