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Importance of In-Process Quality Control for Product Safety and Integrity in Pharmaceutical Packaging

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Keywords

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Abstract

In-process quality control (IPQC) is a crucial aspect of pharmaceutical industries, ensuring accurate packaging processes and high-quality final products. It involves a comprehensive approach, including visual inspection of packaging materials and finished products, weighing and volume checks, sealing integrity assessment, accurate labelling, and monitoring of packaging line parameters. The process also scrutinises the legibility and accuracy of printed packaging information, reviews batch records for adherence to standard procedures and good manufacturing practices, monitors tamper-evident features and environmental conditions, and collects random samples for testing. All IPQC activities are thoroughly documented. The collected data is managed and analysed for trend identification, issue resolution, and continuous process improvement. Effective IPQC implementation reduces the risk of defects and regulatory non-compliance, ensuring product safety, efficacy, and maintaining the company's reputation.

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1. Introduction

Pharmaceutical packaging plays a pivotal role in drug development and distribution, encompassing design, production, and labelling to fulfil a multitude of vital functions. The role of packaging includes identification, protection, information, presentation, and convenience (IPIPC) [1] as shown in Figure 1. Packaging primarily shields pharmaceutical products from environmental factors, such as light, moisture, air, and contaminants, preserving their quality and efficacy. Packaging facilitates accurate dosing and easy dispensing, with critical information provided on labels and inserts [2]. Compliance with regulatory requirements and Good Manufacturing Practices (GMP) is essential. Adherence to pharmacopoeias and the adoption of sustainable, eco-friendly materials are increasingly significant in the pharmaceutical industry. The choice of packaging format varies based on product nature, dosing needs, and regulatory mandates. Ultimately, pharmaceutical packaging is indispensable in upholding the safety, efficacy, and integrity of pharmaceutical products as they reach end-users [3].

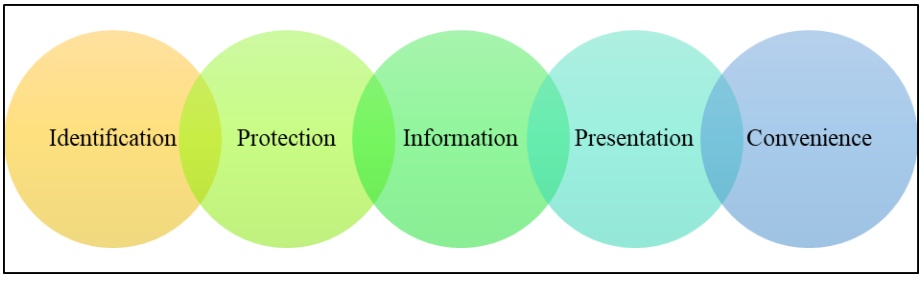

Figure 1: Role of packaging (IPIPC)

Packaging is generally categorized into three main types: primary, secondary, and tertiary packaging. Primary packaging is the first layer that directly encloses and protects the product. Examples include bottles for liquids, blister packs for pharmaceuticals, ampoules for single-dose medications, vials for various drugs, and tubes for semi-solid products. Secondary packaging is designed to group multiple primary packages together, aiding in branding, handling, and logistics [4]. Common forms include shrink wraps for bundling, corrugated boxes for transportation, cardboard sleeves for added information or branding, and display cases used for retail presentation. Tertiary packaging is intended for bulk handling, storage, and shipping. This includes pallets for moving large product quantities, stretch films for securing goods on pallets, strapping to hold heavy loads in place, and shrink hoods to protect items during transportation [5].

2. Packaging Operation

Packaging operations within manufacturing are a sequence of essential processes that culminate in the transformation of products into their final packaging, ensuring protection, labelling, and readiness for distribution. These operations encompass primary packaging, involving containers like bottles and blister packs, and the subsequent steps of filling, capping, labelling, and coding to provide information, traceability, and compliance. Quality control checks are integrated throughout, encompassing visual inspection and weight verification, while secondary packaging combines products into boxes, cartons, or shrink-wrapped units for both protection and marketing purposes [6]. Palletising and shrink wrapping enable efficient storage and transportation, and, ultimately, the products are poised for distribution, involving truck loading and logistics management. In today's landscape, sustainability is an increasingly central concern, with a growing emphasis on reducing waste and employing eco-friendly materials. The effectiveness and precision of these operations are paramount in ensuring product safety and quality while adhering to regulatory standards and advancing sustainability goals [7].

2.1 In-process Quality Control

IPQC is a vital aspect of pharmaceutical manufacturing, ensuring regulatory compliance, product consistency, patient safety, and process efficiency. It involves monitoring critical parameters during production to maintain quality and detect issues early. IPQC is integral to process validation, traceability, and risk mitigation, helping to prevent product defects and recalls. It also contributes to cost-effectiveness by optimising resource utilisation and reducing waste. Data collected during IPQC is used for trend analysis and continuous process improvement. Adequate personnel training and comprehensive documentation are also crucial components of IPQC. Overall, IPQC plays a significant role in producing safe and effective pharmaceutical products [8-10].

IPQC during packaging operations is an essential element in the pharmaceutical and other industries to ensure the accuracy and quality of the packaging process. This involves a series of meticulous steps, including material inspection, visual examination, and labeling accuracy verification to detect and prevent defects or discrepancies in packaging materials and final products. Ensuring proper sealing integrity and environmental conditions, as well as reviewing batch records, are vital to maintaining product quality and regulatory compliance. Sampling and testing, along with thorough documentation and personnel training, further contribute to the reliability of the packaging process. Effective data management and analysis allow for continuous improvement. Overall, these IPQC measures are crucial for error prevention, defect reduction, and upholding both product quality and a company's reputation and regulatory adherence [11-13].

3. Ipqc Tests in Pharmaceutical Packaging Operations

IPQC in packaging operations encompasses a range of tests. These include Visual Inspection, Weight and Volume Checks, Sealing Integrity, Labelling, Accuracy, Packaging Line Parameters, Print Quality, Batch Record Review, Tamper-Evident Features, Environmental Monitoring, Sampling and Testing, Documentation, Training and Compliance, Data Management. All these IPQC tests, along with their advantages and limitations, have been described in Table 1 [14-16].

3.1 Visual Inspection

Visual inspection is a pivotal initial stage in quality control, particularly in packaging operations. Skilled operators meticulously examine packaging materials, labels, and the final product to detect any apparent defects, such as damaged containers, erroneous labels, or printing imperfections. This visual scrutiny plays a fundamental role in maintaining product quality and preventing visible errors in the packaging process [17].

3.2 Weight and Volume Checks

Weight and volume checks are imperative for products that are sold based on their weight or volume. In this quality control step, precise weighing or measuring systems are employed to verify that the accurate quantity of product is dispensed into each container. Any variations from the specified measurements trigger further scrutiny and investigation. This meticulous process ensures that products are consistently packaged with the correct amounts, upholding both quality and regulatory compliance in the packaging operations [18].

3.3 Sealing Integrity

Sealing integrity is a critical aspect of packaging operations, ensuring the protection of the product from contamination and preserving its integrity. A series of seal integrity tests, including visual inspections, leak testing, and seal strength assessments, are conducted to confirm that the packaging is effectively sealed. Visual inspections detect visible seal defects, while leak testing identifies potential leaks that could compromise the product. Seal strength testing assesses the durability and

robustness of the seals. These measures collectively guarantee that packaging remains intact, safeguarding product quality and safety [19, 20].

Leak testing is performed to detect potential leaks in packaging seals, ensuring product integrity and safety. Several methods are commonly used for this purpose. The Bubble Emission Test involves submerging the sealed area in water or a suitable liquid and observing for air bubbles, which indicate the presence of a leak. The Dye Penetration Test applies a colored dye to the seal; if the dye seeps through, it suggests a compromised seal. Another method is the Vacuum or Pressure Decay Test, where the sealed product is subjected to vacuum or pressure conditions, and any subsequent pressure change is monitored to detect possible leaks [21, 22].

3.4 Labeling Accuracy

Labeling accuracy is a vital component of IPQC in packaging operations. This process entails ensuring that labels are not only accurately applied but also contain comprehensive and precise information about the product. Specifically, IPQC checks that the labels display the correct details, including the product's name, dosage, expiration date, lot number, and barcode. By meticulously verifying this information, packaging operations can guarantee the correctness of product labels, which is paramount for regulatory compliance, product safety, and the prevention of labeling errors [23, 24].

3.5 Packaging Line Parameters

Monitoring and controlling packaging line parameters play a crucial role in IPQC during packaging operations. This involves continuous oversight and adjustment of various machine settings to ensure that they fall within specified tolerances. Key parameters include fill levels, capping or sealing pressures, and line speeds. By maintaining these parameters within defined limits, packaging operations can uphold product quality, safety, and compliance with regulatory requirements. This meticulous control is essential for the prevention of deviations and errors in the packaging process [25, 26].

3.6 Print Quality

The assessment of print quality is a critical step in IPQC for products with printed packaging during the packaging operations. This involves scrutinizing the legibility and precision of printed information, including critical data like expiration dates and barcodes. The aim is to confirm that the printed details meet regulatory requirements, ensuring that essential product information is clearly and accurately conveyed. By maintaining high print quality standards, packaging operations can ensure product compliance and safety while avoiding issues related to illegible or erroneous printing [27, 28].

3.7 Batch Record Review

Batch record review is a pivotal element of IPQC during packaging operations. IPQC personnel meticulously examine batch records and log entries to confirm that the packaging process adheres to established standard operating procedures (SOPs) and complies with good manufacturing practices (GMP). This comprehensive review ensures that all steps and activities are executed in accordance with the approved processes, maintaining the quality and integrity of the products being packaged. It also serves as a crucial part of regulatory compliance, traceability, and the prevention of deviations from quality standards. [29-31].

3.8 Tamper-Evident Features

Ensuring the integrity of tamper-evident features is a key responsibility of IPQC in the packaging of certain pharmaceutical products. This verification process involves confirming that tamper-evident packaging components, such as shrink bands or breakable caps, are not only present but are also functioning as intended. These features are essential for providing consumers with visible indications of potential tampering, enhancing the safety and security of pharmaceutical products. Proper IPQC helps guarantee that tamper-evident measures are in place to meet regulatory requirements and protect consumer well-being [32-34].

3.9 Environmental Monitoring

Environmental monitoring is a critical aspect of IPQC during packaging operations. It involves the continuous oversight of environmental conditions, including temperature and humidity, to confirm that the packaging process takes place in an environment that is suitable and won't pose risks to the product's quality. Maintaining the appropriate environmental conditions is essential to safeguard product integrity and prevent environmental factors from compromising the safety and efficacy of the packaged products. IPQC plays a vital role in ensuring that the packaging environment is conducive to product preservation and quality maintenance [35-38].

3.10 Sampling and Testing

Sampling and testing are integral components of IPQC during packaging operations. At various points in the process, random samples are collected, and these samples undergo a battery of tests to verify quality and compliance with established standards. Depending on the product type, these tests can include assessments of content uniformity, disintegration, and dissolution, particularly for solid dosage forms like tablets and capsules. These rigorous tests ensure that the packaged products meet specified quality and regulatory criteria, maintaining their safety, efficacy, and adherence to quality standards [39-41].

3.11 Documentation

Documentation is a fundamental aspect of IPQC during packaging operations. It involves the comprehensive recording of all IPQC activities. These records should encompass detailed information regarding inspections, tests, deviations from established standards, and any corrective actions taken. Strong documentation practices are vital for meeting regulatory requirements, ensuring traceability, and upholding quality assurance. It provides a clear and organised record of all quality

control activities, ensuring transparency, accountability, and the ability to track and address any issues that may arise during the packaging process [42-44].

Table 1: Various IPQC tests along with their advantages and limitations.

S. No.	IPQC Test	Description	Advantages	Limitations	References
1.	Visual Inspection	Detects visible defects in packaging materials.	Quick, cost-effective quality check.	Subject to human error.	[45]
2.	Weight and Volume Checks	Verifies accurate product quantities in containers.	Ensures consistent and compliant packaging.	May require specialized equipment.	[46]
3.	Sealing Integrity	Ensures proper sealing to protect product integrity.	Prevents contamination and preserves product.	Requires specialized testing equipment.	[47]
4.	Labeling Accuracy	Confirms correct and compliant label information.	Ensures accurate product information.	Manual inspection may be labor-intensive.	[48]
5.	Packaging Line Parameters	Monitors and controls machine settings.	Maintains product quality and compliance.	Requires ongoing adjustment and monitoring.	[49]
6.	Print Quality	Assesses legibility and accuracy of printed information.	Ensures compliance and information clarity.	Subject to variations in printing process.	[50]
7.	Batch Record Review	Examines batch records and log entries.	Confirms adherence to procedures.	Relies on accurate record-keeping.	[51]
8.	Tamper-Evident Features	Ensures tamper-evident components are functional.	Enhances product safety and security.	Limited to products requiring these features.	[52]
9.	Environmental Monitoring	Monitors and controls environmental conditions.	Protects product quality from environmental factors.	Continuous monitoring may be resource-intensive.	[53]
10.	Sampling and Testing	Collects and tests random samples during packaging process.	Verifies quality and regulatory compliance.	Testing may involve additional resources or time.	[54]
11.	Documentation	Records detailed information on IPQC activities.	Ensures traceability and regulatory compliance.	Requires consistent record-keeping practices.	[55]

4. IPQC of Tablet Packaging Operation

IPQC for tablet packaging involves a comprehensive set of measures to verify the quality, accuracy, and compliance of the packaging process. This includes inspecting packaging materials, conducting visual assessments of the tablets, ensuring count accuracy, verifying the presence of desiccants for moisture-sensitive products, confirming the accuracy of printing and labeling, and validating the integrity of seals. Batch record reviews, tamper-evident feature checks, environmental monitoring, and extensive sampling and testing further guarantee tablet quality, safety, and compliance. The meticulous documentation of these IPQC activities is vital for regulatory adherence and traceability, ensuring that pharmaceutical tablets are correctly packaged, safe, and in compliance with quality standards, ultimately safeguarding patient well-being and product integrity throughout the packaging process [56].

4.1 Protruding Product Sensor Test

Protruding Product Sensor Test is a critical quality control procedure performed at the start of each batch in tablet packaging operations to ensure accurate tablet

placement and prevent packaging errors. The test begins with the operator placing a tablet so that it protrudes from its blister pocket, then initiating the machine. The system should detect the irregular placement and automatically halt. In the next step, the operator places a tablet on the web, but outside the designated pocket, and restarts the machine. Again, the machine is expected to detect the anomaly and stop. If the machine fails to respond in either case, the operator must adjust the protruding product sensor and repeat the test. This process ensures that any misalignment or improper placement is identified and corrected promptly, preserving the quality and integrity of the packaging process [57].

4.2 Pin Hole Detector Test

The Pin Hole Detector Test is a crucial procedure conducted at the onset of each batch, specifically for packaging operations involving an aluminium base foil. This test is designed to identify any holes or cracks up to 25 microns that may have been created during the cold forming of the blister pockets. The operating temperature range for this test is between 0 and +40°C. If any irregularities are detected, it indicates a need for adjustments in the packaging process to maintain the integrity and quality of the product [58].

4.3 Leak Test Detector

Leak Test Detector is a crucial quality control procedure conducted at the beginning of each batch to ensure the integrity of sealed tablet strips. The test involves several steps. First, strips are collected from the packaging machine. Water is then poured into a desiccator until it is one-third full, followed by the addition of a few drops of methylene blue, which is mixed to produce a blue solution. The collected strips are fully immersed in this solution, and a disc is placed over them to keep them submerged. A vacuum pump is then activated, and once the desired vacuum level is reached, the regulator is locked to maintain the vacuum for a set duration. Afterward, the regulator is unlocked and the valve is opened to release the vacuum. The strips are carefully observed—if any of them turn blue, it indicates the presence of leaks. This test is essential for verifying the seal integrity of packaging and maintaining product quality [59].

4.4 Barcode Sensor Test for Cartons and Leaflets

The Barcode Sensor Test for Cartons and Leaflets is an in-process check conducted by the packing process operator every half an hour. This test aims to ensure that all cartons have accurately embossed data and printed information. The sensor works by using optical scanning heads that convert a printed signal into a series of electronic signals. These signals are then compared with a reference code, often referred to as the Pharmacode, loaded into the code reader. If a barcode does not match the reference, the carton is rejected. Carton Bundle Inspection is a quality control procedure aimed at verifying the accuracy and integrity of packaging before further processing. The procedure involves the following steps: the operator collects a bundle of cartons from the stretch bender. The selected bundle is then examined for several key aspects, including the presence of a correct and legible batch number and expiry date embossed on each carton, ensuring all cartons are neatly folded without creases or dents, and confirming that all cartons are aligned in the same direction. Additionally, the operator checks that the bundle contains the correct number of cartons. This inspection ensures consistency in packaging quality and the accuracy of critical product information provided on each carton [60].

Future Perspective

The future of IPQC in pharmaceutical packaging is set to be transformed by the Internet of Things (IoT) and Industry 4.0 technologies, which will bring about significant advancements in real-time monitoring, predictive maintenance, and process optimization. The integration of IoT devices will provide immediate data on critical parameters, enabling continuous monitoring and predictive analytics to pre-empt equipment issues, thereby ensuring consistent production quality. Sustainability will become a core focus, with the industry adopting eco-friendly materials and optimizing packaging designs to minimize waste, alongside implementing recycling processes. Regulatory compliance will be bolstered by IoT's advanced track-and-trace systems, ensuring adherence to stringent standards and preventing counterfeit products from entering the market. Data analytics will play a crucial role in continuous improvement, analyzing the wealth of data generated by IoT to optimize processes and improve product quality. Automation and system integration will further enhance operational efficiency and product safety. Together, these technological advancements will lead to a proactive approach to quality control, ensuring the highest standards of safety and efficacy for pharmaceutical products and improving patient outcomes. This comprehensive approach will not only address environmental concerns but also lead to cost savings and brand enhancement while maintaining compliance with evolving regulatory standards [61].

Conclusion

The packaging operation sequence is a complex process that transforms raw materials into their final packaged form. This involves several stages, each with its own set of quality control checks. The primary purpose of these checks is to ensure that the product is properly enclosed and protected, correctly labeled, and ready for distribution. Any deviation from the established standards at any stage of this process can have serious implications for the quality and safety of the final product. For instance, in tablet packaging, a comprehensive set of measures are taken to verify the quality, accuracy, and compliance of the packaging process. This includes inspecting materials for defects, conducting visual assessments to detect any abnormalities, ensuring count accuracy to prevent over or under-filling, verifying desiccants to control moisture levels within the package, confirming printing and labeling accuracy to ensure correct product identification and information dissemination, validating seal integrity to prevent contamination or tampering, checking tamper-evident features to provide visible evidence of attempted tampering, monitoring environmental conditions to maintain optimal storage conditions, sampling and testing

tablets to verify their quality and efficacy, reviewing batch records to ensure compliance with manufacturing protocols, documenting IPQC activities for traceability and accountability. These processes collectively contribute to the overall quality assurance of pharmaceutical products. They not only safeguard public health by ensuring that only safe and effective products reach consumers but also uphold industry standards by promoting best practices in pharmaceutical manufacturing. Therefore, IPQC serves as a critical checkpoint in the pharmaceutical manufacturing process that warrants meticulous execution and continuous improvement.

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Author Contributions

M.T. Solely conceptualized, researched, and prepared the manuscript.

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Conflicts of Interest

No conflicts of interest are disclosed by the authors.

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