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Primary and Secondary Packaging Quality Control

Practical 22 - Practical study

Aim

To evaluate primary and secondary packaging against their intended protection, compatibility and information functions.

Principle

Primary packaging contacts or directly contains the product; secondary packaging supports protection, identification and distribution. Material identity, container-closure integrity and compatibility are distinct attributes.

Materials and Requirements

- Approved packaging specification and model components
- Dimension, seal, barrier or integrity data as applicable
- Label, artwork, reconciliation and transport records
- 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. Identify packaging material, supplier, component revision and intended product use.
3. Assess the specified appearance, dimensions, closure fit and mechanical properties using qualified methods.
4. Review required barrier, leak or container-closure integrity evidence and compatibility including extractables/leachables assessment where relevant.
5. Check label legibility, batch and expiry fields, storage text, coding and issued/used/rejected component reconciliation.
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.

Component / lot	Attribute and method	Result / criterion	Disposition
Primary container	Identity / dimensions	Enter	Assess
Closure / seal	Integrity test	Enter	Assess
Secondary carton	Artwork / coding	Enter	Assess

Calculations

- Unreconciled components = issued - (used + rejected + returned), using mutually exclusive documented categories

Worked Example

Illustrative 1,000 labels issued, 960 used, 25 rejected and 15 returned give zero unreconciled labels. Zero discrepancy does not establish that the artwork was correct; both checks are needed.

Result and Interpretation

- Report each component result and the evidence supporting the product-pack system.

Precautions

- Use nonoverlapping reconciliation categories.
- Do not substitute a visual check for a validated integrity method.
- Control artwork revisions.

Viva Questions and Answers

Why assess compatibility?

The product and pack can interact during storage.

What is a secondary pack?

An outer packaging level such as a carton.

Why reconcile labels?

It helps control mix-ups and unexplained component use.

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