

PHARMACEUTICAL PACKAGING AND DRUG SAFETY

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ABSTRACT

Pharmaceutical packaging is a type of packaging that can be used to communicate safety and efficacy information to customers. It can be made up of different materials such as glass, metal and plastic. The evaluation parameters for each of them are discussed in brief. The packaging is primarily of three different types: i.e. primary, secondary and tertiary. The objective here is to understand in detail about the pharmaceutical packaging and how it plays a role in ensuring drug safety. This can be understood by the anti-tampering and anti-counterfeit types of packaging available. Several methods can be used to convey drug safety and efficacy information to the customers. Along with this, the influence of packaging on brand loyalty and perception, as well as the use of it in differentiating a company's products from that of its competitors, is also described. Various quality control tests of different containers are also discussed.

KEYWORDS: Pharmaceutical packaging, Drug safety, Brand loyalty, Anti-tampering, Anti-counterfeit

REVIEW OF LITERATURE

INTRODUCTION

Pharmaceutical packaging refers to the technique of maintaining the integrity of a pharmaceutical product by its confinement from the point of production in a unit until it is used (pareek, 2014). packaging provides several advantages, including protection from environmental factors, and clear and concise product identification for professionals such as pharmacists, nurses, etc. It further helps in encouraging patient compliance and preventing counterfeiting (kumar, 2023).

Product quality, stability, and freshness are preserved during distribution and storage with the appropriate choice of packing materials (kulkarni et al., 2015). rubber, plastic, metal, and glass are the crucial parts of the container closure system. Various kinds of glass, plastic, and metal packaging materials are utilized to manufacture closures and containers (nasa et al., 2014).

TYPES OF PHARMACEUTICAL PACKAGING

A device or material that holds a pharmaceutical product, whether or not it comes into direct touch with the substance, is called a pharmaceutical package container. It must be stable when the container designed for medicinal purposes is used (Nasa et al., 2014b).

Pharmaceutical package containers are made of materials or devices used to hold pharmaceutical products, whether or not the products come into direct contact with the drugs. When the medical container is utilised, it needs to be stable (Ciotea & Popa, n.d.).

MAJOR TYPES OF PHARMACEUTICAL PACKAGING

1 Primary Packaging:

The primary packing envelope is the one that comes into touch with the dosage form or equipment first. Packaging must ensure that it does not interfere with the medication, allowing for the appropriate storage of pharmaceuticals. Blister or strip packing are two examples. (Sabee et al., 2022)

2. Secondary Package

The secondary Package refers to the Package external to the primary Package. In addition to offering extra security during storage, this packaging contains information on pharmaceutical products, such as leaflets (PHARMACEUTICAL PACKAGING: CURRENT TRENDS AND FUTURE, n.d.).

3. Tertiary packaging:

Barrels, containers, edge protectors, and other bulk handling and transportation items are examples of tertiary packaging systems (Kulkarni et al., 2015).

The following container types are utilised as the main Package:

The primary Package for liquid orals is

Well closed containers

These types of containers provide protection from foreign particles and loss during transportation, sale, etc

Airtight containers

These kinds of containers shield the contents from outside threats. These containers stay airtight after being closed if they are meant to be opened multiple times. Hermetic sealed containers are another name for these (Jadhav et al., 2023).

Single Dose Containers

This type of container contains a single dose of medicament; examples are Glass ampoules, Vials, etc.

Multi-Dose Containers

As the name indicates, these containers hold more than a single dose, and their contents are withdrawn at various intervals (Heaton et al., 2017)

Light Resistant Containers

These containers exclude sunlight from entering them (UV light). These are composed of components that prevent UV radiation from penetrating into the contents. For example, Glass vessels in the colour amber (Kumar, 2023b).

Primary Package for solid dosage forms

Strip Package

This has a packet with sealed contents. There are two film layers in the Package. a strip with numerous pockets, each holding one dosage of medication.

Blister Package

It is made up of a base layer (PVC layer) with cavities which contain Pharmaceutical products. This type of Package provides more excellent protection than a strip package. The lid is made up of aluminium or paper foil. Sealing of the package is done by combining lid and base with the application of heat and pressure (Kulkarni et al., 2015).

QUALITY CONTROL OF CONTAINERS

A drug substance or drug product that it is in direct contact with or may come into contact with is intended to be held in the container of a pharmacopoeial object. The closure is part of the container.

Containers must be carefully chosen after taking into account the nature of the contents and the possible effects of transit and storage, even for short periods of time (Hamrah et al., 2020)

GLASS CONTAINERS

There are coloured and colourless glass jars available (Bora & Polshettiwar, 2021). Significant amounts of boric oxide, aluminium oxide, and alkali and/or alkaline earth oxides are present in borosilicate glass that is considered neutral. It is highly resilient to heat shock and hydrolysis (Tangri et al., n.d.).

Evaluation parameters:-**(A) Crushed-glass test:**

This test is official at USP. The container is crushed, sieved, and weighed in order to produce uniform particles.

(B) Whole-Container test:

The European, British, and International Pharmacopoeias all recognise this test as official. It is solely used in the USP for containers of treated soda-lime. All that needs to be done is put the test solution inside the containers and expose them to the test environment.

(C) Chemical resistance of test

For determining the chemical resistance of glass containers, USP and IP provides two tests (Srinivasan et al., 2019).

(D) Powdered Glass Test

The purpose of the powdered glass test is to determine the amount of alkali that has been extracted from the powdered glass. The amount of acid needed (a specified limit) to neutralise the released alkali is specified by the pharmacopoeia. The fundamental analysis involves using methyl red indicator in an acid-base titration. (Islam et al., 2017)

(E) Water Attack Test

Determining if the alkali that has leached from a container's surface is within the permitted limits is the basic principle behind the water attack test (Diallo, 2012).

PLASTIC CONTAINERS

1. Permeation: The shelf life of a medication may be negatively impacted by the transfer of gases, vapours, or liquids through plastic packing materials.

2. Leaching: There is a chance that the substance will leach or migrate from the container because most plastic containers have one or more chemicals added in trace amounts to stabilise the plastic.

3. Sorption: Sorption may lead to severe problems for drug preparation in which essential ingredients are in solution.

4. Chemical Reactivity: Various ingredients which are used in plastic formulations may react chemically with one or more components of a drug product (Sabee et al., 2022).

5. Leak testing: Test the containers for leaks by filling them with a liquid or gas and subjecting them to pressure. (Katarkar et al., 2017)

6. Drop testing: Drop the containers from a predetermined height to test their impact resistance

7. Transparency test: Fill five empty containers with a diluted suspension as per IP 1966. The suspension in each container must be cloudy when compared to a container filled with water (Kovačec et al., 2010)

8. Water vapour permeability test: Fill five containers with water, seal them, and weigh them. After 14 days at 60% humidity and 20-25 degrees Celsius, reweigh the containers. The weight loss of each container should be less than 0.2% (Primary Packaging Materials for Medicinal Products-Particular Requirements for the Application of ISO 9001:2015, with Reference to Good Manufacturing Practice (GMP) COPYRIGHT PROTECTED DOCUMENT, 2017).

METAL CONTAINERS

1. Corrosion testing: Test the containers for resistance to corrosion in a variety of environments, such as saline solution, acidic solution, and alkaline solution

2. Particulate matter testing: Check the inside surfaces of the containers to see whether there are any particles, like metal flakes.

3. Extractables and leachables testing: Test the containers for the presence of extractables and leachables, which are chemicals that can migrate from the container into the product (INDIAN PHARMACOPOEIA 2007 Volume 1 THE INDIAN PHARMACOPOEIA COMMISSION GHAZIABAD, 2007).

BRAND LOYALTY AND CONSUMER PERCEPTION

When it comes to leveraging the power of its brands, the pharmaceutical industry has not been as thriving as the fast-moving consumer goods (FMCG) sector (Abd & Hassan, n.d.). This is mainly because pharmaceuticals have always engaged in competition with one another based on functional characteristics (clinical and product-related features) (Ahmad & Lakhan, 2012). However, because generics are causing competition in the market due to patent expiration, this issue has gotten more challenging (Panchal et al., 2012). The phrase "customer perception regarding brand loyalty" refers to a consumer's recurrent purchases of goods and services from the same company instead of choosing alternatives supplied by rival companies (Srivastava et al., 2022). Customers' perception is how they identify a brand from their frequent purchases (Benachenhou et al., 2018). This view may also impact the brand. The real-time performance of a product is not always affected by the perceptions of its users (Rangsang & Journal, 2020).

The brand image represents the emotional and logical perception of consumers that have a particular brand attached to them (Shah et al., n.d.). Brand In terms of business markets, the image has a significant role to play where it is hard to find a distinction between products or services or when they possess the characteristics of a tangible quality (Yeo et al., 2020). The offer is identical, but buyers are more interested in the goods: a company's mind image or the name of a product or service. A different reaction is shown in the production (Al-Hasan et al., 2015).

Consumer perception of brand loyalty refers to a consumer's consistent use of the goods and services of one company rather than switching to those of a rival company (Ladha, n.d.). Consumer perception is the acknowledgement of a brand by people based on their frequent purchases ("The Impact of Packaging on Customer's Buying Decision," 2021). Additionally, the brand may be impacted by this view. The real-time performance of the product is only sometimes affected by how users perceive it (Panchal et al., 2012).

HOW PHARMA COMPANY USES PACKAGING TO DIFFERENTIATE FROM COMPETITORS

Pharmaceutical companies employ various tactics, with packaging being one crucial area, to set their products apart from rivals (Griffiths, 2008). Pharma companies can use packaging to emphasise the advantages of their products, make them stand out on the shelf, and establish a distinctive and memorable brand identity (Grabowski & Vernon, 1992).

Pharma businesses utilise packaging in the following unique ways to set themselves apart from competitors:

Use unique and innovative design elements: Employ distinctive and creative design elements. To differentiate their packaging, pharmaceutical businesses might utilise distinctive forms, colours, images, and materials. For instance, some businesses employ blister packs with distinctive designs or hues, while others use unique materials like foil or plastic to give their packaging a more upscale appearance (Panigrahi & Joshi, 2021)

Highlight the product's benefits: Use inventive and distinctive design elements. Pharma businesses can differentiate their packaging using distinctive materials, colours, forms, and graphics. Companies employ different materials like foil or plastic to give their packaging a more upscale appearance, while others use blister packs with eye-catching designs or hues (Oppong & Phiri, 2018).

Create a strong brand identity: Use unique and imaginative design elements: Pharma companies can set themselves apart with their packaging by using unique forms, colours, materials, and graphics. For example, some companies use blister packs with eye-catching patterns or colours, and others use particular materials—like plastic or foil—to make their packaging look more sophisticated (Eslami, 2020).

Use storytelling: Pharma businesses can utilise their packaging to convey information about their brand and line of products. Text, graphics, or even QR codes that provide links to more online content can be used to do this.

Make their packaging sustainable: Pharma firms can set themselves apart from the competition by improving the sustainability of their packaging. Recycled materials can be used, packaging waste can be reduced, or recyclable packaging can be designed (Bednarik & Lilly, 2005).

Here are some specific examples of how pharma companies are using packaging to differentiate themselves from competitors:

Pfizer: Pfizer's EpiPen allergy auto-injector is packaged in a bright yellow case that makes it easy to find in an emergency. The case is also designed to be durable and water-resistant so that it can protect the EpiPen even in harsh conditions(Panchal et al., 2012).

GlaxoSmithKline: GlaxoSmithKline's Aquaphor Healing Ointment is packaged in a tube with a unique dispensing tip that makes it easy to apply the product to the skin. The tube is also designed to be recyclable, which is essential for environmentally conscious consumers(Panchal et al., 2012).

Eli Lilly: Eli Lilly's Trulicity diabetes medication is packaged in a pre-filled pen that makes it easy for patients to inject their medication. The pen is also designed to be discreet, so patients can use it in public without drawing attention(Panchal et al., 2012).

HOW CAN PACKAGING BE USED TO COMMUNICATE SAFETY AND EFFICACY INFORMATION TO CUSTOMERS

Packaging plays a vital role in communicating safety and efficacy information to customers. It can be used to highlight the product's active ingredients and their benefits, provide instructions on how to use the product safely and effectively, include warnings about potential side effects and interactions with other medications, and display information about the product's expiration date and storage requirements(Kawecka, 2014).

IMPORTANCE OF COMMUNICATING SAFETY AND EFFICACY INFORMATION

Customers should be informed about a product's safety and effectiveness so they may decide for themselves whether or not to use it and how to use it safely. Pharmaceutical drugs, in particular, require careful use to avoid potentially dangerous side effects; therefore, this knowledge is critical(Kumar Agariya et al., 2012).

There are several ways that packaging can be used to communicate safety and efficacy information to customers. Some common methods include:

Using clear and concise language: Packaging information should be written in a style that is easy for customers to understand, brief and straightforward. Steer clear of employing technical or jargon terminology that your customers might need help understanding(Wijaya & Annisa, 2020).

Using visuals: Information on safety and efficacy can be communicated more effectively and engagingly by using visuals like graphs, icons, and pictures. To alert consumers that a product is unsafe for expectant mothers, for instance, a picture of a pregnant woman with a cross over her could be utilised("The Effect of Packaging on Perceived Quality and Purchase Intention of Made-In-Ghana Brands," 2019).

Using multiple languages: The safety and efficacy information should be translated into the relevant languages if the product is sold in different countries. By doing this, it is made sure that every consumer may get the knowledge they require to utilise the product securely(Garcia et al., 2017).

PACKAGING TO PREVENT COUNTERFEITING

According to WHO report, "A counterfeit medicine is deliberately and fraudulently mislabelled concerning identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging"(Counterfeit Medical Products Report by the Secretariat, 2010).

The development of resistance is one of the main risks associated with utilising medications that are either substandard or counterfeit(Pathak et al., 2023). Economically, too, it results in expenses for medical facilities, and governmental authorities may become engaged, particularly in the case of public health services(Sichel, 2017).To prevent this, there are various methods of anti-counterfeiting packaging which the company can apply. The methods can be classified as overt methods, covert methods, serialization, or track and trace methods(Bansal et al., 2013). Overt features allow the user to visually inspect the packaging and instantly authenticate it without the need for specialised knowledge (Gupta, 2013). A covert feature is meant to help the owner of the brand recognise products that are counterfeit(Kumar, 2023b). Serialization entails giving each stock item a distinct identity throughout the manufacturing process, which is retained along the supply chain

until used (INNOVATIONS_IN_PHARMACEUTICAL_PACKAGING, n.d.). The pharmaceutical sector uses barcodes to identify products at every stage of the supply chain (Patel et al., n.d.).

RFID (Radiofrequency Identification) is a wireless method for gathering data that identifies items using radio waves. The fundamental idea underlying RFID systems is using tags to identify objects (Gupta, 2013). Overt methods include holograms, Colour Shifting Security Inks and Films, Security Graphics, Sequential Product Numbering, and On-Product Marking. In contrast, covert methods include Invisible Printing, Embedded Image, Digital Watermarks, Hidden marks and printing, Laser coding, Substrates, Anti-copy and Anti-scan design, and Odour (Chouhan, 2023). The box can also be covered with heat-activated ink that shifts from being colourless to having a strong colour alert, such as blue, green, black, or red (Kumar, 2023b).

Blockchain technology is another innovative tool that can be applied to the pharmaceutical supply chain to improve security, visibility, and traceability of the medication supply chain. In the industry, it can be used to monitor medications from the time they are manufactured until the patient receives them (Haq & Muselemu, 2018).

ANTI-TAMPER PACKAGING

Pharmaceutical product packaging is developing, and one of the main factors presently taken into account is the need for tamper-resistant packaging (INNOVATIONS_IN_PHARMACEUTICAL_PACKAGING, n.d.). According to FDA, "A package that features an indicator or barrier to entry that, if it is breached or trussed, can fairly be expected to give customers obvious proof that tampering has taken place is said to be tamper-resistant. When handled reasonably during manufacture, distribution, and retail display, the tamper-resistant packaging may include immediate container/closure systems, secondary container/carton systems, or any combination of these to provide a visual indicator of package integrity" (Patel et al., n.d.). Tamper-evident packaging or containers allow you to verify whether an item has been opened before it is sold in the store (Gupta, 2013). The following arrangements are accepted by the FDA as tamper-resistant packaging: Strip packages, Film wrappers, Bubble packs, Blister packages, plastic pouches, Shrink seals, and bands Oil, Breakable caps, Bottle seals, Aerosol containers and Tape seals (Chouhan, 2023).

ADVANCEMENTS IN PACKAGING

The packaging business is under pressure to provide sustainable and environmentally friendly products. This pressure has even started to affect pharmaceutical packaging, one of the most complex sectors of the industry (PHARMACEUTICAL PACKAGING: CURRENT TRENDS AND FUTURE, n.d.-a). With unbleached paperboard and a clay-coated surface, Ecoslide-RX is a sustainable compliance package manufactured entirely of recycled materials (Mittal et al., 2021). It is intended to hold blister packaging that contains the least amount of non-sustainable film and foil (Pareek, 2014b). The cutting-edge packaging technology used by Cypak in its sophisticated medication monitoring and report card systems allows it to track the time and information of a pill's intake based on when it is taken out of its blister pack (Chouhan, 2023). The German company Wipak Walsrode GmbH offers a system called "TalkPack" that can be seamlessly included into any printed image on any kind of packaging—but it requires a specific kind of scanning pen (Arun Shete et al., 2020). Another advancement involves the use of tags with NFC (Near Field Communication) based technology connected to NFC-enabled mobile phones to download text, audio, or web page product information that can be played back on their handset. This is being done by the VTT Technical Research Centre of Finland (INNOVATIONS_IN_PHARMACEUTICAL_PACKAGING, n.d.).

For extremely toxic medications, a tear-resistant and reclosable carton works best. Pharma small hands resistant was introduced by Bosch and Stora Enso (SHR) (Sandeep Dessai, n.d.). Reclosable carton that is kid resistant is called Stora Enso Pharma SHR. It works well with extremely hazardous medications and is simple to use for older persons (Sohail Ali et al., 2017).

One sort of packaging that is quickly becoming popular is smart packaging. It comprises a range of kinds, including Active packaging, Intelligent packaging and Sensor-enabled packaging (Developing Anti-Counterfeiting Measures: The Role of Smart Packaging 1 2, n.d.). Active packaging is a type of pharmaceutical packaging that enhances safety and helps to display quality information. It may be able to detect the product's quality, the package's inside atmosphere, or the shipping environment. Intelligent packaging is more interactive and offers methods for re-entering, storing, and/or delivering information from sources like printed electronics, smartphones, apps for smartphones, the Cloud, and the Internet, as well as QR codes, Near-Field Communication, and Radio Frequency Identification. Sensor-enabled packaging records data using microchip sensors to ensure precise dosing and dose monitoring (Gahtori, n.d.).

Smartphone technology includes the packaging code that allows customers to access product content on their smartphones in addition to what they can already view on printed packaging, inserts, and medicine labels. This would verify and validate the product's validity in addition to improving patient compliance(Kulkarni et al., 2015).

METHODOLOGY:

The literature search was limited to articles published from 2005-2023. A comprehensive literature search was conducted on Google Scholar using the keywords: Pharmaceutical packaging, Drug safety, Brand loyalty, Anti-tampering, Anti-counterfeit type of packaging. Platforms such as Wiley, Elsevier, ScienceDirect, Academia and Frontiers was used to conduct the search.

ANALYSIS

The Preferred Reporting Item for Systemic Reviews and Meta analytic (PRISMA) method approach is used. All those articles that made it through the selection process were reviewed and summarised on the basis of year of publication, number of citations, goal and any suggestion for further research.

INCLUSION & EXCLUSION CRITERIA

To be included in current study, studies have to meet some criteria

- (a) Studies have included some kind of selection criteria (pharmaceutical packaging, drug safety). These criteria limited the number of studies.
- (b) Accordingly excluded the studies in which it is based on irrelevant information there is no proper Title, Abstract & Review.

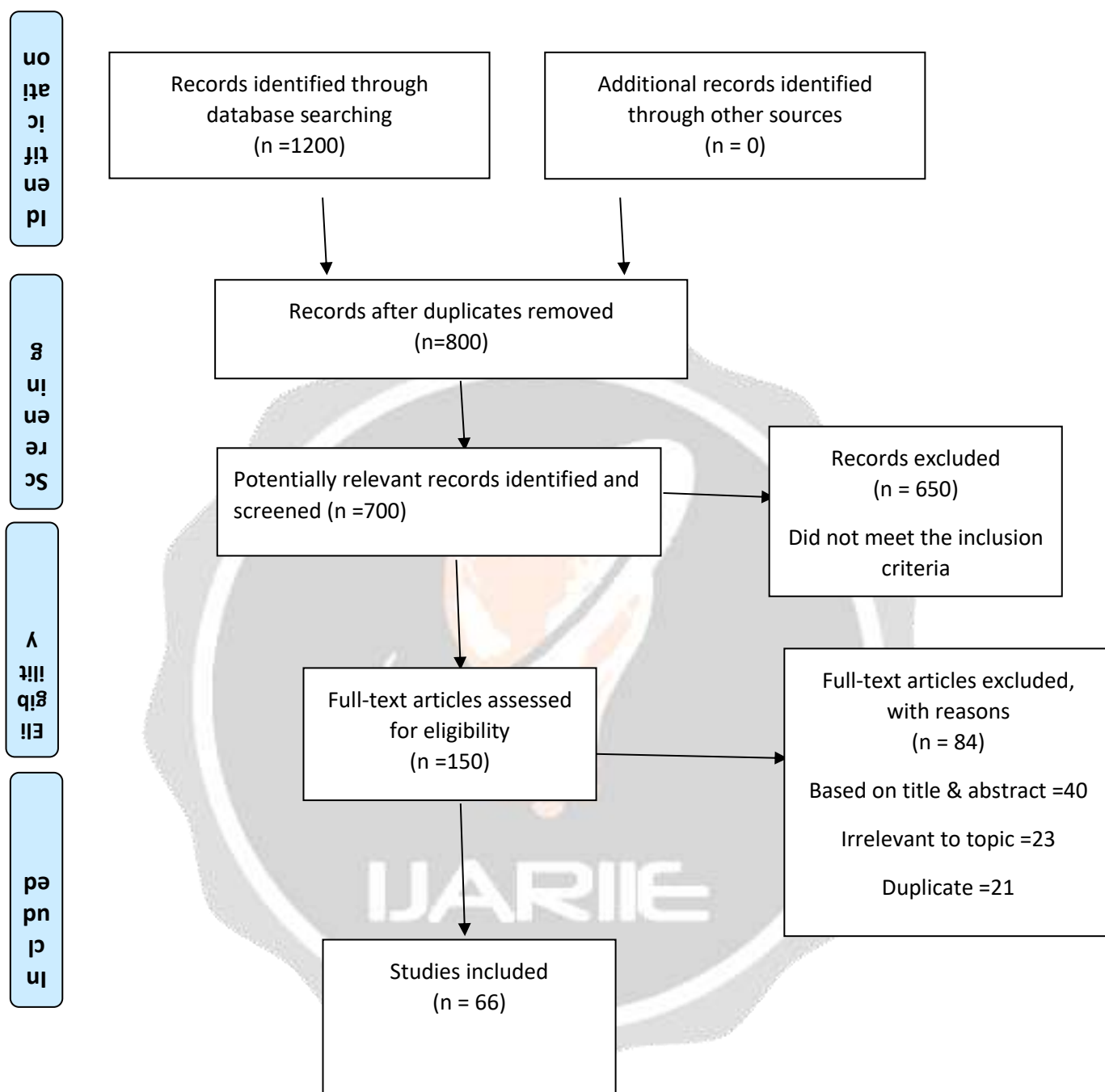
FINAL DATA SET

1200 research articles were found using all of the keywords that were searched in the research data. Once the title was studied the same article was found in two distinct databases. 800 articles remain after removing the duplicates. 800 articles were screened in all. Because they did not match the inclusion requirements, 650 articles were excluded. There are 150 articles that can be accessed for eligibility. 84 articles were eliminated in total based on title and abstract (40) Irrelevant to topic (23) Duplicate (21).

The final data set consists of 66 articles.

The oldest included study was published in the year 2005 and the most recent study was conducted on 2023. The Entire process is shown in figure

PRISMA Flow Diagram



DISCUSSION

Pharmaceutical packaging has a complex role in maintaining the integrity of the product and guaranteeing patient safety, among other vital roles. Primary packaging is essential for protecting contents from outside hazards. For liquid orals, this means using well sealed, airtight containers. To ensure that materials, including glass and plastics, are suitable for medical use, extensive quality control tests, such as the crushed-glass test and permeation checks, are performed.

Pharmaceutical businesses use packaging as a strategic strategy to set themselves apart in a competitive market, going beyond simple utilitarian considerations. Building a distinct identity is facilitated by innovative design

aspects, environmental initiatives, and distinctive branding. Pfizer, GSK, and Eli Lilly are just a few companies that demonstrate how carefully considered packaging improves user experience and strengthens brand loyalty.

Most importantly, packaging serves as a medium for informing customers about product efficacy and safety. Multilingual content, clear language, and graphics provide accessibility and comprehension. The sector uses cutting-edge traceability tools including RFID, holograms, and blockchain technology in response to the worldwide problem of counterfeiting.

Pharmaceutical packaging is expected to evolve in the coming years to incorporate smart packaging with active and intelligent features, sustainability trends, and improved customer involvement through smartphone technologies. These developments highlight the industry's dedication to satisfying changing consumer expectations in a tech-savvy and ecologically sensitive world, in addition to safeguarding its products.

CONCLUSION

1. Importance of Pharmaceutical Packaging: Pharmaceutical packaging is crucial for maintaining the integrity of medicinal products, and ensuring their protection, identification, and patient compliance.
2. Types of Pharmaceutical Packaging: Primary, secondary, and tertiary packaging play distinct roles, safeguarding medications at different stages from production to usage.
3. Container Types: Well-closed, airtight, single-dose, multi-dose, and light-resistant containers for liquid orals; strip and blister packages for solid dosage forms.
4. Quality Control: Rigorous evaluation parameters, such as crushed-glass and water attack tests for glass containers, and considerations for plastic and metal containers.
5. Brand Loyalty and Consumer Perception: The pharmaceutical industry faces challenges in brand loyalty compared to fast-moving consumer goods, but packaging can contribute to differentiation and consumer perception.
6. Packaging for Differentiation: Unique design elements, highlighting benefits, creating a strong brand identity, storytelling, and sustainability contribute to setting pharmaceutical products apart from competitors.
7. Communication of Safety and Efficacy: Clear language, visuals, and multilingual information on packaging are vital in conveying safety and efficacy information to customers.
8. Counterfeiting Prevention: Innovative packaging features such as holograms, RFID, and blockchain technology are employed to prevent counterfeiting and ensure the authenticity of pharmaceutical products.
9. Anti-Tamper Packaging: Tamper-evident packaging, accepted by the FDA, provides visual indicators of package integrity, ensuring customers can verify if a product has been opened.
10. Advancements in Packaging: Sustainable and environmentally friendly packaging, smart packaging with active, intelligent, and sensor-enabled features, and innovations like tear-resistant and reclosable cartons showcase the evolving landscape of pharmaceutical packaging.

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