HALALSPHERE

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MS 2424:2019: A mini review on contemporary issues and challenges of halal pharmaceuticals in Malaysia

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Abstract

The demand for halal pharmaceutical products has increased significantly due to growing consumer awareness and the need for medicines that comply with *Shari'ah* principles while ensuring safety, quality, and efficacy. Despite the introduction of the Malaysian Standard MS 2424:2019, implementing halal pharmaceutical requirements remains challenging due to complex supply chains, diverse raw material sources, and sophisticated manufacturing processes. Although previous studies have focused on specific issues such as animal-derived ingredients and halal certification, limited attention has been given to the broader implementation challenges addressed by MS 2424:2019. Therefore, this review examines the contemporary implementation challenges affecting Malaysia's halal pharmaceutical industry and analyses the role of MS 2424:2019 in safeguarding halal integrity. A qualitative literature review was conducted by systematically analysing peer-reviewed articles, conference papers, industry reports, regulatory documents, and MS 2424:2019, followed by thematic analysis. The review identified three major challenges: raw material traceability, cross-contamination during manufacturing, and limited halal knowledge and competency among industry stakeholders. The findings further highlight the importance of Halal Assurance Systems, supplier verification, documentation, and personnel competency in maintaining halal integrity. Overall, MS 2424:2019 provides a comprehensive framework for addressing these challenges. However, its effective implementation requires transparent supply chain management, competent personnel, and collaborative efforts among industry, regulatory authorities, and other stakeholders to strengthen the sustainability and global competitiveness of Malaysia's halal pharmaceutical industry.

1. Introduction

The halal pharmaceutical sector has become a crucial component of the global halal industry due to increasing demand for medicines and healthcare products that comply with Islamic principles. Statistics show that its valuation increased from US$ 94 billion in 2019 to US$ 105 billion in 2024 (Naimat *et al.*, 2023). Compared with halal food, halal pharmaceuticals require more complex formulations, advanced manufacturing technology, and various sources of raw materials, including both animal-derived and biotechnology-based ingredients (Herdiana *et al.*, 2024). This complexity indeed increases both issues regarding the halal status of pharmaceutical products and problems such as ingredient verification, contamination in processing facilities (Naimat *et al.*, 2023), and a lack of human capital (Amid *et al.*, 2024).

In Malaysia, the halal pharmaceutical industry plays an important role in supporting the country's goal to become a global halal hub. Moreover, under the New Industrial Master Plan 2030 (NIMP 2030), halal pharmaceuticals are a priority for advancing Malaysia into high-value, advanced manufacturing. To be able to support the country's target, a strong halal assurance is required within the pharmaceutical sector, and that is the reason for the Department of Standards Malaysia to introduce the Malaysian Standards (MS) 2424: 2019 – Halal Pharmaceuticals, which contains comprehensive guidelines to ensure compliance with the *Shari'ah* requirements throughout the production of pharmaceutical products (Department of Standards Malaysia, 2019). The standard highlights that compliance with the Shari'ah requirements covers all steps from the beginning until the end of the production of pharmaceutical products.

Recent studies have highlighted several challenges affecting the halal pharmaceutical industry, including the use of animal-derived ingredients, raw material traceability, cross-

contamination during manufacturing, and inadequate halal knowledge among industry personnel (Naima *et al.*, 2023; Herdiana *et al.*, 2024). While these studies have improved understanding of the operational and regulatory challenges faced by the industry, they primarily discuss these issues independently or from broader perspectives on halal pharmaceuticals and supply chains. Limited attention has been given to critically examining how the provisions of MS 2424:2019 address these contemporary implementation challenges within the Malaysian pharmaceutical industry. Furthermore, as MS 2424:2019 serves as the primary standard governing halal pharmaceutical compliance in Malaysia, there is a need to reassess its relevance in addressing current industry challenges, particularly in light of increasingly complex global supply chains and the continued growth of the halal pharmaceutical sector. Therefore, this review seeks to bridge this gap by examining contemporary implementation challenges alongside the requirements of MS 2424:2019 to provide a comprehensive understanding of its role in safeguarding halal integrity.

2. Challenges in the implementation of halal pharmaceuticals

2.1 Halal pharmaceutical

Recently, consumer preferences have shifted significantly towards products that align with religious beliefs, ethical values, and quality standards, driving increasing global demand for halal pharmaceutical products. This trend reflects not only the growth of the Muslim consumer market but also broader concerns regarding product safety, transparency, ethical sourcing, and sustainability in healthcare. Previous studies have reported that multiple factors, including religious obligations, confidence in product quality, ingredient traceability, and trust in halal certification systems, influence consumers' acceptance of halal pharmaceuticals. Consequently, halal pharmaceuticals have emerged as an important segment of the global pharmaceutical industry rather than merely a niche market for Muslim consumers.

The concept of halal pharmaceuticals extends beyond the prohibition of specific ingredients. It encompasses the entire pharmaceutical value chain, including raw material selection, manufacturing processes, storage, packaging, transportation, and quality management to ensure compliance with *Shari'ah* principles while maintaining product safety, efficacy, and quality. Halal Food Council USA (2023) defines halal pharmaceutical products as medications manufactured in accordance with Islamic principles, ensuring that both their ingredients and production processes comply with Islamic dietary laws and ethical standards. Similarly, the Malaysian Standard MS 2424:2019 (Halal Pharmaceuticals General Requirements) defines halal pharmaceutical products as pharmaceutical products that contain ingredients permitted under *Shari'ah* law and *fatwa*, free from prohibited animal-derived substances, *najs* (filth or impurities), human body parts and their derivatives, while being safe, efficacious, and physically segregated from non-halal materials throughout processing, preparation, handling, storage, and distribution (Naimat *et al.*, 2023)

Although these definitions establish the fundamental principles of halal pharmaceutical products, previous literature emphasizes that achieving halal integrity is considerably more complex than complying with ingredient requirements alone. Pharmaceutical manufacturing commonly involves numerous raw materials, excipients, processing aids, shared production facilities, and complex global supply chains, all of which increase the risk of contamination, cross-contamination, or the incorporation of non-halal substances. Consequently, maintaining halal integrity throughout the pharmaceutical supply chain has become one of the most critical challenges facing the halal pharmaceutical industry, necessitating comprehensive regulatory standards, effective halal assurance systems, and robust traceability mechanisms (Herdiana *et al.*, 2024).

2.2 Common contamination risks in halal pharmaceuticals

Despite the establishment of comprehensive definitions and regulatory requirements for halal pharmaceuticals, ensuring halal compliance in practice remains a significant challenge. The complexity of modern pharmaceutical manufacturing, characterised by diverse raw material sources, sophisticated production processes, and global supply chains, increases the potential for halal integrity to be compromised. Previous studies have highlighted that contamination and cross-contamination with non-halal substances can occur at multiple stages of the pharmaceutical value chain if appropriate control measures are not implemented. Consequently, understanding the sources and pathways of contamination is essential for maintaining halal integrity and strengthening consumer confidence in halal pharmaceutical products.

According to the Institute for Foods, Drugs, and Cosmetics LPPOM (2025), contamination in halal pharmaceuticals refers to the presence or involvement of non-halal (haram or doubtful) substances at any stage of drug development, production, or distribution. One of the most common risks arises from raw materials, especially active ingredients and excipients derived from animal sources such as gelatine, enzymes, glycerine, or stearates. When these substances are sourced from pigs or from animals not slaughtered according to Islamic law, the halal status of the medicine becomes compromised. Another major contamination risk occurs during manufacturing and processing. Pharmaceutical facilities often produce both halal and non-halal products using the same equipment. If proper cleaning (*taharah*) and segregation procedures are not strictly followed, cross-contamination may occur. This includes shared mixers, pipelines, storage tanks, or packaging lines that previously handled non-halal substances, particularly porcine-based materials (Zaimy *et al.*, 2025).

2.3 Raw material in pharmaceutical products

Previous reviews have consistently identified the use of animal-derived pharmaceutical ingredients, particularly porcine excipients such as gelatine, glycerine, and magnesium stearate, as one of the most significant challenges in halal pharmaceutical development, as their origin is often difficult to verify. Suitable halal alternatives may not always provide equivalent technological and functional properties (Herdiana *et al.*, 2024). A Malaysian study on the halal pharmaceutical industry identified raw material traceability and documentation as important considerations for halal assurance, noting that complex supply chains and variations in certification practices can pose challenges during verification. (Nasihah, *et al.*, 2023). Although regulatory frameworks for halal pharmaceuticals continue to evolve, enhancing transparency in raw material sourcing remains an important consideration for strengthening halal verification and ensuring

consistent halal integrity (Alzeer, 2025). Consequently, these challenges may compromise compliance with Clause 4.4.2(i) of MS 2424:2019, which requires pharmaceutical products to be produced using ingredients that comply with *Shari'ah* requirements and are supported by appropriate verification and documentation.

2.4 Contamination in the processing facility

Cross-contamination remains a critical operational challenge in halal pharmaceutical manufacturing because many facilities use shared production equipment for multiple products to optimize efficiency and reduce costs. While this practice is common under Good Manufacturing Practice (GMP), it presents additional challenges for halal-certified production when equipment has previously been used to process materials containing *najis mughallazah*, particularly porcine-derived ingredients. In such cases, maintaining halal integrity requires not only compliance with conventional sanitation procedures but also adherence to *Shari'ah*-specific cleansing (*sertu* or *taharah*), validated cleaning protocols, equipment segregation, and documented verification procedures to prevent contamination throughout the manufacturing process. However, studies have reported that implementing these requirements can be challenging due to the need for dedicated production facilities, additional operational costs, specialized personnel training, and integration of halal requirements into existing pharmaceutical quality management systems. (Rahman *et al.*, 2024)

To address these risks, MS 2424:2019 requires pharmaceutical manufacturers to implement preventive controls rather than relying solely on end-product inspection. In practice, compliance with Clause 4.4.2(ii)(c) and Clauses 4.9.6–4.9.7 is achieved through the establishment of dedicated halal production lines or validated conversion procedures for equipment previously exposed to *najis mughallazah*, supervised *sertu* cleansing, physical segregation of halal and non-halal production areas, comprehensive cleaning validation records, and routine monitoring under a Halal Assurance System (HAS). These measures are intended to minimize the risk of cross-contamination while providing documented evidence of halal compliance during regulatory inspections and halal certification audits. Failure to implement these controls may compromise the halal integrity of pharmaceutical products and affect compliance with MS 2424:2019 (Yana, 2025; MS 2424:2019).

2.5 Lack of halal-based knowledge

Beyond technical and operational challenges, the effective implementation of halal pharmaceutical requirements also depends on the competency of personnel responsible for maintaining halal compliance throughout the pharmaceutical value chain. Previous studies have identified limited halal-related knowledge and a shortage of qualified personnel as important barriers to the sustainable development of the halal pharmaceutical industry. Amid (2024) reported that insufficient knowledge among manufacturers, suppliers, regulators, and prospective industry participants regarding halal requirements, certification procedures, and regulatory expectations may hinder industry development and market expansion. Similarly, Lowe (2010) noted that consumers and some healthcare stakeholders often have limited awareness of the ingredients used in medicines and their corresponding halal status, which may affect informed decision-making and confidence in halal pharmaceutical products.

The knowledge gap extends beyond general awareness and includes specialized competencies in *Shari'ah* requirements for pharmaceutical ingredients, halal risk assessment, raw material verification, halal assurance system (HAS) implementation, traceability, documentation, and the application of *sertu* (*taharah*) procedures where applicable. Without personnel possessing these competencies, pharmaceutical manufacturers may encounter difficulties in consistently implementing halal control measures throughout procurement, manufacturing, storage, and distribution processes. Consequently, the availability of trained halal professionals is essential to support compliance with Clauses 4.2.3, 4.2.4, 4.4.2(ii)(a), 4.6.1, and 4.7 of MS 2424:2019, which require organizations to establish competent halal management personnel, provide appropriate training, implement effective halal control measures, and maintain a documented Halal Assurance System.

3. Analysis and discussion

3.1 Issue 1: Use of non-halal raw materials and unclear ingredient origin

Halal pharmaceutical production is a reality in which, unfortunately, porcine-based excipients are still used among animal-derived raw materials due to their good availability, functional reliability, and cost-effectiveness. Apart from porcine-derived ingredients, halal verification also extends to other pharmaceutical materials such as active pharmaceutical ingredients (APIs), processing aids, solvents, synthetic materials, and biotechnology-derived materials, including cell culture media, growth media, cell banks, and seed lots used in the production of biological products and vaccines. The halal status of these materials must also be verified because they may originate from animal-derived or other non-halal sources. However, pharmaceutical companies usually buy raw materials through a complex global supply chain with many suppliers and negotiators, making it hard to trace the true origin of ingredients and increasing reliance on supplier declarations.

Apart from that, a Malaysian study on the halal pharmaceutical industry found that verifying the origin and documentation of raw materials remains complicated due to complex supply chains and inconsistent certification practices, raising consumer concerns about halal compliance (Nasihah *et al.*, 2023). Although Malaysia has established MS 2424:2019 as a comprehensive standard for halal pharmaceutical production, implementing halal verification remains challenging because pharmaceutical manufacturers often source raw materials from multiple countries with different halal certification systems and varying levels of transparency. These challenges are not limited to conventional pharmaceutical ingredients but also involve specialized materials used in biotechnology and vaccine production, where complete documentation and traceability are required to maintain halal integrity (Alzeer, 2025).

Thus, these challenges may compromise compliance with Clause 4.4.2 (i) of MS 2424:2019, which requires all raw materials used in halal pharmaceutical products to originate from halal sources and be properly verified and documented. Therefore, manufacturers are required not only to verify porcine-derived excipients but also to establish effective traceability and supplier verification systems for all pharmaceutical materials used throughout the production process to ensure continuous halal compliance.

3.2 Issue 2: Cross-contamination during manufacturing processes

One of the main reasons for cross-contamination in halal pharmaceuticals is their common production alongside non-halal products. This risk is posed by contamination of pharmaceutical products through the use of shared equipment with improper purification techniques (*samak* or *taharah*). This poses a significant risk of contamination when pharmaceutical products come into contact with *Najis*, such as porcine-derived materials. Besides contamination from shared manufacturing equipment, halal risks may also arise during the handling of processing aids, biological materials, cell culture media, growth media, and cell banks used in the production of vaccines and other biotechnology-based pharmaceutical products. Therefore, effective segregation and verification are required throughout the manufacturing process to ensure these materials remain free of contamination. Malaysian standards like MS 2424:2019, through Clauses 4.4.2(ii)(c), 4.9.6, and 4.9.7, would control this risk by requiring proper segregation, validated cleaning procedures, and efficient contamination control measures. However, difficulties in fulfilling these requirements arise from the high financial burden of establishing dedicated halal facilities, the limited halal-cleansing know-how of staff, constraints on production scheduling, and the lack of comprehensive halal-specific cleaning validation guidelines. Thus, manufacturers might accidentally fall short of halal-specific contamination control standards while adhering to general GMP requirements.

3.3 Issue 3: The lack of halal knowledge and expertise among industry stakeholders

Beyond technical issues related to raw materials and manufacturing processes, the sustainable implementation of halal pharmaceutical practices also depends on the availability of competent personnel with interdisciplinary expertise in both pharmaceutical sciences and *Shari'ah* requirements. Unlike conventional pharmaceutical production, halal pharmaceutical manufacturing requires professionals to understand not only pharmaceutical quality, safety, and efficacy, but also halal-specific requirements, including ingredient verification, halal risk assessment, traceability, documentation, supplier qualification, and implementation of the Halal Assurance System (HAS). However, previous studies have identified a shortage of personnel possessing these combined competencies, particularly among manufacturers, suppliers, quality assurance personnel, and regulatory stakeholders (Amid, 2024; Herdiana *et al.*, 2024). The limited availability of halal expertise presents broader implications than a simple knowledge gap. In practice, inadequate understanding of halal requirements may affect decision-making during supplier selection, verification of animal-derived ingredients, management of shared manufacturing facilities, and documentation required for halal certification. These challenges become more pronounced as pharmaceutical supply chains increasingly involve multinational suppliers, contract manufacturers, and complex sourcing networks, requiring personnel to interpret both pharmaceutical regulations and halal requirements simultaneously. Furthermore, previous studies have highlighted that organizational commitment, continuous professional training, and management support remain important determinants of successful halal implementation, yet these aspects are not consistently prioritized across the pharmaceutical industry (Mohezar *et al.*, 2016; Khan *et al.*, 2023). The contemporary challenges facing Malaysia's halal pharmaceutical industry extend beyond regulatory compliance and reflect broader operational, technical, and human capital constraints. While issues relating to animal-derived ingredients, cross-contamination risks, and limited halal expertise have been widely reported in the literature, they are closely interconnected rather than occurring independently. For example, difficulties in verifying raw material origins are compounded by increasingly complex global supply chains. In contrast, effective contamination control relies not only on infrastructure but also on competent personnel who can consistently implement halal assurance procedures. Similarly, the shortage of halal expertise may affect manufacturers' ability to integrate halal requirements into existing pharmaceutical quality management systems.

Rather than merely prescribing compliance requirements, MS 2424:2019 provides a structured framework to address these interconnected challenges through requirements on ingredient verification, contamination prevention, personnel competency, documentation, and the implementation of a Halal Assurance System. Nevertheless, the continued growth of the halal pharmaceutical industry requires complementary efforts beyond regulatory compliance, including greater investment in halal competency development, stronger collaboration between regulatory authorities and industry, harmonization of halal standards across international supply chains, and wider adoption of digital traceability technologies to improve transparency and supply chain integrity. Addressing these areas will be essential for enhancing the global competitiveness and long-term sustainability of Malaysia's halal pharmaceutical industry.

4. Implications

The findings of this review indicate that contemporary challenges in halal pharmaceutical manufacturing extend beyond technical compliance with halal requirements and have broader implications for pharmaceutical governance, supply chain management, healthcare practice, and consumer confidence. As pharmaceutical supply chains become increasingly globalised, ensuring the halal integrity of raw materials, manufacturing processes, and finished products requires greater transparency, traceability, and collaboration among manufacturers, suppliers, certification bodies, and regulatory authorities. Consequently, halal compliance should be viewed as an integrated quality management approach rather than solely a certification requirement. From an industrial perspective, pharmaceutical manufacturers are increasingly expected to incorporate halal considerations into existing pharmaceutical quality management systems throughout the product life cycle. This includes strengthening supplier qualification procedures, improving ingredient traceability, validating cleaning and segregation protocols, implementing robust Halal Assurance Systems (HAS), and maintaining comprehensive documentation to support halal verification. Such measures not only facilitate compliance with MS 2424:2019 but also enhance operational transparency, strengthen consumer confidence, and improve the competitiveness of Malaysian halal pharmaceutical products in international markets. The review also highlights that strengthening halal governance requires coordinated efforts among multiple stakeholders rather than relying solely on halal certification authorities. Regulatory agencies, halal certification bodies, pharmaceutical manufacturers, professional associations, academic institutions, and training providers each have complementary roles in developing industry competency. Continuous professional education, interdisciplinary training that integrates pharmaceutical

sciences with *Shari'ah* principles, and closer collaboration between academia and industry are essential to developing a workforce capable of consistently implementing halal requirements across increasingly complex pharmaceutical supply chains. Such collaborative initiatives are likely to improve organizational readiness for halal certification while supporting long-term industry sustainability. For healthcare professionals, greater transparency regarding the halal status of pharmaceutical ingredients is important for supporting patient-centred care, particularly when advising Muslim patients on treatment options. Improved access to reliable information on ingredient sources and halal certification can facilitate informed clinical decision-making, strengthen communication between healthcare providers and patients, and enhance confidence in prescribed medications without compromising therapeutic effectiveness. From a societal perspective, maintaining halal integrity is fundamental to protecting consumer trust and upholding the ethical principles underpinning halal pharmaceutical products. Public confidence depends not only on the availability of halal-certified medicines but also on transparent supply chains, credible certification systems, and consistent regulatory oversight. Therefore, strengthening halal pharmaceutical governance through improved traceability, digital documentation systems, competency development, and stakeholder collaboration will be critical for supporting the sustainable growth and international competitiveness of Malaysia's halal pharmaceutical industry.

While MS 2424:2019 provides a comprehensive framework for safeguarding halal integrity, its effectiveness depends on consistent implementation supported by competent personnel, robust Halal Assurance Systems, transparent supply chain management, and effective collaboration among industry, regulatory authorities, healthcare professionals, and academic institutions. Future efforts should therefore focus on strengthening integrated halal governance, enhancing workforce competency, improving traceability technologies, and promoting international harmonization of halal pharmaceutical standards. Addressing these priorities will contribute to a more resilient, transparent, and globally competitive halal pharmaceutical industry while reinforcing consumer confidence in halal-certified medicines.

5. Conclusion and recommendations

In conclusion, this review demonstrates that the implementation of halal pharmaceutical requirements in Malaysia is influenced by a combination of technical, operational, and organizational challenges rather than by isolated compliance issues. The review identified three interrelated implementation challenges: verification and traceability of halal raw materials, prevention of cross-contamination during pharmaceutical manufacturing, and limited availability of halal-specific knowledge and expertise among industry stakeholders. As pharmaceutical products increasingly involve complex formulations, biotechnology-derived ingredients, multinational supply chains, and multiple manufacturing partners, maintaining halal integrity requires a comprehensive, integrated approach across the entire pharmaceutical value chain.

The findings further suggest that MS 2424:2019 provides a comprehensive regulatory framework for safeguarding halal integrity by establishing requirements for ingredient verification, contamination control, personnel competency, documentation, and the implementation of a Halal Assurance System. Nevertheless, the effectiveness of the standard depends not only on regulatory compliance but also on consistent implementation by pharmaceutical manufacturers, transparent supplier verification, robust quality management practices, and effective collaboration among regulatory authorities, halal certification bodies, industry, academic institutions, and healthcare professionals. Therefore, the successful implementation of halal pharmaceutical requirements should be viewed as a shared responsibility that requires coordinated governance and continuous capacity-building across the pharmaceutical ecosystem.

This review contributes to the current body of knowledge by synthesizing contemporary implementation challenges within the Malaysian halal pharmaceutical industry and highlighting the practical role of MS 2424:2019 in supporting halal integrity. Moving forward, greater attention should be directed towards strengthening halal competency development, enhancing digital traceability and supply chain transparency, harmonizing halal verification practices across international supply chains, and investigating emerging issues associated with biotechnology-derived pharmaceuticals and advanced pharmaceutical manufacturing technologies. Addressing these priorities will strengthen the resilience, credibility, and global competitiveness of Malaysia's halal pharmaceutical industry while supporting the sustainable implementation of halal pharmaceutical standards.

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