PHARMSOL NEWS

CONTAINER CLOSURE SYSTEM SELECTION CRITERIA: CRITICAL QUALITY ATTRIBUTE FOR NON-STERILE DRUG PRODUCTS

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Container closure system encompasses all components of the packaging system that hold and protect the drug product. Selection of an appropriate container closure system for a drug product is of utmost importance since the probability of interaction of the drug product with the packaging component is highest for all dosage forms. Impingement of container closure integrity leads to compromised stability of the drug product system. The selected container closure system must be suitable for its intended use like protection, compatibility, stability, safety and performance and meet quality control requirements.

Ideal characteristics of Container closure system:

1) Containment: It is the most fundamental function of packaging for medicinal products
2) Protection: Protect the contents from environmental hazards like moisture, temperature, light, atmospheric gases, particles and microorganism, from mechanical hazards like vibration, compression, shock, abrasion etc.,
3) Presentation, Identification & Information:
It must have a pharmaceutically elegant appearance like easy to label and identify the product
4) Convenience: is associated with product use or administration

Types of Packaging system:
Primary packaging system:
It holds the material and comes directly in contact with it. It may have a direct effect on the product shelf life e.g., Blister pack, Strip pack, glass bottles, plastic bottles & pouches, film wrappers etc.
Secondary packaging system:
It is next to primary packaging and used to group primary packages together e.g., cartons, boxes, shipping containers, paper and boards etc.
Tertiary packaging system:
It is used for bulk handling and shipping e.g., corrugated box, brown cardboard box, wooden pallets etc.
Packaging selection for pharmaceutical products:
It depends upon the product types and other factors which include:
a) Packaging material compatibility with the contents of the product formulation
b) Protect the product from environmental conditions
c) It must not interact with product with impact on taste, odor and color.
d) Pack must be non-toxic, and meet the applicable tamper-resistance requirements.
e) Material of construction of components must meet the standard regulatory requirements (USFDA, EMA etc.,) and must be generally regarded as safe (GRAS).

Above factors ensure that the finished product formulation in selected packaging has appropriate seal strength and integrity to protect against microbial contamination. This is of utmost importance for long-term product success.

Bottles, Blister and strip packing are the most common form of packaging for tablets and capsules. Pouches and foil papers are used for powder or granules packing. Collapsible tubes are used for semisolid preparations.

Container: It is intended to contain a drug substance or drug product with which it is, or may be in direct contact. It can be available as single dose, multidose and light resistant containers, aerosol containers, air-tight containers

Closures: A closure is the part of the container which prevent the contents from escaping and allow no substance to enter the container.

Closures are available in five basic designs:
1. Screw on, threaded or lug
2. Crimp on (crowns)
3. Press on (snap)
4. Roll on and
5. Friction

Closure Liners: A liner is any layered material that is inserted in a cap to affect a seal between the closure and the container.
Liners can be homogenous (one piece) or heterogeneous (layers of different materials).

During selection of packaging material, emphasis should be given on type of glass material for bottles (Type I, II, III), Plastic (thermoplastic or thermosets) and type of plastic used (polypropylene, polypropylene, polystyrene, polyvinyl chloride etc.,) based on finished product characteristics. This shall help in maintaining stability and integrity of the product.
The selected material for container, closure and closure liners are tested for stringent quality control test including extractables and leachable, photostability, leak test depending on the type of pack selected to assure that they are acceptable for the intended use. Additionally, during stability study for suspension, liquids and semi solid dosage forms, impact of the position of the container (inverted or upright) is also evaluated.

Conclusion: Container closure integrity is a critical quality attribute of pharmaceutical products. Hence, container closure components are required to be selected with careful consideration and extensive evaluation of the drug product and manufacturing attributes.

How PharmSol can help you?

- PharmSol helps in development and tech transfer of Pharmaceutical products.
- PharmSol help in establishment of manufacturing facility for Pharmaceutical products with required Regulatory certification (EU, US, etc.,)

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