UDC 621.3.095.2 **doi: 10.26906/SUNZ.2024.4.119**

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SMART PACKAGING OF PHARMACEUTICAL PRODUCTS

Abstract. Smart packaging of pharmaceutical products covers modern technologies that are transforming packaging approaches in the pharmaceutical industry. The study demonstrates how the use of intelligent systems, such as temperature and humidity sensors, RFID tags, and time indicators, improves control over the storage and transportation of products. In particular, smart packaging not only ensures the safety and quality of medicines, but also meets modern market requirements for transparency and regulatory compliance. The importance of smart technologies in packaging is growing due to the needs of consumers, who demand reliability and additional information about products. Thus, investments in smart packaging are becoming essential to maintain competitiveness in the global market.

Keywords: smart packaging, pharmaceutical products, packaging technologies, RFID, monitoring storage conditions, intelligent systems, quality control, transparency, regulatory requirements, technology investments.

Introduction

In the modern pharmaceutical industry, smart packaging plays a key role in ensuring the quality, safety and traceability of medicines at all stages of their life cycle - from production to delivery to the end consumer. Today, the development of the Industry 4.0 concept, characterized by the integration of smart technologies and automation of production processes, poses new challenges for pharmaceutical companies in terms of implementing innovative solutions for monitoring and controlling product quality. Smart packaging, which includes temperature, humidity and other sensors, allows for continuous monitoring of storage conditions, instant detection of violations and prevention of possible negative consequences for patients. Given the high requirements for drug safety and the growing importance of product traceability, the use of smart packaging technologies is becoming an integral part of sustainable and safe production. The implementation of such solutions helps pharmaceutical products meet international quality standards and allows companies to adapt to the new realities of Industry 4.0, where digitalization, quick access to data and its analysis for making informed management decisions are of particular importance.

The purpose of the article is to study and substantiate the feasibility of introducing smart packaging technologies for pharmaceutical products in terms of improving the quality, safety and efficiency of managing the storage and transportation of medicines. The study aims to identify the key advantages and challenges associated with the use of smart packaging equipped with temperature, humidity and other parameters, as well as to determine their role in the current conditions caused by the concept of the Industry. The results of the study should help to understand the need to integrate innovative solutions into the pharmaceutical packaging industry to ensure high product quality standards and compliance with international norms and standards in the supply chain.

Main part

The trend of smart packaging in the pharmaceutical industry, which includes temperature and humidity indicators, is an important area for ensuring the quality and safety of medicines at all stages of their life cycle - from production to delivery to the consumer. Smart packaging is designed to solve the problem of monitoring storage and transportation conditions, as many medicines are sensitive to changes in temperature and humidity.

The development of smart packaging for pharmaceuticals is based on international standards that define the requirements for quality, safety and control over storage conditions. The main standards governing this area are: ISO 15378 is a standard for primary packaging of medicines that covers requirements for materials, production, and quality control. It applies the principles of GMP (Good Manufacturing Practice) and describes the requirements for the packaging of sensitive pharmaceutical products [1]; ISO 13485 is a standard for quality management systems in the production of medical devices, which also covers technologies for controlling the storage and transportation of pharmaceuticals [2]; USP 1079 - a standard developed in the United States, it contains recommendations for optimal storage conditions, protection against temperature fluctuations, humidity and other factors that may affect medicines [3]; GDP (Good Distribution Practice) is a European Union standard that defines the rules for ensuring the quality of pharmaceutical products during their transportation and storage. GDP contains requirements for smart packaging that controls environmental conditions.

Smart packaging requires the use of special electronic devices that allow you to monitor storage conditions and send information in real time:

1. Temperature and humidity indicators are small sensors that can continuously or periodically measure the temperature and humidity levels inside the package. These sensors often have the function of automatically recording data. They can be disposable or reusable, depending on the type of drug and the needs of the company" [4].

2. RFID (Radio Frequency Identification) is a technology that allows for wireless tracking of goods. RFID chips can be integrated into packaging and contain temperature and humidity data that is updated when conditions change. This technology allows you to automate the monitoring process and read data using an RFID reader at different stages of transportation [5].

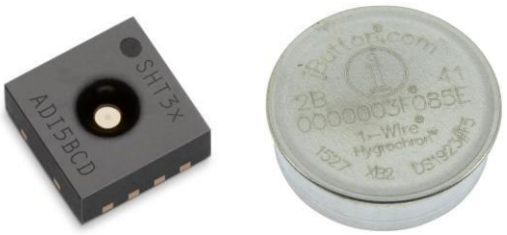
3. NFC (Near Field Communication) - allows you to get information about storage conditions using a smartphone or other NFC-enabled device. This ensures that data on the condition of the drug is available even to the end user, which can be of particular value for temperature-sensitive drugs [6].

4. Bluetooth Low Energy (BLE) - modules that allow the transmission of data on storage conditions over a short distance. BLE sensors can be configured to transmit data to mobile devices or the cloud, providing access to real-time storage data.

Single-use sensors - some packaging includes disposable indicators that change color when a certain temperature or humidity is reached, indicating a possible deterioration in product quality. This simple solution is cost-effective and easy to use, although it does not provide full real-time monitoring" [7].

A general view of the above sensors is shown in Fig. 1 and Table 1 shows a comparison of their technical characteristics.

The conclusions on the use of Sensirion SHT35-DIS-B and Maxim Integrated DS1923 iButton in smart packaging of pharmaceutical products show that both sensors have their advantages depending on specific requirements. The SHT35-DIS-B provides high accuracy and continuous real-time monitoring of temperature and humidity, which is suitable for products that require constant monitoring of storage conditions. However, it requires an external power supply and direct connection to the monitoring system. The DS1923 iButton, on the other hand, is convenient for tracking historical data due to its built-in memory and autonomous power supply, making it ideal for long-term monitoring during transportation. Thus, the choice between these devices depends on the need for continuous or intermittent monitoring and the storage conditions of the product.



a b

Fig. 1. Common temperature and humidity sensors used for smart packaging of pharmaceutical products: a – SHT35-DIS-B sensor [8]; b – Maxim Integrated DS1923 iButton logger [9]

Table 1 – **Comparison of technical characteristics of SHT35-DIS-B sensor and Maxim Integrated DS1923 iButton logger**

Characteristics	Sensirion SHT35-DIS-B [8]	MaximIntegratedDS1923 iButton [9]
Type	Digital sensor of temperature and humidity	Temperature and humidity logger
Temperature accuracy	±0.2°C (0to 60°C)	±0.5°C (0to 70°C)
Humidity accuracy	±1.5% RH (20% to 80% RH, at 25°C)	±5% RH (10% to 90%RH)
Temperature measurement range	-40°C to +125°C	-20°C to +85°C
Memory	Absent (transmits data in real time time)	8192, temperature and humidity records
Power consumption	Low	Works autonomously for a long time
Appointment	Continuous monitoring of conditions	Data logging for tracking purposes storage conditions
Form factor	Compact sensor	Compact in iButton format

Let's analyze disposable sensors that can be used for smart packaging of pharmaceutical products, providing temperature and humidity control during transportation in smart packaging of pharmaceutical products. Disposable sensors for smart pharmaceutical packaging usually have limited functionality and are used for one-time monitoring of temperature or humidity during transportation or storage. They do not store detailed data, but only indicate when thresholds are exceeded, often through a color change or other simple visual signal. Their specialty is that they are cost-effective, do not require batteries, and can be easily integrated into packaging. In contrast, reusable sensors for smart packaging are often equipped with more sophisticated electronics, can store data for long-term monitoring, and have the ability to transmit data in real time. Such sensors are used for continuous monitoring and analysis, which allows for detailed tracking of storage conditions and optimization of logistics processes for pharmaceutical products. A general view of disposable sensors that can be used for smart packaging of pharmaceutical products is shown in Fig. 2, and their technical characteristics are shown in Table 2.

Table 2 – **Comparison of technical characteristics of Temptime LIMITMarker and 3M MonitorMark**

Characteristics	TemptimeLIMITMarker [10]	3M MonitorMark[11]
Type	Disposable temperature indicator	
Temperature accuracy	Triggered at specified temperature thresholds	
Temperature measurement range	Depends on the model (thresholds from 0°C to +38°C)	
Data recording	Visual color change indicator	
Energy consumption	Does not require batteries	
Features	Instant detection of temperature regime violations	Easy to use, ideal for monitoring during transportation
Application	Control of the “cold chain”	Temperature control in pharmaceutical packaging

The analysis of the technical parameters of Temptime LIMITMarker and 3M MonitorMark shows their high efficiency in one-time monitoring of the temperature of pharmaceutical products. Both indicators do not require batteries, making them easy to use and cost-effective. The Temptime LIMITMarker offers flexibility in setting temperature thresholds, allowing it to be adapted to different storage conditions, while the 3M MonitorMark provides reliable control with fixed temperatures, which can be useful for standard products.

a b

Fig. 2. General view of single-use sensors that can be used for smart packaging of pharmaceutical products: a – Temptime LIMITMarker [10]; b – 3M MonitorMark [11]

The visual color change indicator in both models allows for instant detection of temperature abnormalities, which is critical to ensuring the quality and safety of pharmaceutical products. Due to their compact size, both sensors can be easily integrated into the packaging, making them ideal for monitoring the cold chain during transportation. Thus, the choice between these two indicators depends on the specific requirements for temperature control and flexibility in use. Obtaining data from disposable sensors for smart pharmaceutical packaging involves several steps that ensure monitoring of storage and transportation conditions. The main components of this structure include:

- the sensor part, disposable sensors such as Temptime LIMITMarker or 3M MonitorMark, equipped with sensors that respond to changes in temperature or humidity. The sensors constantly monitor the surrounding conditions, detecting violations of the set temperature thresholds; visual indicator, when conditions exceed the set values, the sensors activate a visual indicator, usually in the form of a color change. This indicator allows you to instantly detect whether the product has been exposed to unfavorable conditions, which is critical for pharmaceutical products;

- data storage, as a rule, does not store data on temperature conditions, as their purpose is to provide instant information about violations. Once the indicator is activated, the violation data cannot be saved or analyzed further;

- packaging integration, the sensors are designed to be easily integrated into the packaging of goods, which allows them to be used directly during transportation. This makes them effective for monitoring the "cold chain" during the transportation of temperature-sensitive pharmaceutical products.

- testing and verification, after receiving the results from the sensor, manufacturers or logistics companies can conduct verification by analyzing whether the color change of the indicator is really an indication of a violation of conditions;

- interaction with logistics systems, although disposable sensors do not transmit data in real time, they can be used in conjunction with other monitoring systems that automatically record the temperature conditions in containers during transportation. Such systems can be integrated into larger logistics platforms to provide comprehensive control.

Smart packaging in the pharmaceutical industry offers numerous benefits that significantly improve product management and safety. Firstly, the technologies used in smart packaging allow for continuous monitoring of storage conditions such as temperature and humidity, which is critical to maintaining the quality of pharmaceuticals. This significantly reduces the risk of loss of efficacy or product safety due to improper transportation conditions. In addition, smart packaging makes it possible to track the history of goods movement in real time, which contributes to increased transparency in the supply chain. An important aspect is also the ability to detect counterfeits, as modern technologies such as QR codes and RFID make it easy to verify the authenticity of goods. However, the use of smart packaging also has some disadvantages. The cost of implementing such technologies can be significant, making them less affordable for small businesses. There is also a need for staff training, which may require additional time and resources. In addition, the technologies may face compatibility issues with existing management systems. Despite these challenges, smart packaging remains an important step in the development of the pharmaceutical industry, as its advantages far outweigh its disadvantages, ensuring a high level of product control and safety.

The prospects for the use of sensors in smart packaging in the pharmaceutical industry look promising as the technology continues to evolve and improve. First of all, the integration of the latest sensor technologies, such as IoT (Internet of Things), can ensure continuous monitoring of storage and transportation conditions. This will reduce the risk of product spoilage and improve product quality. In addition, new sensors with self-learning capabilities will be able to adapt to different conditions, making them even more versatile and efficient. Advances in microelectronics will make it possible to create smaller and cheaper sensors, which will facilitate their widespread use even in small businesses. Connectivity to cloud platforms will enable in-depth analysis of sensor data, helping to identify trends and optimize processes. Users will also be able to receive real-time notifications of any deviations, which will facilitate timely response. At the same time, the introduction of blockchain technologies will provide an additional level of security and transparency, allowing for easy tracking of product history. Expanding the functions of sensors, such as measuring not only temperature but also other parameters such as oxygen or pH, will open up new horizons for quality control. Thus, the use of sensors in smart packaging is becoming not only a necessity, but also an opportunity to significantly improve efficiency and safety in the pharmaceutical industry. In the course of the study and analysis of scientific publications, the percentage of use of sensors, loggers and disposable sensors for smart packaging of pharmaceutical products was determined. The results obtained are shown in the graph in Fig. 3.

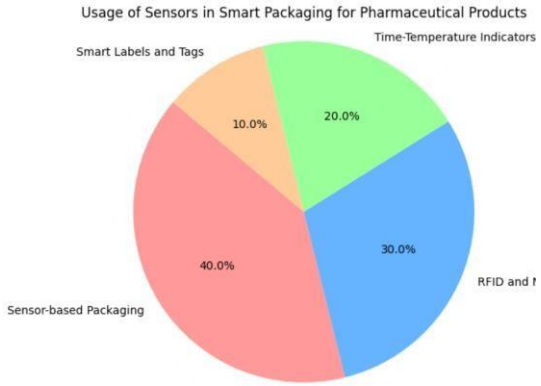


Fig. 3. Graph of the use of sensors, loggers and disposable sensors for smart packaging of pharmaceutical products

The pie chart below illustrates the distribution of sensor usage in smart pharmaceutical packaging, emphasizing the important role that each type of sensor plays in ensuring product safety and quality. Sensors based on touch technologies are the most common technology, accounting for 40% of the total usage, indicating the critical need to monitor environmental conditions such as temperature and humidity, which are vital to maintaining the effectiveness of pharmaceutical products. RFID and NFC technologies are next in importance, accounting for 30% of the total, demonstrating their importance in improving traceability and supply chain management by providing detailed product information and tracking capabilities throughout the distribution process. Time and temperature indicators account for 20% of the total, showing their function in alerting users to any temperature irregularities that could threaten product integrity. Finally, smart labels and tags, while making up the smallest portion at 10%, still play a valuable role by providing additional product information and improving the consumer experience. The trend towards increased adoption of smart packaging technologies is in line with the growing demand for improved product safety, regulatory compliance and consumer transparency in the pharmaceutical sector. This emphasis on integrating advanced technologies into packaging not only improves operational efficiency, but also supports sustainability efforts by potentially reducing waste and ensuring that products are stored and transported in optimal conditions.

Conclusions

During the study, it was found that smart packaging of pharmaceutical products has a significant impact on ensuring the quality and safety of goods. The integration of modern technologies, such as temperature and humidity sensors, RFID tags, as well as time and temperature indicators, allows not only to control the storage conditions of products but also to reduce the risk of product spoilage. This is especially important in the pharmaceutical sector, where compliance with product safety and quality standards is critical. Studies show that the introduction of smart packaging supports regulatory compliance, which significantly increases the responsibility of companies for the safety of their products. In addition, smart packaging provides convenience for consumers by providing access to additional information through smart labels, which contributes to better product awareness. Innovations in this area also help to reduce the negative impact on the environment by optimizing the use of resources. Thus, smart packaging not only meets modern market requirements, but also opens up new opportunities for the development of the pharmaceutical industry. It is important to note that investments in smart packaging technologies are becoming critically important for maintaining competitiveness in the growing global pharmaceutical market and improving the interaction between producers and consumers.

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Received (Надійшла) 25.08.2024
Accepted for publication (Прийнята до друку) 22.10.2024

Smart пакування фармацевтичної продукції

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Анотація. Смарт пакування фармацевтичної продукції охоплює сучасні технології, які трансформують підходи до упаковки в фармацевтичній індустрії. Дослідження демонструє, як використання інтелектуальних систем, таких як датчики температури та вологості, RFID-мітки та індикатори часу, покращує контроль за умовами зберігання та транспортування продукції. Зокрема, смарт пакування забезпечує не лише безпеку та якість лікарських засобів, але й відповідає сучасним вимогам ринку щодо прозорості та відповідності регуляторним нормам. Важливість смарт технологій у пакуванні зростає у зв'язку з потребами споживачів, що вимагають надійності та додаткової інформації про продукцію. Таким чином, інвестиції в смарт пакування стають необхідними для підтримки конкурентоспроможності на глобальному ринку.

Ключові слова: смарт пакування, фармацевтична продукція, технології упаковки, RFID, моніторинг умов зберігання, інтелектуальні системи, контроль якості, прозорість, регуляторні вимоги, інвестиції в технології.