



Guideline for the Tamper- Evident Packaging

Version 2.0

Date of publication	27 December 2016
Date of implementation	20 May 2019



Guideline for the Tamper- Evident Packaging

Version 2.0

Drug Sector

Saudi Food & Drug Authority

Please visit SFDA's website at

http://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx

for the latest update

For inquires and comments Drug.Comments@sfda.gov.sa



Saudi Food and Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed



Document Control

Version	Author	Date	Comments
1.0	Drug Sector	27 December 2016	Draft
2.0	Executive Directorate of Regulatory Affairs	20 May 2019	This document separated from the “Guidelines on Container Closure Systems”



Table of Content

1. Introduction	6
1.1 Background	6
1.2 Scope	6
1.3 General considerations	6
2. Acceptable TEP	7
2.1 Film wrappers.....	7
2.2 Blister or strip packs.....	8
2.3 Heat shrink bands or wrappers	8
2.4 Sachet	9
2.5 Bottle mouth inner seal	10
2.6 Tape seals	11
2.7 Breakable caps.....	11
3. Recommended Labeling Statement	12
4. References:	13

1. INTRODUCTION

1.1 Background

This guidance is prepared to improve the safeguard of the pharmaceutical products available in Saudi market, which will lead the consumer to detect any visible evidence that tampering has occurred.

Definition of Tamper-Evident Packaging (TEP): Packaging having an indicator or barrier to entry, which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

1.2 Scope

This guidance is applicable to medicinal products intended for human use in Saudi Arabia.

1.3 General considerations

- The design of the packaging must contribute to preventing the tampering of certain products.
- The TEP should allow the visual inspection of the product before use.
- The visual indication is recommended to be accompanied by appropriate precautionary label statements to describe the tamper-evident feature(s) to the consumer and to warn that the absence of or damage to such feature(s) at the time of purchase is an indication of possible tampering with the product.
- TEP may involve in primary and/or secondary packaging.
- TEP must not be regarded as replacing the need for child resistant closures for bottles, since SFDA request the companies for such protection.

2. ACCEPTABLE TEP

Manufacturers are free to use any packaging included in this guidance. Packaging features must be properly designed and appropriately applied to be effective TEP.

2.1 Film Wrappers – transparent

A transparent colorless film is wrapped securely around the entire product container. The film must be cut to open the container and remove the product.

A reasonably tight "fit" of the film around the container must be achieved, e.g., by a shrink-type process.

A film wrapper sealed with overlapping end flaps must not be capable of being opened and resealed without leaving visible evidence of entry.

The film wrappers are preferably to be imprinted with identifying characteristic (such as: product name, registered or company's logo) that cannot be readily or easily duplicated and repackaged.

- Recommended label statement:
 - Do not use if film wrapper is damaged or missing.

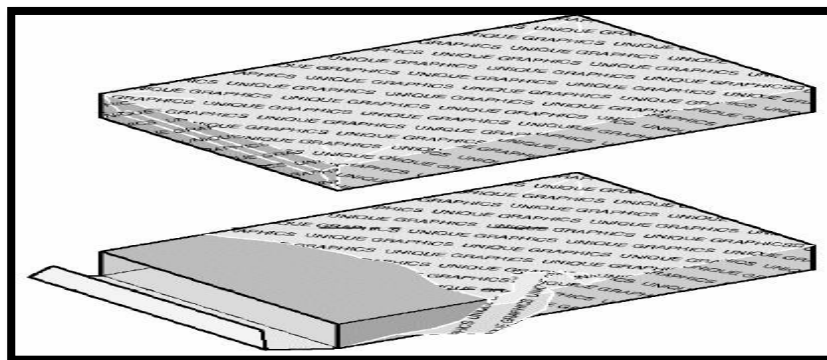


Figure 1

2.2 Blister or strip packs

Dosage units (e.g., tablets or capsules) are individually sealed in plastic or foil. The blister must be broken to take out the product.

The backing materials cannot be separated from the blisters or replaced without leaving visible evidence of entry.

- Recommended label statement:
 - Do not use if blister seal is broken or damaged.

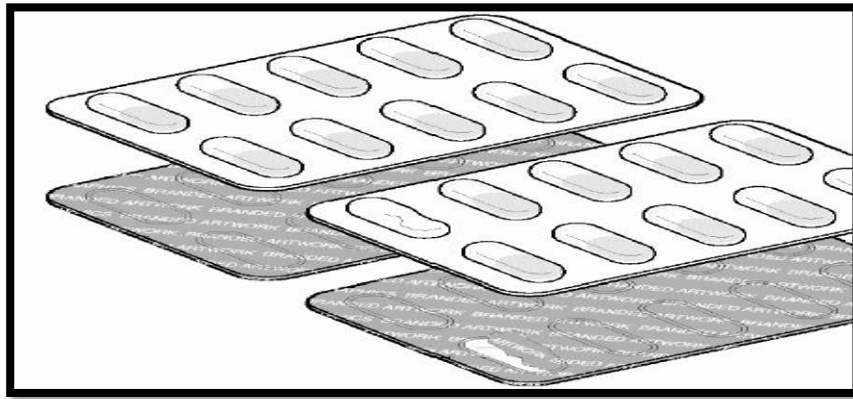


Figure 2

2.3 Heat shrink bands or wrappers

The band and wrapper must be cut in order to utilize the product.

The band or wrapper cannot easily be removed and reapplied without visible damage to the band.

Shrink bands and wrappers are preferably to be imprinted with identifying characteristic (such as: product name, registered or company's logo) and shrunk by heat to seal the union of the cap and container.

- Recommended label statements:
 - Do not use if seal around cap is broken or missing.
 - Do not use if tape around cap is damaged.
 - For your protection, this bottle has an imprinted seal around the neck.

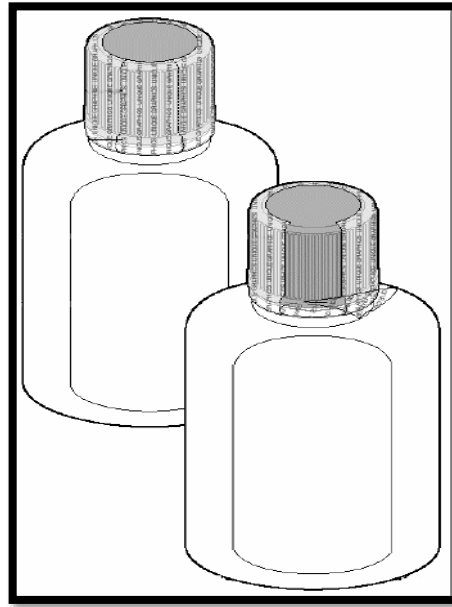


Figure 3

2.4 Sachet

The product is enclosed in an individual sachet that must be broken to obtain the product. The end seams of the pouches cannot be separated and resealed without showing visible evidence of entry.

- Recommended label statement:
 - Do not use if sachet is damaged or broken.

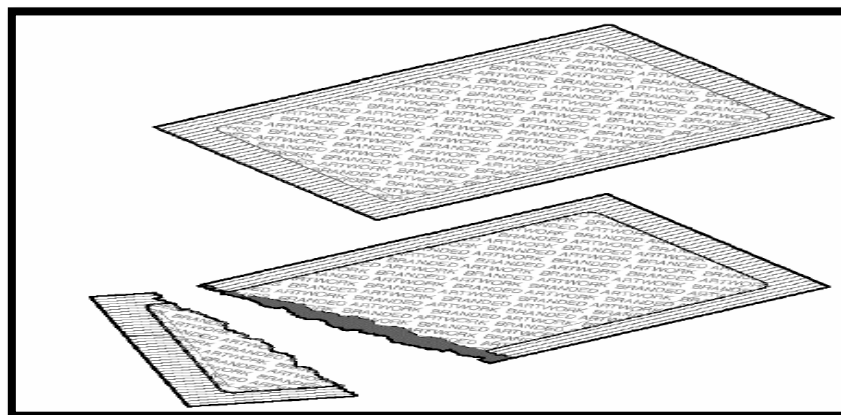


Figure 4

2.5 Bottle mouth inner seal

Paper, thermal plastic, plastic film, foil, or a combination can be used as a sealed to the mouth of the bottle under the cap.

The seal must be broken to open the container and remove the product.

The seal cannot be removed and reapplied without leaving visible evidence of entry.

Seals applied by heat induction to containers appear to offer a higher degree of tamper evidence than those that depend on an adhesive to create the bond.

The seal are preferably to be imprinted with identifying characteristic (such as: product name, registered or company's logo) that cannot be readily or easily duplicated and reapplied.

- Recommended label statements:
 - Do not use if inner foil liner is missing or broken.
 - Bottle sealed under cap for your protection.

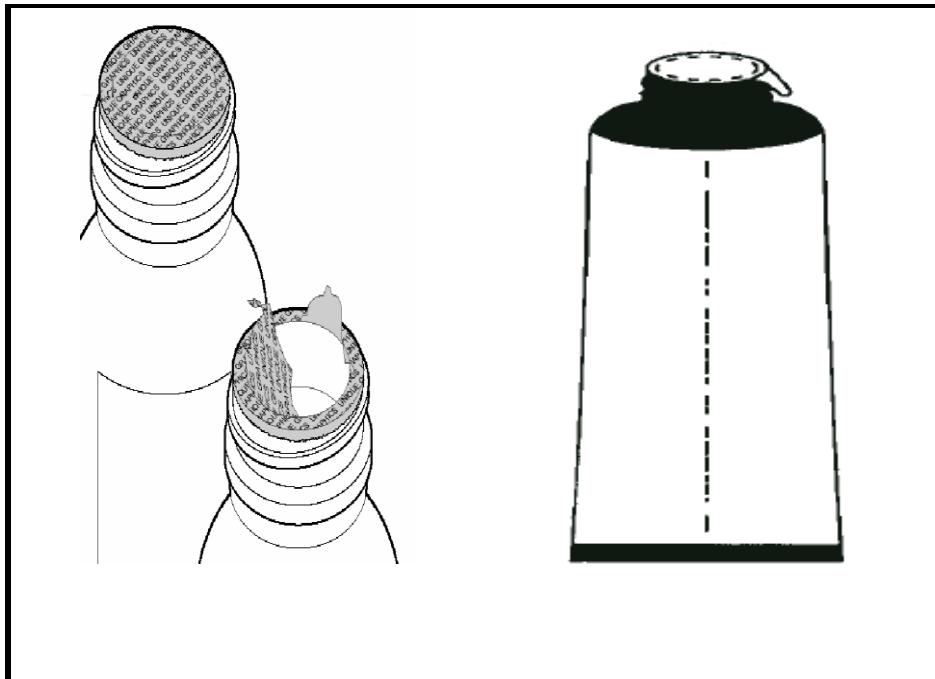


Figure 5

2.6 Tape seals

Tape seals are acceptable if they contain a feature that makes it obvious if the seals have been removed and reapplied e.g. a permanent adhesive.

The tape seal is preferably to be imprinted with identifying characteristic (such as: product name, registered or company's logo) that cannot be readily or easily duplicated.

- Recommended label statements:
 - Tape over carton flaps must be unbroken.
 - Use only if carton seal is unbroken.
 - Do not use if seals over carton ends are missing or broken.

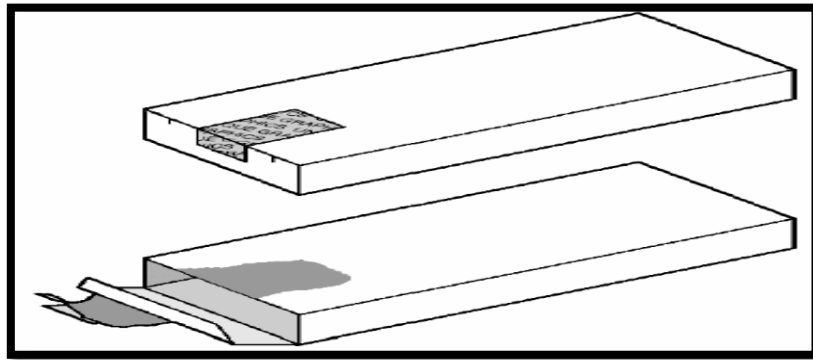


Figure 6

2.7 Breakable caps

The container (e.g. bottle) is sealed by a plastic that either breaks away completely when removed from the container or leaves part of the cap attached to the container.

The cap, or a portion thereof, must be broken in order to open the container and remove the product. Once opened or removed they cannot be repositioned.

The cap cannot be reapplied in its original state.

- Recommended label statements:
 - Use only if seal is unbroken.
 - Do not use if cap seal is broken.

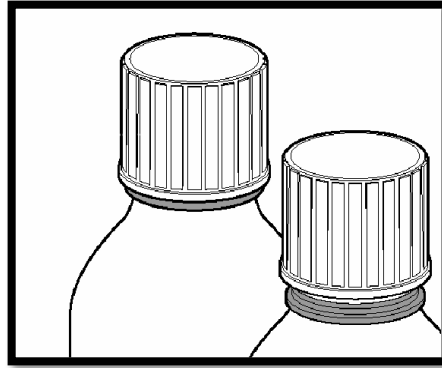


Figure 7

3. RECOMMENDED LABELING STATEMENT

The precautionary label statements should be translated into Arabic language.

The label statement is required to be:

- Displayed in a prominent place on the primary and secondary pack.
- Unaffected if a TEP feature is breached or missing
- Described the tamper evident features of the container.

If manufacturer choose to deviate from the recommended label statements included in this guidance, it is important to choose a statement that deliver the feature of the TEP.

4. REFERENCES:

- TGA Guideline for the Tamper-Evident Packaging of Medicines, Complementary Healthcare Products and Medical Devices, December 2000.
- FDA Tamper-Resistant Packaging Requirements for Certain over-the-counter Human Drug Products, January 1988.