EAS Journal of Pharmacy and Pharmacology
Abbreviated Key Title: EAS J Pharm Pharmacol
ISSN: 2663-0990 (Print) & ISSN: 2663-6719 (Online)
Published By East African Scholars Publisher, Kenya

OPEN ACCESS

Volume-2 | Issue-2 | Feb-2020 | DOI: 10.36349/easjpp.2020.v02i01.02

Review Article

A Brief Review on Packaging Technology

Patil Vasanti G[*1], Pandya Sudhir[1], Patil Aishwarya[1] and Shinde supriya[1]

[1]Dr. D. Y. Patil College of Pharmacy Akurdi, Pune, India

Article History
Received: 14.01.2020
Accepted: 28.01.2020
Published: 15.02.2020

Journal homepage:
https://www.easpublisher.com/easjpp

Quick Response Code

Abstract: After product development packaging is most important operation which transform the medicinal or food product in to attractive and marketable product packaging is beneficial to reach the product in most economical way possible and creates ease of storage. Due to busy lifestyle packed product are more preferred because people have limited time to eat and shop in fast tempo of today such goods have more transport ease. Packaging regulations such as drug product inspection criteria, labeling issuance, guidelines for tamper evident packaging for OTC product and expiration dating helps to build high quality packed product. Recent advancement in RFID packaging provide detail information about packaging.

Keywords: medicinal or food product, OTC product and expiration dating.

PACKAGING

A Pharmaceutical Package container is an article or device which contains the Pharmaceutical Product and the container may or may not in direct contact with the product. The container which is designed for pharmaceutical purpose must be stable (Council of Europe. 2004).

Types of packaging material

- Glass
- Plastic
- Metals
- Paper and Board
- Rubber
- Cotton
- Adhesives and Inks
- Closures

Types of Packaging

1. Primary Packaging:- Primary packaging are those package which are in direct contact with the Pharmaceutical formulation. The main aim of primary package is to protect the formulation from environmental, chemical, mechanical and/or other hazards. E.g. strip packaging, blister packaging and **Droppers.**

2. Secondary Packaging:- The package external to Primary package is known as secondary package. This package provide additional protection during warehousing and also provide information about drug product for **e.g. Leaflets**.

3. Tertiary packaging:- Examples: Barrel, crate, container, pallets, slip sheet. It is outer package of secondary packaging & prevents damage to the products. It is used for bulk handling & shipping (Indian Pharmacopoeia. 1996).

Components of packaging

1. Container:-. The material in which the product or medicine is placed and packed.

2. Closure:- It tightly packs the container to exclude oxygen, carbon dioxide, moisture & prevents the loss of water and volatile substances from the products.

3. Carton/outer:- Which gives secondary protection against mechanical and other environmental hazards. It is the outer covering. Cartoons are made up of cardboard, wood pulp etc.

4. Box:- In this multiples of products are packed. It provides primary defense against external hazards. The boxes are made up of thick cardboard and wood (Indian Pharmacopoeia. 1996; & Singh, A. *et al.*, 2011)

***Corresponding Author:** Patil Vasanti G Email:

Properties to be checked for Selection of Packaging Material

- Mechanical properties.
- Physico-chemical properties
- Biological properties.
- Economic aspects.
- Pharmaceutical properties.
- They must be non-toxic.

Concepts related to packaging (www.fssai.gov.in):

"Best before" means the date which signifies the end of the period under any stated storage conditions during which the food shall remain fully marketable and shall retain any specific qualities for which tacit or express claims have been made and beyond that date, the food may still be perfectly safe to consume, though its quality may have diminished. However the food shall not be sold if at any stage the product becomes unsafe.

"**Date of manufacture"** means the date on which the food becomes the product as described;

"Date of packaging" means the date on which the food is placed in the immediate container in which it will be ultimately sold;

"Infant" means a child not more than twelve months of age;

"Lot number" or "code number" or "batch number" means the number either in numerical or alphabets or in combination thereof, representing the lot number or code number or batch number, being preceded by the words "Lot No" or "Lot" or "code number" or "Code" or Batch No" or "Batch" or any distinguishing prefix by which the food can be traced in manufacture and identified in distribution.

"Multipiece package" means a package containing two or more individually packaged or labelled pieces of the same commodity of identical quantity, intended for retail either in individual pieces or packages as a whole.

"Non- Vegetarian Food" means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient;

"Prepackaged" or "Pre-packed food", means food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.

"**Principal Display Panel"** means that part of the container/package which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the commodity contained therein.

"Use – by date" or "Recommended last consumption date" or "Expiry date" means the date which signifies the end of the estimated period under any stated storage conditions, after which the food probably will not have the quality and safety attributes normally expected by the consumers and the food shall not be sold;

"Vegetarian Food" means any article of Food other than Non- Vegetarian Food as"Non- Vegetarian Food" means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient;

"Prepackaged" or "Pre-packed food", means food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.

Note: The expression "package" wherever it occurs in these Regulations, shall be construed as package containing pre-packed food articles.

"Principal Display Panel" means that part of the container/package which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the commodity contained therein.

"Use – by date" or "Recommended last consumption date" or "Expiry date" means the date which signifies the end of the estimated period under any stated storage conditions, after which the food probably will not have the quality and safety attributes normally expected by the consumers and the food shall not be sold.

"Vegetarian Food" means any article of Food other than Non- Vegetarian Food as defined in regulation

Regulatory Aspects of Packaging

About 90 % of all PRODUCT RECALLS are caused byFAULTY PACKAGING AND LABELLING.

Those products recall results in loss of thousands of money for industry so now a day industry are putting more and more concern about the accuracy and efficacy of the pharmaceutical packaging and labeling (Council of Europe. 2004).

For that almost all the regulatory agencies are providing stricter specifications for the packaging and labeling of the pharmaceuticals

Packaging and Labeling Control

Materials Assessment and Utilization Criteria

- There will be systems depicting in adequate detail the receipt, identification, storage, inspecting, assessing, and additionally testing of materials used for packaging; Primary secondary and tertiary packaging materials will be representatively inspected, and analyzed upon receipt and before use.
- Primary secondary and tertiary packaging materials which meet the specifications laid down and are approved shall be used for operations, those which are not as per specifications shall be sent back to the vendor.
- Each consignment received of any primary secondary and tertiary packaging material shall be duly recorded. The records shall reflect the date of receipt, testing and acceptance or non-approval.
- There shall be classified areas for storage of primary secondary and tertiary packaging material for, each different drug product, each strength, each dosage form and the access to these areas shall be restricted to personnel allocated only.
- Material which have become redundant shall be destroyed and records maintained.
- Use of continuous sheets or gang-printed labels for different drug products, or for different strengths and net contents of the same drug product, is not advisable unless the labeling from continuous sheets or gang-printed sheets is differentiated by size, shape, or color.
- one of the following special control procedures needs to be included If cut labeling is used for immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers, but are yet to be packed in individual unit cartons, packaging and labeling operations.
    1. Dedicated system for labeling and packaging for each different strength of each different drug product;
    2. hundred percent examination with the help of appropriate electronic or electromechanical equipment to emphasize correct labeling during or after completion of finishing operations; or
    3. Use of to conduct a 100-percent examination visual inspection to check for correct labeling online or after completion of operations for hand-applied labeling. Such examination shall be independently verified by a second person..
    4. use of automated technique , which shall help differentiation by label size and shape that physically prevents incorrect labeling from being processed, by the labeling and packaging equipment.
- Online /Offline Printing devices which are associated with, manufacturing lines and are used to imprint labels upon the drug formulation unit label shall be monitored to assure that all imprintconforms to the print specified in the batch production record.[5]

Labeling issuance

- Labels issued for use in drug product labeling operations shall be given under strict supervision
- The quantity issued for a batch shall be carefully scrutinized for identity and conformity to the labeling specified in the master or batch production records.
- Reconciliation procedures shall be in place for the quantities of labels issued, used, and returned. Evaluation of discrepancies found between the quantities of drug product finished and the quantity of labeling issued shall be done when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with standard operating procedure. Labeling reconciliation is waived for cut or roll labeling if a 100-percent examination for correct labeling is performed in accordance as stated above. Labeling reconciliation is also waived for 360 deg wraparound labels
- All excess overprinted unused labels bearing lot or control numbers shall be destroyed.
- To prevent mix-ups and provide proper identification returned labels shall be maintained and stored as per standard operating procedure
- Standard Operating Procedures shall be written in sufficient detail describing the control procedures employed for the issuance of labeling; which shall be strictly followed (www.accessdata.fda.gov).

Packaging and Labeling Operations

There shall be written standard procedures designed and followed to assure that correct labels, labeling, and packaging materials are used for drug products; these procedures shall include the following features:

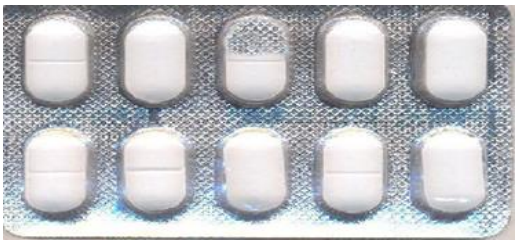
- Physical or spatial separation to prevent mix-ups and cross-contamination from operations on other drug products.
- Filled drug product containers that are set aside and held in unlabeled condition for future labeling operations shall carry precise Identification and procedures for handling, so as to preclude wrong labelling of individual containers, lots, or portions of lots. Identification shall be sufficient to determine name, strength, quantity of contents, and lot or control number of each container and need not be applied to each individual container.
- a lot or control number that permits Identification of the drug product anddetermination of the history of the manufacture and control of the batch.
- Suitability and correctness of packaging and labeling materials its examination before packaging

operations, and documentation of such examination in the batch production record.

- Assurance that from the previous operations all the drug products of the previous batch has been removed by inspection of the packaging and labeling facilities immediately before use. During inspection it is also mandatory to assure that packaging and labeling materials not required for subsequent operations have been removed. Documentation of the results of inspection shall accompany the batch production records (www.accessdata.fda.gov).

Tamper-evident packaging requirements for over-the-counter (OTC) human drug products

FDA under federal food, drug and cosmetic act has given guidelines related to tamper evident packaging of OTC product for its safety and effectiveness. OTC product except a dermatological, dentifrice, insulin or lozenge product for retail sale packed and labeled under section 501 of the act or misbrand under 502 or both (Council of Europe. 2004).



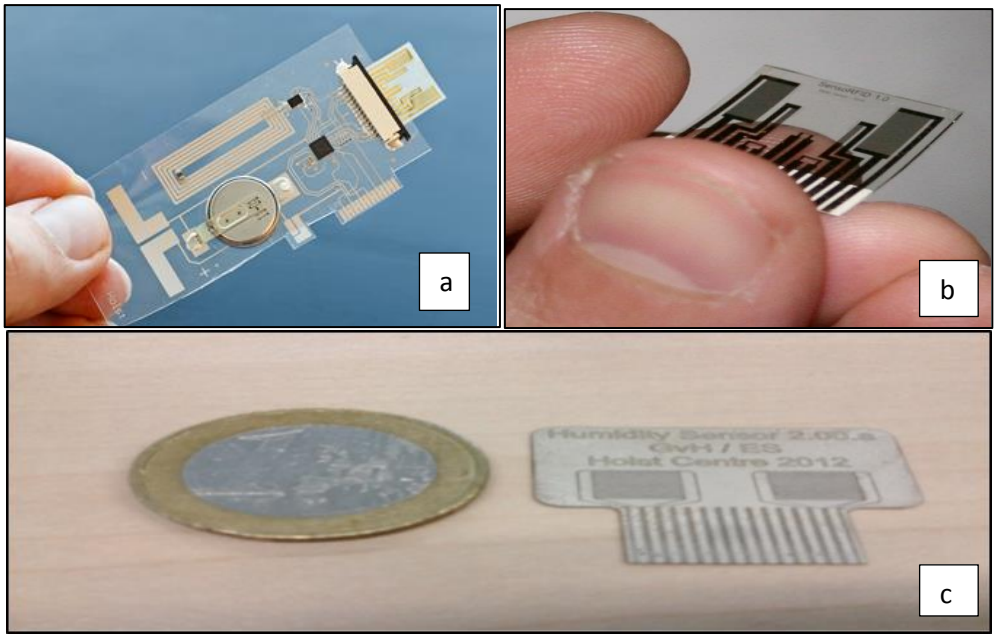
Expiration Dating

- An expiration date determined by appropriate stability testing to assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, shall be clearly mentioned. The calculation of expiration date shall be as per the legal norms and ICH guidelines
- Expiration dates shall be related to the product formulation along with any storage conditions stated on the labeling, as determined by stability studies as per the legal norms.
- In case of dry syrups where the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and dry syrup drug products.
- Expiration dates shall be overprinted on labels in accordance with the legal requirements
- The above regulations shall not apply to Homeopathic drug products.
- Approved Drug Products / approved extracts that have "No Standard of Potency" are exempt from the requirements of this section after due approval from the Legal authorities.
- These requirements are also not applicable to Investigational new drug products, with the provision that they meet appropriate standards or specifications as demonstrated by stability studies during their use in clinical investigations. In case products for investigational use are to be reconstituted at the time of dispensing, of dry syrups where the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for the reconstituted drug product (www.accessdata.fda.gov).

RFID PACKAGING

Radiofrequency identification system uses a microchip present in a label used to transmit the data when exposed to the microwaves. It consists of three components RFID Tags, RFID reader (antenna and trans receiver) and the host computer. RFID reader is also called as interrogator which emits a field of electromagnetic radiations from the antenna which are absorbed by the tags this absorbed energy used to power the tags microchip and the signal that includes the tags identification number is sent back to the interrogator. RFID Reader consist of three component radio frequency module, control unit and antenna coil which generates high-frequency electromagnetic field in contrast tags act as passive component which contains antenna and electronic microchip so when it

comes near to the electromagnetic field of trans receiver, because of induction voltage generates in a antenna coil and this voltage act as a power supply for the microchip.



a)Photograph of a 'Smart Label', The complete system includes the printed circuitry, IC's and a foil containing the sensor elements.
b) Photograph of sensors on PEN foil comprising of interdigitated Au electrodes functionalized with sensing polymers.
c) Photograph of sensors fabricated by screen printed interdigitated silver electrodes on PET foil and functionalized with sensing polymers (Delen, D. *et al.*, 2007; Van den Brand, J. *et al.*, 2010, September; & Adams, G. 2007).

CONCLUSION

Packaging after product development has importantrole in pharma industry. When packaging and labelling is done as per the guidelines given by FASSI and FDA it not only improves the chances of patient compliance but also act as guide for patient. Many manufacturing companies are working on improving the packaging operations to reduce high cost of the packaging and labelling of medicinal well as food products. Innovative packing operations will lead to increase in demand and sales of products.

REFERENCES

1. Adams, G. (2007). Pharmaceutical manufacturing: RFID – reducing errors and effort. Filtration & Separation, 44 (6), 17-19.
2. C.P.Croce, A.Fischer & R.L.Thomas, Packaging material Science, *The theory & Practice of Industrial Pharmacy* by Leon Lachman, Third edition, p 711-732
3. Cooper., & Gunn's. (2005). Tutorial pharmacy. Edited by Carter SJ. Delhi: CBS publisher &distributors, Delhi. 6th edition.
4. Council of Europe. (2004). European Pharmacopoeia, 5th ed., Strasbourg: Council of Europe.
5. Delen, D., Hardgrave, B. C., & Sharda, R. (2007). RFID for better supply-chain management through enhanced information visibility. *Production and operations management*, *16*(5), 613-624.
6. http://news.thomasnet.com/images/large/450/450948.jpg
7. http://walmartstores.com/FactsNews/NewsRoom/6039.aspx .
8. http://www.dailymail.co.uk/news/article468022/Product-packaging-cost-times-whats-inside.html
9. http://www.devicelink.com/pmpn/archive/98/08/002.html
10. http://www.fda.gov
11. http://www.gosdar.com
12. http://www.indiamart.com
13. http://www.mhra.gov.uk/home/idcplg
14. http://www.samedanltd.com/members/archives/archives1.asp
15. http://www.sha.org/bottle/finishes.htm
16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1&subpartNode=21:4.0.1.1.11.7
17. https://www.fssai.gov.in/upload/uploadfiles/files/Packaging_Labelling_Regulations.pdf
18. https://www.packagingdigest.com › rfid
19. Indian Pharmacopoeia. (1996). Vol I. The Controller of Publication. New Delhi, 9-10
20. Landt J. (2005). "The history of RFID", Potentials, 24(4), pp.8-11.
21. Liebe, D. C. (1996). Packaging of pharmaceutical dosage forms. *Drugs and the pharmaceutical sciences*, *72*, 681-726.

22. Mehta Kunal, C., Akhilesh, D., & Kumar, B. S. (2012). Recent trends in pharmaceutical packaging: A review. *International journal of pharmaceutical and chemical sciences*, *1*(3).
23. Mehta Kunal, C., Akhilesh, D., & Kumar, B. S. (2012). Recent trends in pharmaceutical packaging: A review. *International journal of pharmaceutical and chemical sciences*, *1*(3).
24. Pilchik, R. (2000). Pharmaceutical blister packaging, Part I. *Pharmaceutical technology*, *24*(11), 68-78.
25. Plastic Packaging. (1487). *Remington: The Science and Practice of Pharmacy*, 19th edition, Volume II, p.
26. Poulter, S. (2007 July13). "Product packaging can cost three times as much as what's inside".
27. Singh, A., Sharma, P. K., & Malviya, R. (2011). Eco friendly pharmaceutical packaging material. *World Applied Sciences Journal*, *14*(11), 1703-1716.
28. United State Pharmacopoeia. Appendices. pp.no. 2653, 2654, 2558, 2580.
29. USP 24, NF 19, 2000. p 10.
30. Van den Brand, J., Kusters, R., Heeren, M., van Remoortere, B., & Dietzel, A. (2010, September). Flipchip bonding of ultrahin Si dies onto PEN/PET substrates with low cost circuitry. In *3rd Electronics System Integration Technology Conference ESTC* (pp. 1-6). IEEE.
31. Wal-Mart Stores, Inc. (2006Nov1). "Wal-Mart Unveils 'Packaging Scorecard' to Suppliers".
32. WHO Technical Report Series, No. 902, Annex 9,2002
33. Wu, D. L., Ng, W. W., Yeung, D. S., & Ding, H. L. (2009, July). A brief survey on current RFID applications. In *2009 International Conference on Machine Learning and Cybernetics* (Vol. 4, pp. 2330-2335). IEEE.
34. www.fda.gov/cder/guidance/index.htm