

Halal Pharmaceutical Excipients: Unveiling the Legal Normative Gap in Indonesia's Halal Product Assurance System for the Pharmaceutical Sectors

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ABSTRACT

The expansion of halal product assurance into the pharmaceutical sector has not been fully accompanied by a legal framework capable of addressing *pharmaceutical excipients* as integral components of drug formulations. Existing regulations remain oriented toward halal status at the product level, while the origin, processing, traceability, and use of excipients with halal concerns remain insufficiently regulated. This study aims to examine the adequacy of Indonesian regulations governing *pharmaceutical excipients* and to formulate a normative reconstruction for strengthening halal assurance in pharmaceutical products. Employing a qualitative normative juridical method, this study applies statutory, conceptual, and comparative approaches to secondary data comprising primary, secondary, and tertiary legal materials, analyzed through qualitative-prescriptive analysis. The findings demonstrate normative insufficiency and regulatory fragmentation concerning the legal status of *pharmaceutical excipients*, risk-based control, source and process verification, traceability, *darūrah*-based exceptions, and institutional coordination. The novelty of this study lies in proposing a normative model that integrates halal assurance with pharmaceutical regulation through explicit recognition of excipients, risk-based regulation, traceability, controlled *darūrah* exceptions, and continuous oversight. The model provides a basis for BPJPH, BPOM, and the Ministry of Health to strengthen coordinated halal oversight. This study is limited to normative juridical analysis and secondary legal materials and does not empirically assess the proposed model.

Keywords:

halal pharmaceutical, halal product assurance, pharmaceutical excipients, pharmaceutical law

Introduction

Questions regarding the halal status of medications can no longer be adequately answered by simply determining whether or not they contain haram ingredients. The issue has evolved into a matter of the extent to which the law can guarantee the halal integrity of pharmaceutical excipients, which are actually more susceptible to non-halal elements than the active pharmaceutical ingredients themselves. The globalization of pharmaceutical supply chains has placed *pharmaceutical excipients* within complex cross-jurisdictional networks involving diverse raw material sources and regulatory requirements that are not always harmonized (Doerine J Postma, Peter A G M De Smet, Aukje K Mantel-Teeuwisse, Hubert G M Leufkens, 2025; Haider, 2023; Heri Nurranto, 2025). This complexity creates regulatory challenges for verifying the origin, processing, and traceability of excipients, particularly where halal requirements differ across jurisdictions. Global halal pharmaceutical regulations have moved beyond the logic of certifying the final product toward ensuring halal compliance throughout the entire supply chain. Malaysia, through MS 2424:2019 (Latiff et al., 2023), and the Standards and Metrology Institute for Islamic Countries (OIC/SMIIC) which is developing international standards for halal pharmaceuticals serve as important examples of this shift (Putri & HM, 2025). Consequently, the halal status of a drug can no longer be assessed based solely on the final product; instead, all

constituent components including pharmaceutical excipients, which are a critical factor in halal compliance must be traced.

Indonesia's Halal Product Assurance regime has expanded its regulatory scope to include pharmaceutical products through Law No. 33 of 2014 on Halal Product Assurance, which was subsequently developed through Government Regulation No. 39 of 2021 and updated through Government Regulation No. 42 of 2024 on the Implementation of Halal Product Assurance. (Zulfa et al., 2023). However, this expansion has not been accompanied by the establishment of standards that specifically regulate pharmaceutical excipients as an integral part of drug formulations particularly regarding the source of materials, processing, verification, and traceability. This limitation becomes even more apparent when compared to the food sector, which is already supported by the Halal Assurance System (HAS) 23000 as a framework for controlling ingredients and processes to meet halal criteria (Fauzi & Rodin, 2024). The expansion of halal obligations in the pharmaceutical sector reveals a regulatory asymmetry: the scope of obligations has expanded, while the regulatory framework has not yet fully kept pace with the complexity of the regulated subjects. Ensuring the halal status of drugs should not stop at the final product but must extend to every component and stage that determines its halal integrity, including pharmaceutical excipients.

Research on halal assurance in the food sector has predominantly focused on certification, halal assurance systems, and consumer protection. In the food sector, Masri et al. position Halal Product Assurance as an instrument of legal protection for Muslim consumers, but do not elaborate on the sector-specific characteristics of pharmaceuticals (Masri et al., 2025). In the pharmaceutical sector, Irfany et al. highlight the importance of procurement strategies and supplier selection in maintaining halal integrity in the pharmaceutical industry, but their approach is primarily managerial rather than focused on legal norm construction (Irfany et al., 2025). Meanwhile, research on pharmaceutical ingredients has begun to address concerns regarding animal-derived materials. Herdiana et al. identify the risks associated with animal-derived ingredients in pharmaceutical products, but do not specifically examine *pharmaceutical excipients* within Indonesia's Halal Product Assurance regime. (Herdiana et al., 2026).

From legal and consumer protection perspectives, Romli et al. emphasize the importance of BPOM's role in protecting Muslim consumers from medicines that do not meet halal requirements, but do not examine in depth the respective authorities of BPOM and BPJPH in regulating pharmaceutical ingredients (Romli et al., 2023). Comparative research on Malaysia, Abu-Hussin et al. highlights the development of Malaysia's halal standardization architecture, including MS 2424:2019 as a halal pharmaceutical standard, providing a comparative reference for strengthening Indonesia's regulatory framework (Abu-Hussin et al., 2026). Overall, previous studies on *halal pharmaceuticals* have addressed consumer protection, industry governance, material risks, regulatory institutions, and halal standardization, but these perspectives remain fragmented and have not been integrated into a legal framework specifically governing *pharmaceutical excipients*. There remains a lack of research specifically examining the adequacy of Indonesia's legal norms in regulating *pharmaceutical excipients* as components that determine the halal status of medicines. Accordingly, the novelty of this study lies in the normative reconstruction of *pharmaceutical excipients* to establish legal certainty regarding the halal status of medicines at the level of their constituent materials.

Based on these normative gaps, this study addresses two main questions: (1) how are *pharmaceutical excipients* regulated, and how adequate is their regulation within Indonesia's Halal Product Assurance regime; and (2) how should these norms be reconstructed to establish legal certainty in halal pharmaceutical assurance? The contribution of this study lies in formulating a normative reconstruction that integrates the Halal Product Assurance regime with pharmaceutical regulations to establish a more coherent framework for regulating *pharmaceutical excipients* and ensuring the halal status of medicines.

Methods

This study employs a qualitative normative juridical method aimed at identifying normative gaps and formulating a normative model for regulating *pharmaceutical excipients* within Indonesia's Halal Product Assurance system. The study adopts statutory, conceptual, and comparative approaches. The statutory approach examines Law No. 33 of 2014 on Halal Product Assurance, Government Regulation No. 42 of 2024 on the Implementation of Halal Product Assurance as the currently applicable implementing regulation, Government Regulation No. 39 of 2021 as part of the preceding regulatory framework, Law No. 17 of 2023 on Health, and regulations governing medicines and pharmaceutical ingredients. The conceptual approach is used to analyze the concepts of halal assurance, *pharmaceutical excipients*, traceability, risk-based regulation, and *ḍarūrah*. The comparative approach uses Malaysia as a benchmark because it has a dedicated halal pharmaceutical standard, MS 2424:2019 (*Halal Pharmaceuticals General Guidelines*), which provides a relevant regulatory benchmark for the subject of this study. Malaysia was also selected because of its regional proximity to Indonesia and the more structured development of its halal pharmaceutical standardization framework in the aspects examined.

The study uses secondary data consisting of primary, secondary, and tertiary legal materials. Primary legal materials include legislation, technical regulations, and relevant standards. Secondary legal materials include journal articles, books, legal doctrines, and research findings selected based on their direct relevance to halal pharmaceuticals, *pharmaceutical excipients*, pharmaceutical regulation, consumer protection, and halal governance. Scholarly literature published within the past ten years was prioritized to capture recent regulatory and practical developments, with exceptions for foundational sources and key normative references. The literature was obtained through searches of academic databases and official regulatory sources, while sources lacking substantive relevance to the research focus or whose credibility could not be verified were excluded. Tertiary legal materials, including legal dictionaries and encyclopedias, were used to clarify relevant terminology.

Legal materials were collected through library research using systematic inventory, classification, and retrieval techniques based on the research themes. *Normative gap analysis* was operationalized by comparing existing norms with the regulatory requirements considered necessary based on four main parameters: (1) clarity of legal status, assessing whether *pharmaceutical excipients* are explicitly recognized as part of the objects subject to halal control; (2) substantive adequacy, assessing the regulation of the source, processing, verification, and halal status of materials; (3) traceability and risk control, assessing the availability of traceability mechanisms, risk classification, and controls over changes in materials or suppliers; and (4) institutional coherence, assessing the clarity of the respective authorities and coordination mechanisms among BPJPH, BPOM, and the Ministry of Health. A norm was considered inadequate where it revealed regulatory gaps, ambiguity, overlap, or inconsistency between halal assurance requirements and pharmaceutical regulations. The results were then compared with Malaysia's regulatory benchmark and analyzed qualitatively and prescriptively through grammatical, systematic, and conceptual interpretation. The overall analysis provides the basis for formulating recommendations and a normative model for regulating the sourcing, verification, traceability, *ḍarūrah*-based exceptions, and oversight of *pharmaceutical excipients* to strengthen legal certainty in halal pharmaceutical assurance.

Results and Discussions

Regulatory Asymmetry and the Invisibility of Pharmaceutical Excipients under the Halal Product Assurance Regime

The legal issue regarding the halal certification of medicines in Indonesia does not lie in the absence of medicines as subjects of the Halal Product Certification, but rather in the regulatory asymmetry between the expansion of certification requirements for pharmaceutical products and the depth of regulation regarding their constituent elements. Pharmacologically, drug formulations generally consist of Active Pharmaceutical Ingredients (APIs) and pharmaceutical excipients (Li, 2023). APIs are substances that provide pharmacological activity or therapeutic effects in the diagnosis, treatment, mitigation, or prevention of disease (Khan & Rauf, 2024).

Meanwhile, pharmaceutical excipients are components that enable APIs to be formulated into stable, effective drug preparations that can be delivered into the body (Kankala et al., 2021). Their functions include, among others, acting as solvents, stabilizers, buffers, emulsifiers, and antimicrobials (Yu et al., 2021). Thus, the halal status of a drug cannot be determined solely based on the status of the API, as excipients also contribute to the final composition consumed by the patient; therefore, disregarding their halal status means leaving a portion of the drug product untested for halal compliance.

Law No. 33 of 2014 on Halal Product Assurance (Halal Product Assurance Law) normatively includes medicines within the scope of products subject to halal assurance. Article 1 point 1 defines a product as “*goods and/or services related to food, beverages, medicines, cosmetics, chemical products, biological products, genetically engineered products, and consumer goods that are used, utilized, or benefited from by the public.*” Furthermore, Article 4 stipulates that “*Products entering, circulating, and traded within the territory of Indonesia must be halal-certified.*” Accordingly, medicines are explicitly included within the scope of products subject to halal certification. At the ingredient level, Article 17 paragraph (1) provides that “*Materials used in the Halal Product Process consist of raw materials, processed materials, additives, and processing aids*” (Law Number 33 of 2014 Concerning Halal Product Assurance, 2014). This provision demonstrates that the Halal Product Assurance Law recognizes and classifies materials used in the Halal Product Process. However, it does not specifically articulate *pharmaceutical excipients* as a distinct category of materials within the halal regulation of medicines. The issue, therefore, is not the absence of material categories, but the inadequacy of the parameters for determining the halal status of *pharmaceutical excipients*, including their sources, risk levels, verification, and supply-chain traceability. This creates a gap between the explicit inclusion of medicines within the scope of halal assurance and the predominantly general regulation of their constituent materials. The fundamental question that consequently arises is: how can the halal status of medicines be assured when the halal status of their constituent materials is not yet supported by adequate regulatory mechanisms?

Government Regulation No. 39 of 2021 on the Implementation of Halal Product Assurance constituted the preceding implementing framework of the Halal Product Assurance Law, including provisions relevant to halal assurance for pharmaceutical products. This framework was subsequently developed through Government Regulation No. 42 of 2024 on the Implementation of Halal Product Assurance, which constitutes the applicable implementing framework and the primary reference for this study. Government Regulation No. 39 of 2021 is examined to trace the development of the regulatory framework, while Government Regulation No. 42 of 2024 is used to assess the adequacy of the currently applicable norms. Although Government Regulation No. 42 of 2024 strengthens the administration of Halal Product Assurance, it does not specifically recognize *pharmaceutical excipients* as a distinct regulatory category within the halal assurance framework for pharmaceutical products (Devi & Fatimah, 2025; Government Regulation Number 42 of 2024 Concerning the Implementation of Halal Product Assurance, 2024). In addition, Presidential Regulation No. 6 of 2023 on Halal Certification of Pharmaceuticals, Biological Products, and Medical Devices recognizes the category of “additives” in the context of pharmaceutical products, but has not further developed this category into specific requirements governing the characteristics, sources, risk levels, verification, and traceability of materials used in pharmaceutical formulations. Thus, the Halal Product Assurance framework recognizes medicines and their constituent materials at a general level, but does not yet provide adequate parameters for determining and controlling the halal status of *pharmaceutical excipients* (Lutfia et al., 2025).

Meanwhile, Law No. 17 of 2023 on Health regulates pharmaceutical preparations primarily through the requirements of safety, efficacy, and quality, but does not integrate halal status as a regulatory parameter for controlling *pharmaceutical excipients*. (Probo et al., 2025). The two regulatory regimes therefore address the same objects medicines and their constituent materials, but operate through different regulatory objectives and parameters, the health regime focuses on safety, efficacy, and quality, whereas the Halal Product Assurance regime focuses on the halal status of products and the materials used in their production processes. The issue does not lie in

these different regulatory orientations, but in the lack of integration between the two regimes in regulating the halal status of pharmaceutical ingredients. A *pharmaceutical excipient* may satisfy pharmaceutical requirements for safety, efficacy, and quality without necessarily having a demonstrable halal status based on its source, processing, processing aids, and potential contamination. Conversely, compliance with halal requirements does not by itself establish compliance with pharmaceutical requirements for safety, efficacy, and quality. This condition demonstrates regulatory fragmentation that undermines legal certainty regarding halal claims for medicines, as the halal status of their constituent materials is not yet supported by verification, traceability, and oversight mechanisms integrated with the pharmaceutical regulatory system. Accordingly, normative reconstruction should be directed toward establishing a clear point of integration between halal and pharmaceutical requirements in the regulation and oversight of *pharmaceutical excipients*.

The halal status of pharmaceutical excipients cannot be determined simply by looking at the names of the ingredients listed on the packaging, because Islamic law considers not only what is contained in a product, but also where the ingredients come from and how they are produced. Gelatin, for example, cannot be assessed simply by referring to it as “gelatin”; it is necessary to know whether it comes from pigs or halal animals, and if it comes from halal animals, how it was obtained. The same applies to the other ingredients that make up a medicinal product. Some serve to form the container (gelatin), some fill the volume (lactose), some lubricate the production process (magnesium stearate), some act as preservatives (parabens), and some enhance the appearance (colorants, titanium dioxide), along with other ingredients that may come from different sources, each with its own legal implications (Blundell et al., 2022; Ghadi et al., 2025).

The issue becomes more complex when an ingredient undergoes a transformation process (*istihālah*), involves the use of certain auxiliary materials, or is potentially contaminated by haram or najis substances during production. Under certain circumstances, the use of ingredients that are problematic from a halal perspective may, in principle, be considered permissible based on the principle of *al-ḍarūrāt tubīḥ al-maḥzūrāt* that is, a situation where an emergency may permit something that was originally prohibited (Al-Laṭīf, 2003, pp. 287–290). However, this principle does not mean that every non-halal ingredient is automatically permissible simply because it is used in emergency medication. The determination of *ḍarūrah* still requires the existence of a genuine need, the unavailability of halal and adequate alternatives, and use limited to what is necessary, as emphasized in the principle *al-ḍarūrah tuqaddaru bi-qadarihā* (Al-Laṭīf, 2003). Therefore, before an exception based on *ḍarūrah* can be applied, it is necessary to first determine what ingredients are used, their origin, how they are processed, the extent to which their use is necessary, and whether halal alternatives are still available. Consequently, if the origin, processing, and necessity of the material's use cannot be traced, not only is its halal status uncertain, but the basis for justifying its use on the grounds of *ḍarūrah* also loses its foundation.

The need for halal identification tracking further highlights issues at the institutional level, as information regarding pharmaceutical excipients must navigate both the Halal Product Assurance regime and the pharmaceutical regulatory regime, each of which has different authorities and regulatory parameters. Under the Halal Product Assurance regime, the Badan Penyelenggara Jaminan Produk Halal (BPJPH), pursuant to Law No. 33 of 2014 on Halal Product Assurance, is authorized to administer Halal Product Assurance and halal certification (Law Number 33 of 2014 Concerning Halal Product Assurance, 2014). These regulations are reinforced by Presidential Regulation No. 6 of 2023 on Halal Certification of Medicines, Biological Products, and Medical Devices, which governs the implementation of halal certification for these products (Presidential Regulation Number 6 of 2023 Concerning Halal Certification of Pharmaceuticals, Biological Products, and Medical Devices, 2023). Meanwhile, under the pharmaceutical regulatory framework, Law No. 17 of 2023 on Health establishes safety, efficacy, and quality as requirements for the production of pharmaceutical preparations (Law Number 17 of 2023 Concerning Health, 2023). The supervision of drugs and pharmaceutical preparations also falls under the purview of the Badan Pengawas Obat dan Makanan (BPOM) through Regulation No. 13 of 2022 on the Regulations of the Food and Drug Supervisory Agency (Regulation of the Food and Drug Supervisory Agency Number 13 of 2022 Concerning Amendments to Regulation of the Food

and Drug Supervisory Agency Number 21 of 2020 Concerning the Organization and Work Procedures of the Food and Drug Supervisory Agency, 2022).

On the other hand, the Majelis Ulama Indonesia (MUI), through a number of fatwas, has issued provisions regarding the halal status of medicines and ingredients used in pharmaceutical products, including ingredients derived from animals and those requiring laboratory testing (Decision of the Fatwa Commission of the Indonesian Ulema Council Number 80 of 2022 Concerning Products and/or Materials Requiring Laboratory Testing, 2022; Fatwa of the Indonesian Ulema Council Number 30 of 2013 Concerning Medicines and Medical Treatment, 2013; Fatwa of the Indonesian Ulema Council Number 47 of 2012 Concerning the Use of Hair, Bristles, and Horns from Animals That Are Halal but Not Slaughtered in Accordance with Islamic Law for Food, Medicines, and Cosmetics, 2012). However, these provisions have not yet established a specific and comprehensive framework governing the halal status of pharmaceutical excipients as a separate category. Moreover, halal provisions derived from fatwas do not automatically carry the same binding force as positive regulations enshrined in legislation. This situation indicates regulatory fragmentation among the aspects of halal compliance, safety, quality, and pharmaceutical oversight, which fall under different institutional jurisdictions (Latiff, 2020; Nekha, 2023). Consequently, this fragmentation across regulatory regimes creates a normative gap due to the absence of integrated parameters that bridge pharmaceutical and Sharia standards while providing clarity on the definition and scope of pharmaceutical excipients. These gaps include halal risk classification, proof of ingredient origin, verification, documentation, supply chain traceability, and oversight of changes in ingredients or suppliers following certification.

This gap becomes even more apparent when compared to Malaysia, a Muslim-majority country that has developed specific halal standards for the pharmaceutical sector through the Malaysian Standard (MS) 2424:2019 Halal Pharmaceuticals (Latiff et al., 2021, 2023). According to Nur Hanie Mohd Latiff and her fellow researchers, the scope of halal regulations for pharmaceuticals in MS 2424:2019 extends beyond merely determining the halal status of the final product; it encompasses controls from the procurement of raw materials through to the production of the finished product. These regulations cover the verification and traceability of raw materials and their halal sources, supplier and supply chain controls, prevention of cross-contamination during production and handling, personnel competence, documentation as evidence of compliance, and the implementation of a Halal Assurance System as a mechanism for continuous control. For pharmaceutical excipients, this mechanism is crucial because their halal status cannot always be determined solely by the name or function of the ingredient; rather, it requires evidence regarding their origin, processing, handling, and procurement history (Latiffa et al., 2026). Thus, while Indonesian regulations have recognized these ingredients, they have not yet fully established laws capable of ensuring that these ingredients are truly halal, as is the case with Malaysia's Halal Pharmaceuticals standard under MS 2424:2019.

The significance of this issue extends beyond comparisons with a single jurisdiction. On a broader scale, the Organization of Islamic Cooperation, through the Standards and Metrology Institute for Islamic Countries (SMIIC), has also published OIC/SMIIC 50-1:2022 Halal Pharmaceuticals as a cross-member-state reference framework governing general requirements for the production and distribution of halal pharmaceuticals based on Sharia principles. At the same time, Yedi Herdiana and her fellow researchers have also argued that pharmaceutical excipients represent a critical point because their halal status can depend on the source of the materials, the raw ingredients, the production process, and their purification. This means that as the standardization of halal pharmaceuticals has moved to the international level, the issue for Indonesia is no longer whether halal pharmaceuticals need to be regulated, but rather whether national law is capable of guaranteeing the halal status of medicines down to the level of their excipients.

Ultimately, this issue demonstrates that the expansion of halal certification requirements for medications has not been fully accompanied by the legal capacity to comprehensively verify the basis for their halal status. When the origin of ingredients, production processes, and critical points regarding halal compliance cannot be adequately proven and traced, the issue is no longer

merely one of legal certainty but also touches upon the Sharia basis of the halal claim itself. Ironically, medications are treated as halal objects under regulations, yet their Sharia basis cannot be traced; legitimacy is granted, yet the foundation legitimizing it is not fully substantiated. If this is the case, then what is at stake is no longer merely legal certainty, but rather the credibility of Sharia as the source of halal legitimacy itself. For without a traceable Sharia basis, the halal label ultimately risks becoming nothing more than a legal claim regarding something whose very halal status cannot be accounted for.

Repositioning Pharmaceutical Excipients as the Basis for Legal Certainty Regarding the Halal Status of Medicines

The findings in the previous section indicate that the issue with Indonesia's Halal Product Assurance regime does not lie in the absence of drugs as objects of certification, but rather in the inadequacy of the regulations governing the ingredients that determine a drug's halal status. Pharmaceutical excipients play a crucial role because these ingredients may come from different sources, undergo different processing methods, and present varying levels of halal risk. From the perspective of Gustav Radbruch's legal certainty, the formal existence of a norm is insufficient if it fails to provide clarity regarding the regulated object, the obligations to be fulfilled, the procedures for proof, and predictable legal consequences (Radbruch, 2006). Based on this, this study proposes the Pharmaceutical Excipients Halal Assurance Chain as a reconstructive model built through the integration of the theory of legal certainty, a risk-based approach, the concept of *maqāṣid al-syarī'ah*, and the principle of *ḍarūrah*. Thus, the theory does not remain merely a framework for analysis but is translated into an implementable normative architecture.

1. Clarification of Pharmaceutical Excipients as Part of the Scope of the JPH

The starting point for this reconstruction is to affirm that pharmaceutical excipients are not merely technical components in drug formulations, but rather ingredients that determine whether a product meets halal standards. Pharmaceutical excipients must be defined as ingredients other than active ingredients used in drug formulations that serve specific pharmaceutical functions. Pharmaceutical excipients must be considered part of the scope of halal control for a drug, so that inspections do not stop at the final product. This classification serves as the basis for determining a proportionate level of inspection, ensuring that ingredients with a high halal risk are subject to stricter verification requirements than those with a low risk. Legal certainty must be established through clarity regarding which ingredients are subject to control and the level of control that must be applied.

2. Regulations on Pharmaceutical Excipients Based on Halal Risk Levels

Once the legal status of *pharmaceutical excipients* is established as part of the objects subject to halal control, the next issue is determining a proportionate level of regulation based on the characteristics of each material. Applying uniform requirements to all *pharmaceutical excipients* does not fully reflect the differences in halal risks arising from the source of the material, the complexity of the manufacturing process, the use of processing aids, and the potential for contamination. Accordingly, this study adopts a *risk-based regulation* approach, (Hayani et al., 2025), referring to the *Quality Risk Management* framework under ICH Q9 as a conceptual basis for linking risk identification, assessment, and control with proportionate levels of oversight. This approach does not mean that ICH Q9 directly establishes halal risk classifications for *pharmaceutical excipients*; rather, it is used as a *regulatory benchmark* for developing the halal risk classification model proposed in this study. Based on the characteristics of material sources and processing, the model is classified into three risk levels as follows:

Table 1. A Risk-Based Regulation Model for Pharmaceutical Excipients

Category	Characteristics	Normative Consequences
Low risk	The material source and manufacturing process can be clearly identified, the material originates from a source that	Document-based verification and relevant evidence of compliance.

	does not raise halal concerns, and the risk of contamination is low.	
Medium risk	There is uncertainty or complexity regarding the material source, processing, processing aids, or supply chain, requiring additional evidence.	Additional verification of the source and processing, including supplier traceability and supporting documentation.
High risk	The material is derived from animal sources that may raise halal concerns, involves complex or multi-stage processing, or presents a significant risk of contamination.	Stricter verification and auditing, <i>full traceability</i> , and continuous control and evaluation.

This classification constitutes a normative construction developed by the study to operationalize the principles of risk management within the context of halal assurance for *pharmaceutical excipients*. The risk categories are therefore not intended to constitute permanent labels attached to particular materials, but rather to provide a basis for determining the intensity of verification and oversight according to the actual conditions of the material and its manufacturing process. The higher the risk to halal status, the stronger the evidentiary, traceability, and oversight requirements should be. This approach enables legal obligations to be applied proportionately without imposing the same level of requirements on all *pharmaceutical excipients*, while ensuring stricter controls for materials presenting higher halal risks.

3. Verification and Traceability as the Halal Chain of Evidence

Halal status cannot be determined based solely on the name or function of an ingredient. Pharmaceutical excipients such as gelatin, lactose, magnesium stearate, parabens, colorants, titanium dioxide, and many others may come from different sources and undergo different processing methods, thus requiring verification of their origin and production processes. Consumer protection theory holds that the right to be informed requires consumers to receive accurate and reliable information regarding the characteristics of the products they consume (Mihajlović & Micovic, 2024). This principle is relevant to ensuring the halal status of medicines, as consumers are unable to assess for themselves the sources and processing methods of the excipients used in medicinal formulations. Any excipient posing a halal risk must be traceable, at a minimum, in terms of the origin of the material, the manufacturer or supplier, the processing methods, auxiliary materials, production facilities, potential for contamination, certification status, and any changes to the source or supplier. The traceability chain is structured as follows:

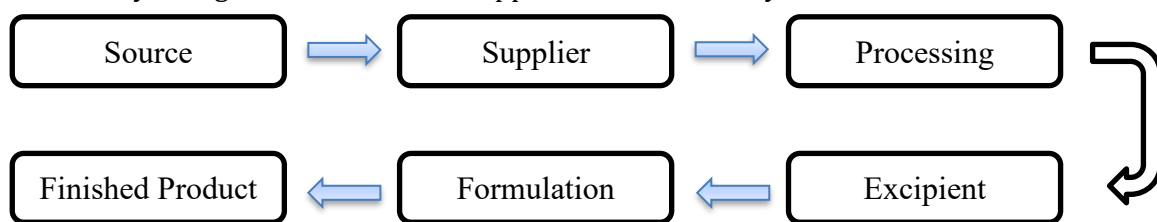


Figure 1. Normative Traceability Model for Halal Assurance of Pharmaceutical Excipients

Therefore, traceability serves not merely as an administrative tool, but as a mechanism for business operators to ensure accountability, so that claims regarding the halal status of medicines are supported by verifiable and verifiable information throughout the production chain.

4. *Ḍarūrah* and the Limits of Exceptions in Ensuring the Halal Status of Medicines

Halal assurance for medicines should be situated within the framework of *maqāṣid al-sharīʿah*, particularly the balance between *ḥifẓ al-dīn* (protection of religion) and *ḥifẓ al-naḥs* (protection of life). The relevance of protecting life can be seen in vaccination practices for Hajj and Umrah pilgrims. In January 2025, the Class I Padang Health Quarantine Office discovered the use of counterfeit *International Certificates of Vaccination* (ICVs) by Umrah pilgrims and required the affected pilgrims to undergo vaccination before departure. This case demonstrates that compliance with vaccination requirements is not merely an administrative matter but is directly related to health protection and the prevention of potentially life-threatening diseases (CNN

Indonesia, 2025). In this context, medical necessity may come into tension with concerns regarding the halal status of materials used in pharmaceutical products, requiring a legal mechanism to determine when an exception to halal requirements may be justified.

From the perspective of *maqāṣid al-sharī'ah*, the use of *pharmaceutical excipients* that do not meet halal requirements may, under certain circumstances, be considered permissible based on the principle *al-ḍarūrāt tubīḥ al-maḥẓūrāt* (necessity permits what is otherwise prohibited), but such use is not automatically justified. Any exception must be constrained by the principle *al-ḍarūrah tuqaddaru bi-qadarihā* (necessity is determined according to its extent), requiring genuine medical necessity, the absence of adequate halal alternatives, and use limited to what is necessary. Accordingly, the normative framework should position *ḍarūrah* as a limited and verifiable exception. Its application should consider medical urgency, the availability of halal alternatives, the level of material risk, and the duration and scope of use. Thus, *ḍarūrah* should not serve as a general justification for disregarding halal requirements, but rather as a narrowly defined, evidence-based, and accountable exception mechanism.

5. Institutional Integration in the Supervision of the Halal Status of Medicines

The reconstruction of legal norms must ultimately ensure that halal obligations are not only established normatively, but can also be effectively implemented and monitored. Lawrence Friedman emphasises that the effectiveness of a legal system is determined by the interplay between legal substance, legal structure and legal culture (Friedman, 1975). With regard to legal structure, the nature of medicines which intersects with halal compliance, safety, quality, efficacy and medical needs requires coordination between the BPJPH, the BPOM and the Ministry of Health, in accordance with their respective remits. The BPJPH carries out functions relating to the assurance and supervision of halal aspects; the BPOM deals with the safety, quality and efficacy of medicines; whilst the Ministry of Health provides input from the perspective of medical needs. The reconstruction of norms is not sufficient merely by producing regulations on pharmaceutical excipients; it must also involve establishing an institutional structure capable of translating these norms into an integrated supervisory mechanism.

In terms of legal substance, halal compliance should not stop at the issuance of a certificate, but should be established through continuous halal assurance throughout the product's life cycle. This mechanism encompasses audits, post-market surveillance and change control, with an obligation to carry out an evaluation whenever there is a change to the source of excipients, suppliers, material specifications, facilities or production processes that could potentially affect halal status. Meanwhile, the legal culture aspect demands compliance from business operators and institutional awareness to make halal assurance an integral part of production governance, rather than merely an administrative formality. Under this framework, certification serves as the starting point for halal assurance, whilst continuous monitoring acts as the instrument for maintaining halal status throughout the medicinal product's life cycle.

Conclusion

This study addresses two main issues. First, regarding the structure and adequacy of the regulatory framework, the regulation of *pharmaceutical excipients* within Indonesia's Halal Product Assurance regime remains inadequate and normatively fragmented. Although medicines have been included within the scope of halal assurance, the existing regulations do not provide a clear legal framework concerning the status of *pharmaceutical excipients*, halal risk classification, source and process verification, *traceability*, or continuous oversight. Second, regarding normative reconstruction, the regulatory framework should position *pharmaceutical excipients* as an integral part of the objects subject to halal control through a risk-based approach, mandatory traceability, limitations on the use of non-halal materials based on the principle of *ḍarūrah*, and integrated oversight involving BPJPH, BPOM, and the Ministry of Health. This normative reconstruction may strengthen legal certainty, Muslim consumer protection, and the coherence of halal governance in the pharmaceutical industry. This study is limited to a normative juridical approach and secondary legal materials and therefore does not empirically assess the implementation of the proposed model in industry or institutional practice. Future research should empirically examine the feasibility of the proposed model, while policymakers may

operationalize it through implementing regulations or technical guidelines on *halal pharmaceutical assurance* that specifically regulate *pharmaceutical excipients* and their oversight mechanisms.

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None.