

Good Manufacturing Practices

(PHAR 533)

Fifth Grade – Spring Semester

Faculty of Pharmacy

Pharmacy Department

Tishk International University



Lecture 8

Packaging and Labeling Control

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Outlines

- Tamper-Resistant Packaging Requirements
- Packaging Systems
- Tamper-Resistant Packaging Labeling
- Expiration Date



Learning Outcomes

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

1. Explain the concept and importance of tamper-resistant packaging.
2. Identify different packaging systems and tamper-resistant technologies used in pharmaceutical products.
3. Apply GMP requirements for tamper-resistant labeling.
4. Interpret expiration date requirements.

Tamper-Resistant Packaging

A **tamper-resistant package** has **one or more indicators or barriers to entry**, which, if breached or missing, can reasonably be expected to provide visible evidence to consumers indicating that tampering has occurred.



Tamper-Resistant Packaging Requirements

To reduce the likelihood of successful tampering and to increase the likelihood that consumers would discover whether a product has been tampered with or not, the package is required to be **distinctive by**:

1. **Design** (e.g., an aerosol product container).
2. The use of **one or more indicators or barriers** to entry.
3. The use of an **identifying characteristic** (e.g., a pattern, name, registered trademark, logo, or picture).



The term “**distinctive by design**” means the packaging cannot be duplicated with commonly available materials or through commonly available processes.

Packaging Systems

Examples of packaging technologies capable of meeting the tamper-resistant packaging requirements:

1. Blister or Strip Packs
2. Foil, Paper, or Plastic Pouches
3. Container Mouth Inner Seals



VS



Blister Pack

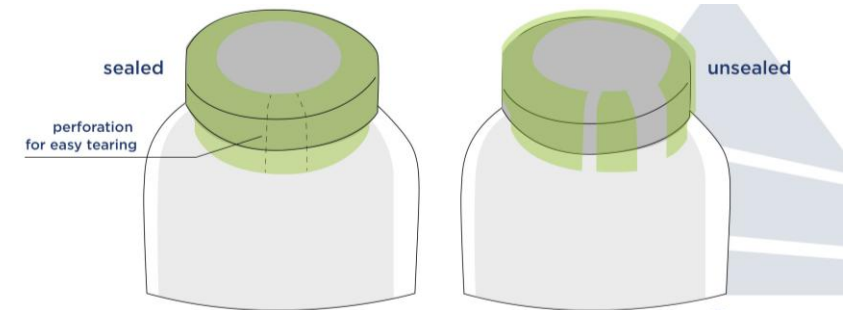
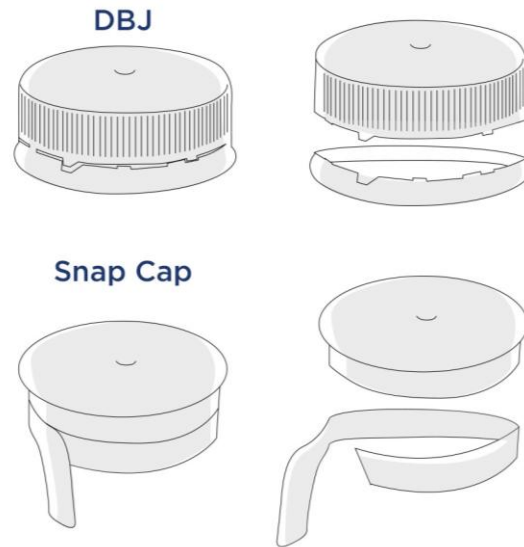
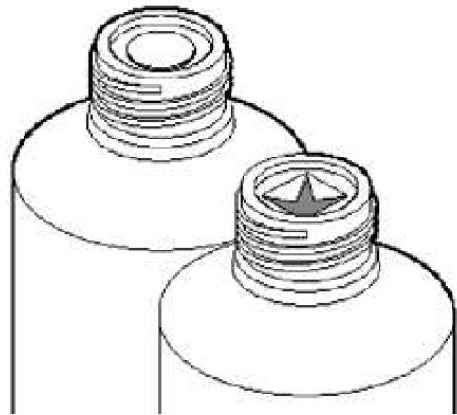
Strip Pack



Packaging Systems

Examples of packaging technologies capable of meeting the tamper-resistant packaging requirements:

- 4. Tape Seals
- 5. Breakable Caps
- 6. Sealed Metal Tubes





Tamper-Resistant Packaging Labeling

1. **Bottle caps:** Tamper-resistant warnings **should not** be placed only on bottle caps because caps can be easily replaced without showing tampering.
2. **Package inserts:** Tamper-resistant information **should not** be written only inside package inserts; it must appear on the product label.
3. **Carton and inner container:** If the tamper-resistant feature is on the outer carton, the **inner container must state** that it should be inside a carton when purchased.
4. **Identifying characteristics:** If the tamper-resistant feature has a unique mark (e.g., printed seal), this must be clearly **described on the label**.
5. **All features must be listed:** The label must mention all tamper-resistant features used (e.g., capsule seal + packaging seal).

TAMPER-EVIDENT BOTTLE
DO NOT USE IF INNER SAFETY SEAL UNDER CAP IMPRINTED WITH
"SEALED for YOUR PROTECTION" IS BROKEN OR MISSING

Drug Facts

Active ingredients (in each caplet) Purpose

Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID*)	Pain reliever
Caffeine 65 mg	Pain reliever aid

*nonsteroidal anti-inflammatory drug

Uses • temporarily relieves minor aches and pains due to:

- headache • a cold • arthritis • muscular aches
- toothache • premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening • blisters • rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives • facial swelling • asthma (wheezing) • shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take





Expiration Date

- a. Expiration dates shall **appear on labeling** to assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use determined by appropriate stability testing.
- b. Expiration dates shall be **related to any storage conditions** stated on the labeling, as determined by stability studies.
- c. If the drug product is to be **reconstituted at the time of dispensing**, its labeling shall bear **expiration information for both the reconstituted and unreconstituted** drug products.

Students' Presentations

References

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

