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Oral Pharmaceutical Product Packaging – An Enhanced Quality-Based Approach of Performance Evaluation

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ABSTRACT

A critical aspect of drug delivery that ensures the product's safety, efficacy, and compliance with regulations is Pharmaceutical Packaging (PhP). In this process, the packaging material choice mostly relies on factors like the drug's characteristics, required level of protection, and cost. Prior studies regarding the packaging materials, market movement, and quality deficiency studies were limited, though the significance of packaging was well-known. Therefore, analysing the quality-based approach for the packaging of oral pharmaceuticals is the main aim of the present study. The present study adopts a mixed method and collects data from primary and secondary sources. 100 eligible participants (n=20 material converters, n=80 end-consumers) are selected for the study utilizing a purposive sampling method and a standardised questionnaire. In the study outcomes, an enhanced market movement and market preference (50%) of flexible materials in various industries was proven. It also verified that the products' quality was highly influenced by the packaging defects (44%). Furthermore, the preference for flexible materials and their potential demand in future packaging industries was highlighted in the present findings.

Keywords: *Pharmaceutical Packaging Technology, Oral Pharmaceuticals, Defect Detection, and Quality by Design.*

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1. INTRODUCTION

PhP plays a vital role in drug development and distribution, including design, production, and labelling, to fulfil an assembly of important functions. It is a multifaceted group of products, encompassing materials like numerous plastic polymers, glass, paper, steel, cardboard, and metals (Salmenperä et al., 2022). To safeguard the product and extend its shelf-life, a combination of manual and automated processes is involved in packaging (Pal et al., 2024). Primary packaging is directly associated with the drug. However, multiple primary packages are clustered by secondary packaging, and bulk transport, like pallets, is handled by tertiary packaging (BormioliPharma, 2024). Initially, the packaging protects the products from chemicals, environmental impacts, organic factors, and mechanical risks. It also preserves their quality as well as efficacy (Thakur, 2025). Nevertheless, major challenges in product development are manufacturing failure, cost-effectiveness, quality control failure, scale-up issues, and regulatory demand. During packing, drugs require extra care as packaging defects cause disease, injury, or even patients' deaths. Thus, to enhance the quality, safety, and efficacy of the products, regulatory bodies and pharmaceutical industries are relentlessly working by adopting a transformative and systematic approach named Quality by Design (QbD) (Khan et al., 2024; Kumar, 2023). To align with predetermined product quality, QbD designs and develops pharmaceutical formulations and manufacturing processes (Mohseni-Motlagh et al., 2023). QbD can reduce development time by up to 40% and material wastage by up to 50% by optimizing formulation parameters before full-scale manufacturing compared to traditional quality control methods (Duarte et al., 2025). In Figure 1, the benefits and risks of oral PhP are displayed.

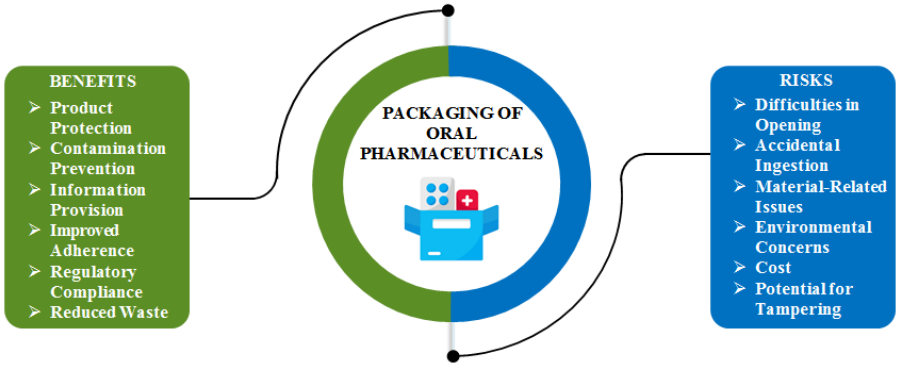

Figure 1: Advantages and hazards of oral pharmaceutical packaging

Moreover, to produce high-quality products, pharmaceutical QbD identifies the Quality Target Product Profile (QTPP) and refines the oral Controlled Release (CR) drug delivery systems. Regarding quality assurance, the pharmaceutical industry is still facing challenges (Atre & Rizvi, 2025; Lou et al., 2023). In particular, a major role in product perseverance and quality guaranteeing throughout the shelf-life period was retained by the typology of packaging and its material selection (Piovosi, 2025). Previously, in many pharmaceutical companies, product packaging had the lowest priority. But, the quality of packaging was given higher priority when compared with the product development process (Alhosseini et al., 2015). Furthermore, the brand quality and customer loyalty in the health market were also increased by the distinctive packaging and brand association (Mensah et al., 2022). Earlier, in quality checking, inefficient and time-consuming conventional defect detection methods were used. However, for inspection, prompt detection, and defect correction, real-time defect detection models like CBS YOLOv8 were used (Vijayakumar et al., 2024). In addition, certain safety risk factors like substandard packaging and shipment, falsified product information, detection of undeclared chemicals, and quality variability were exposed by online drug purchasing (Mackey et al., 2022). Therefore, to optimize the safety, efficacy, quality, and economic benefits of the drug in developmental stages, an in-depth understanding and efficient packaging frameworks were essential (Gerrans et al., 2023). Improved medication adherence and reduced healthcare costs were shown by the blister-packaged medications (Borrelli et al., 2024). Despite the profound impact of oral PhP, a limited number of studies only assess the quality-based product package approach. Also, a crucial study gap is acknowledged in the process of designing and developing PhP. A dearth of a comprehensive, integrated, and scientifically robust approach that lies among oral pharmaceutical product packaging evaluation caused reduced product quality, safety, and shelf-life. Moreover, to mitigate these issues and to enhance the processes of formulation, manufacturing, and packaging quality, various feature fusions and advanced models should be implemented. So, the present study aims to assess the quality-based approach for the packaging of oral pharmaceuticals to emphasize product quality, safety, and efficacy. Additionally, analysing the domestic and export market movement and influencing factors of product packaging materials and details of packaging material users' status by sector is the objective of the study. Further, to measure the packaging errors, the quality deficiencies and packaging defects proportion of pharmaceuticals are analysed. In addition, to understand the quality-based approach of oral pharmaceuticals, the significant relationship between the PhP and performance is evaluated.

2. MATERIALS AND METHODS

The details of the research design, population and sampling techniques, data collection, and analysis methods of this study are outlined in the research methodology. In Figure 2, the study progress is detailed.

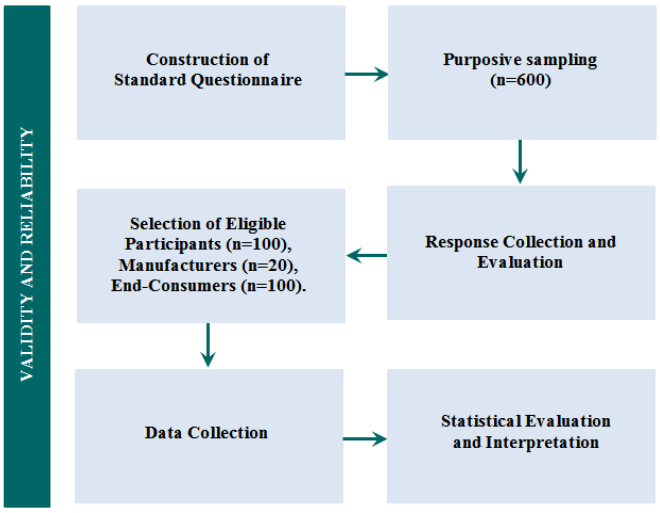

Figure 2: Workflow of the present research

2.1 Research design

The research design was an organized framework, which ensured that the study was carried out systematically and efficiently and demonstrated the reliability and dependability of the results. To collect response data from the study participants, the present study comprised questionnaire tools. Furthermore, a mixed method was used in the present analysis for assessing the quality-based approach of oral pharmaceuticals packaging.

2.2 Sources of data

Once the study purpose was acknowledged, the relevant data were gathered from primary and secondary sources. In the present study, by using surveys and questionnaires from the packaging material converters and end-consumers, the primary data were gathered. Then, the obtained responses were categorised centered on their relevance to the pharmaceutical industry, pharmaceutical marketing, and packaging. To collect precise insights, opinions, and experiences of the respondents, the questionnaire incorporated a survey method design.

Secondary data was the pre-existing information that was obtained and processed by the third party. The reliability, suitability, and adequacy of the data were considered for an impeccable report while using the secondary data. Moreover, from various sources, including publications, online platforms, academic journals, and reports, the secondary data was collected.

2.3 Population and sampling

The data were gathered from individuals related to the PhP industry to assess the quality-based approach for the packaging of oral pharmaceuticals. The participants were selected through a purposive sampling method, which primarily focused on the PhP industry. For the study, a target sample of 600 participants was purposively chosen. A standardised questionnaire with 35 queries was administered through online platforms. For the selection of eligible participants, the responses were cautiously considered. Only 100 eligible participants were selected for further studies due to the unsatisfactory responses to the questionnaire. The eligible participants included 20 individuals from converting the packaging material, and 80 were end consumers.

2.4 Data collection

The questionnaire was composed of both open as well as closed-ended questions. By using the standard procedures, the primary responses were collected from all the individual participants. Further, to generate suitable ranking data for data analysis, the gathered data was evaluated using a 5-point Likert-Scale (1= Strongly Disagree, 2= Disagree, 3= Neutral, 4= Agree, and 5= Strongly Agree).

2.5 FDA data

FDA data were analysed to understand and improve the quality of the medications in the present oral PhP quality assessments. In this study, based on the Information under the Right to Information Act 2005, the authorized data were obtained from the Department of the FDA, Goa. A total of 8 complaints related to the drugs were obtained from consumers from 2015 to April 2022. Then, to enhance the PhP quality, the complaint descriptions were analyzed and processed.

2.6 Data analysis

To ensure the comprehensiveness and trustworthiness of the organized questions, the questionnaire and responses were pre-evaluated. Further, to summarise and characterise the dataset, the descriptive statistical analysis was used. The central tendency, frequency, and variance of responses were interpreted statistically. Moreover, to find the relationship between the type of industry and usage rate, the hypothesis testing was done using the Chi-Square test, and packaging material preferences were carried out using the Kolmogorov-Smirnov D test. Further, using the Chi-Square test, the statistical significance ($p<0.05$) was also examined.

2.7 Ethical consideration

All the participants responded to the voluntary consent agreement before answering the online questionnaire. Throughout the study, the obtained consent and data were kept confidential and private.

3. RESULTS

The present study mainly concentrated on the quality concerns of oral PhP centered on packaging material converters and customer responses. By using statistical methods, the responses were evaluated. Then, the obtained data were presented in tabular and graphical formats.

3.1 Packaging material converter response details

In this research, from the packaging material converters, a total of 20 eligible responses were collected. The participants worked in rigid (glass, metal, plastic, and composite) and flexible (paper or board, aluminium foil, and other flexible materials) packaging material manufacturing industries. In this study, most eligible replies (n=13) were collected from the flexible material industries instead of the rigid material industries (n=7). Table 1 displays the circulation of packaging material movement in domestic and export markets.

Table 1: Packaging material movement in domestic and export marketing

Packaging Material	Status (%)					
	Low		Moderate		High	
	Domestic	Export	Domestic	Export	Domestic	Export
Glass	25	30	35	50	40	20
Metal	20	25	40	60	40	15
Plastic	15	15	20	50	65	35
Composite	75	50	25	40	0	10
Flexible	0	10	20	30	80	60

The flexible material showed high mobility in both domestic (80%) and export (60%) markets based on the response of the 20 converters. The metal (40% in domestic, 60% in export) and glass (35% in domestic, 50% in export) expressed a moderate movement. Moreover, the lowest domestic movement was reported by 75% of composite converters, and 50% reported the lowest export movement. Furthermore, 15% of the respondents claimed low market movement of plastic in both markets. However, the quality and performance of the packaging materials were influenced by certain factors. In Figure 3, the range of influencing factors is illustrated.

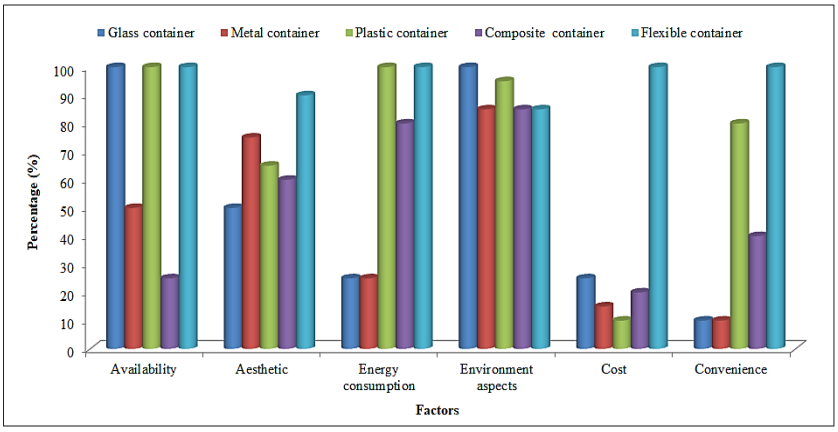

Figure 3: Factors influencing the packaging materials

As per the 20 respondents, the packaging materials were highly influenced by factors like availability, aesthetics, energy

consumption, environmental aspects, cost, and convenience. The availability significantly affected the glass, plastic, and flexible containers. The energy consumption played a significant role in plastic and flexible containers, and the flexible containers were highly influenced by cost and convenience (100%). Moreover, the flexible packaging material unquestionably excels in suitable material selection. However, equal (100%) accessibility, energy consumption, and environmental impact were represented by the flexible material. Moreover, the composite container didn't exhibit extreme values for any study factors.

3.2 End-consumer response details

Here, a total of 80 end-users were chosen as participants. The participants were utilizing the packaging materials in numerous sectors, like food, pharmaceuticals, cosmetics/toiletries, and other sectors. Table 2 shows the usage status.

Table 2: Packaging material usage status in different sectors

Sector	Number of End-users (N)	Status (N)		
		Large	Medium	Small
Food	52	12	22	18
Pharmaceuticals	12	7	4	1
Cosmetic/Toiletries	8	3	3	2
Others	8	2	3	3
Total	80	24	32	24

Among the 80 feedbacks, 52 were from food, 12 from pharmaceuticals, 8 from cosmetics/toiletries, and 8 from other sectors. The respondents played significant roles in 32 medium-sized enterprises, encompassing the food industry (22), pharmaceutical industry (4), cosmetics industry (3), and other sectors (3). 24 companies were designated as large-scale and 24 as small-scale industries. The number of participants working in the food industry was 12 and 18 in large and small-scale industries, respectively. But, the least number of operators (2) were from other sectors in large-scale business, whereas the pharmaceutical sector (1) was the least in small-scale business. Figure 4 reports the types of packaging material preference of end-users.

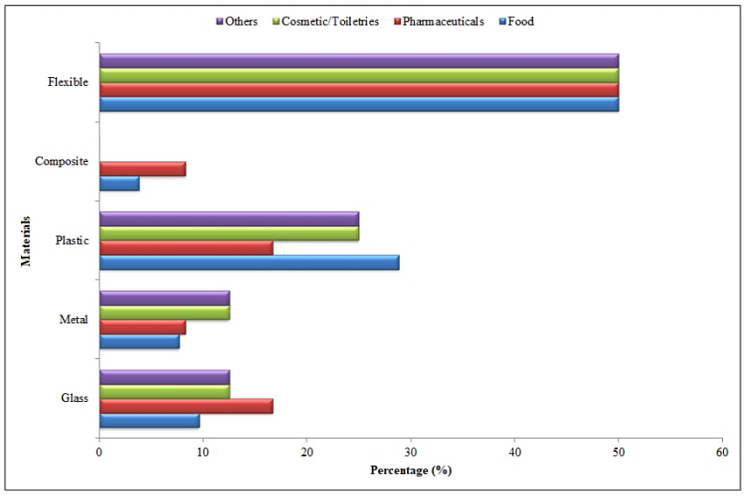

Figure 4: Types of packaging material preference of end-users

In food, pharmaceuticals, cosmetic/toiletries, and other industries, glass, metal, plastic, composite, and flexible materials were used. The flexible containers were highly preferred (50%) in all the industries based on the users' replies. Composite was least preferred in cosmetic/toiletries (0%), other sectors (0%), food (3.85%), and pharmaceuticals (8.33%), whereas metal is also the least preferred in pharmaceuticals (8.33%). Moreover, the flexible materials played a major role in domestic and export markets in high-scale market mobility. Composites showed the major market mobility on a low scale, whereas glass exhibited the highest market movement on a moderate scale.

3.3 Packaging quality deficiency studies

The imperfections in the packaging were recognized as the major quality issue in the pharmaceutical industry. To reduce the risks, the error findings in the packaging helped to implement preventive measures. Regarding hazards associated with the specific pharmaceutical products and risk regulatory measures, 9,486 complaints were registered from 4846 pharmacies according to the AMK 2021 reports. In Figure 5, the risk factors associated with pharmaceuticals are shown.

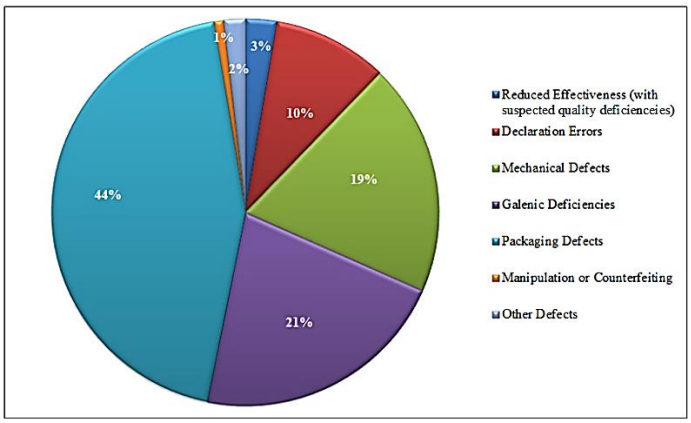

Figure 5: Risk factors associated with pharmaceuticals

As per the data, the majority of the issues were concerned with the product packaging and quality (6,527). The product packaging and quality exhibited 44% of packaging defects, 21% of galenic defects, 19% of mechanical defects, 10% of declaration errors, 3% of quality deficiencies, and counterfeiting issues (1%) were the least reported problems. In Table 3, the proportion of the packaging defects from 2014-2021 is presented.

Table 3: Proportion of Packaging Defects

Years	Proportion of Packaging Defects
2014	34%
2015	24%
2016	38%
2017	42%
2018	43%
2019	42%
2020	44%
2021	44%

The reports proved that an increased defect proportion of 44% was shown in the advancing years (2020 and 2021). Further, in the present study, a significant relationship between the packing issues and galenic deficiencies (ABDA, 2024) was also identified. Figure 6 portrays the quality deficiencies and packaging defects from 2014 – 2021.

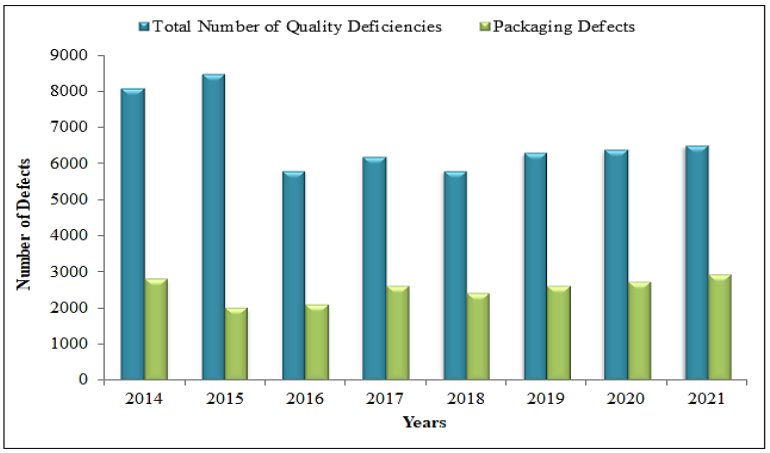

Figure 6: Quality deficiencies and packaging defects (2014-2021)

3.4 Hypothesis testing

Hypothesis development and testing expressed the presumptions (hypotheses) about the study and assessed whether the data supported or refuted the hypothesis. By using the Chi-Square test, the relationship between the type of industry and the packaging material usage rate was evaluated centered on the 80 valid responses. Table 4 exhibits the outcomes.

H0: There is no significant relationship betwixt the type of industry and the packaging material usage rate.
H1: There is a significant relationship betwixt the type of industry and the packaging material usage rate.

Table 4: Results of hypothesis testing

Description	Value	Df	p-value
Pearson Chi-Square	6.950	6	0.326
Likelihood Ratio	7.057	6	0.316
Linear-by-Linear Association	0.501	1	0.479

* p-value (significance <0.05)

Here, the p-value of 0.326 is higher compared to the assumed p-value (0.05). Therefore, the non-significant relationship between the type of industry and the packaging material usage rate was confirmed. Here, the null hypothesis was accepted, and H1 was rejected. Further, by using the Kolmogorov-Smirnov D test, the significance of flexible packaging material preference on various industries was assessed, and the results are shown in Table 5.
H0: Flexible Packaging material is not a widely preferred packaging material in numerous industries.
H1: Flexible Packaging material is a widely preferred packaging material in numerous industries.

Table 5: Results of hypothesis testing

Kolmogorov Smirnov D Test Parameters	Value
N	51.000
Minimum	1.000
Maximum	5.000
Absolute	0.375
Positive	0.125
Negative	-0.375
Z	3.354
p-value	0.000

* p-value (significance <0.05)

Here, the obtained absolute value (0.375) was positive. It exhibited statistical significance (p-value<0.05) and proved the rejection of the null hypothesis. As per the outcomes, in the present study, a high demand for flexible packaging material in various industries and its potential importance in packaging in the future were exposed.

3.5 FDA data

The medications' transparency, identity, and effectiveness were inspected by the Food and Drug Administration (FDA). FDA also examined the packaging quality, which preserved the drugs' potential throughout their shelf life. In the present study, drug-related complaint data from 2015 to April 2022 were officially obtained with the help of Information under the Right to Information Act 2005 from the Department of FDA, Goa. Table 6 displays the attained issues.

Table 6: Complaints related to drugs

Complaint No.	Date	Description
1	11/04/2016	Dirt particles seen in disodium hydrogen citrate syrup (100ml) – Alkastar dispensed from ESI dispensary.
2	23/05/2016	Found black particles on Waterbury's compound.
3	05/02/2018	Beclate forte tablets released grey smoke and grey fumes from the mouth soon after intake.
4	18/11/2019	Fungus in tablet Purecod B. No. ABT 18064.
5	28/06/2020	A tobacco-like substance found in Dabur Chawanprash.
6	29/06/2020	Colour change in gripe water.
7	24/11/2020	Spots seen on ondansetron tablets (IP 4mg). Manufactured by M/s Stallion Lab Pvt. Ltd, Ahmedabad.
8	11/10/2021	Different coloured Rosiva-10 tablets.

Table 6 shows that the present research identified various upstream issues with products that were FDA-approved and currently in circulation to consumers. Out of 8 complaints, 4 complaints (3, 4, 6, and 7) proved the contamination of drugs. Toxic chemicals, microbes, and other undesirable factors that raised various health issues contaminated the exposed medication. Additionally, the quality issues were revealed by three complaints (1, 2, and 5). As per the outcomes, product packaging significantly posed health hazards to the patients. Therefore, the FDA should approve the quality of the

medication and packaging for safe and effective treatment before marketing the medicine. Further, the authorities should approve the packaging for retail distribution. Furthermore, to increase the patients' well-being, enhanced medication accessing and screening approaches and flexible packaging material utilization should be employed.

4. DISCUSSION

The packaging industry played a noteworthy role in the growth as well as development of the pharmaceutical industry. Various complaints were still raised about the quality and consistency of the packaging by consumers, although a vast number of analyses were conducted to find out the root cause of the problem. Therefore, assessing the quality-based approach for the packaging of oral pharmaceuticals is the aim of the present study. Here, the highest and lowest domestic and export market mobility of various packaging materials were claimed by the packaging material converters. As per the outcomes, the enhanced market movement and potential usage of flexible materials in various sectors were proven. Similarly, (Nexdigm, 2025) also showed a vast growth of flexible materials like papers/boards, aluminium foils, and other flexible materials. As per the report, the retail sector of Indian packaging solutions attained a growth of over $99 billion in turnover in 2023. This research also identified that the quality of packaging materials was majorly influenced by factors like acceptability, environmental state, cost, and convenience. According to (Bhakar, 2024), acceptability, capability, mode of administration, marketing area, cost, content reactivity, and environmental status played a significant role in packaging materials' quality and shelf-life. According to quality deficiency studies, the packaging defects highly affected the product quality and resulted in an adverse impact on various sectors. Similarly, (Ghourichay et al., 2021) also identified the major association between the quality controls and packaging considerations. It also recommended the necessity for advanced technologies and optimum environmental conditions for enhancing the mechanical strength and distinct packaging of the oral pharmaceutical products. The material type did not play a major role in the packaging industry, although the flexible materials were highly preferred by various industries. Moreover, the outcomes of (Newton, 2023) also suggested that suitable packaging materials were preferred by the industries based on the type of product. But, it didn't impact the packaging industries. Over 77% of pharmaceutical manufacturers in India were liable for the development of pharmaceutical formulations. But, 32% of pharmaceuticals were rejected globally due to the lack of quality control, and 70% of goods were slated for export. Therefore, to enhance the market movement, an established and well-organised system should be implemented to manufacture and verify the quality and maintenance of packaging materials.

5. CONCLUSION

In the present study, the need for a quality-based approach for the packaging of oral pharmaceuticals was shown. The domestic and export market mobility of the various packaging materials was analysed in this research. In addition, the increased market demand for flexible materials (80% in domestic and 60% in export markets) was expressed by the outcomes. The study also assessed the packaging material influencing factors and identified that the material quality was majorly (100%) influenced by the acceptability, environmental state, cost, and convenience. The preference for flexible materials (50%) in various industries was also confirmed by the end-consumer responses. Moreover, the interlink between packaging defects (44%) and product quality was also exposed by the quality deficiency studies. Furthermore, a significant relationship (p-value<0.05) between the flexible material preference on various industries was also proven in the studies. Therefore, to enrich the market mobility of the materials and products' quality, advanced techniques should be employed to verify the quality control of packaging materials. However, the precision of the study was reduced by inaccurate respondent replies, limited primary and secondary data, and incorrect population reflections. To enhance the study outcomes, an immense amount of primary and secondary data, enriched consumer preference awareness, and more uniform representations should be included in the future.

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