

A risk-based framework for identifying halal critical points in traditional medicines and health supplements



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ABSTRACT

Traditional medicines and health supplements combine ingredients, excipients, processing aids, and shared facilities whose origins and production histories can complicate halal assurance. This study aimed to identify halal critical points across the product life cycle and develop an expert-informed, risk-based verification framework. A qualitative descriptive design combined one semi-structured in-depth interview with each of five purposively and snowball-recruited experts during 2025 – 2026 with targeted document analysis. The team expanded written field notes into structured summaries. A retrospective inventory of the cited documentary corpus identified 18 substantive journal articles and 20 official documents; methodological references were classified separately. The document component supported triangulation and was not a systematic review. Reflexive thematic analysis identified five interdependent domains: material origin; process inputs and processing aids; formula and dosage form; facility and cleaning control; and evidence continuity and traceability. High-priority concerns included animal derivatives, dual-source glycerol and stearates, ethanol, fermentation inputs, capsule shells, compound formulations, uncontrolled alternatives, rework, and shared facilities. Informants emphasized that laboratory testing is question-specific and cannot replace supplier transparency, formula reconciliation, or batch traceability. The proposed framework distinguishes inherent from residual priority and directs verification toward gaps that could change halal status. It can inform halal-by-design, supplier approval, and change control while keeping halal decisions distinct from safety and quality assessment. Further validation is required before standardized application.

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INTRODUCTION

Traditional medicines and health supplements occupy an increasingly important position in preventive health, self-care, and the broader halal economy. Their apparently natural image can obscure the technical complexity of modern formulations. A single product may contain botanical extracts, vitamins, minerals, amino acids, probiotic cultures, enzymes, capsule shells, coating systems, flavors, carriers, lubricants, and processing aids supplied through multiple tiers. These materials may originate from animal, plant, mineral, synthetic, or microbial sources, and different source pathways can produce a chemically identical ingredient. Consequently, halal status cannot be inferred reliably from the product name, the word 'natural,' or the declared active ingredient alone ([Herdiana et al., 2024](#); [Lababidi et al., 2025](#); [Wang et al., 2025](#)).

Indonesia's current regulatory environment makes this issue operationally urgent. Law Number 33 of 2014, as amended through the Job Creation framework, and Government Regulation Number 42 of 2024 establish the national halal product assurance framework (Government of Indonesia, 2014, 2023, 2024). The phased obligation for natural medicines, quasi-drugs, and health supplements ends on October 17, 2026, with mandatory certification applying from October 18, 2026 (The Halal Product Guarantee Agency, 2026). In parallel, the national food and drug regulator has updated requirements for natural-medicine registration, safety and quality, labeling, stability, probiotics, and raw-material risk assessment (Indonesian Food and Drug Authority, 2023a, 2023b, 2023c, 2024, 2025a, 2025b, 2025c, 2026). These regulatory systems intersect, but their decisions are not interchangeable: a material can satisfy pharmaceutical quality specifications while its source remains insufficiently documented for halal purposes.

Existing studies have identified animal-derived pharmaceutical ingredients, alternatives to gelatin, and analytical approaches for porcine authentication (Ali et al., 2018; Hameed et al., 2018; Herdiana et al., 2024; Rohman et al., 2020). Other work has examined halal considerations for plant-derived materials and microbial products (Jumiono et al., 2023, 2024; Karahalil, 2020). A recent JHSR review mapped critical points in milk and dairy derivatives and demonstrated the value of product-specific analysis (Mulyaningtias & Maulani, 2026). However, traditional medicines and health supplements require a broader framework because their criticality is distributed across active ingredients, minor excipients, fermentation inputs, alternative suppliers, dosage-form technologies, and shared facilities. A list of high-risk ingredients alone does not show whether the actual material used in a batch matches the approved manufacturer, site, formula, and supporting evidence.

A further conceptual problem is the tendency to merge halal criticality with food-safety or quality hazards. Halal, safety, and quality controls can share documents and operational systems, but they answer different questions. Safety assessment evaluates whether a product presents unacceptable harm under intended use; quality assessment evaluates identity, strength, purity, consistency, and performance; halal assessment evaluates the permissibility and integrity of materials and processes under applicable Islamic and certification requirements. Treating one domain as proof of another can create false assurance. Conversely, integrating their data flows through supplier qualification, change control, and traceability can reduce duplicated work while keeping the decision criteria distinct (International Council for Harmonisation, 2023; International Organization for Standardization, 2018).

This study addresses this gap through expert-informed qualitative inquiry supported by regulatory and scientific triangulation. It asks three questions: (1) where can halal status change or lose traceability during the life cycle of traditional medicines and health supplements; (2) what evidence is required to control and verify those points; and (3) how should audit effort be prioritized when materials, processes, facilities, and documents vary in complexity? The study contributes an integrated five-domain framework that links inherent criticality to residual priority after controls are verified. This approach extends earlier material-based classifications into a product- and evidence-based audit model.

RESEARCH METHOD

Methods

This study used a qualitative descriptive design combining semi-structured in-depth interviews with targeted document analysis. A qualitative design was selected because halal critical-point identification requires interpretation of source pathways, production practices, documentary sufficiency, and professional judgment that cannot be reduced to a single analytical measurement (Creswell & Poth, 2018). The document component covered Indonesian laws and regulations, relevant fatwas, international guidance, and peer-reviewed literature available up to August 2026. Documents informed the interview guide and were used to challenge or corroborate interview interpretations; they did not constitute a systematic review or meta-analysis.

During 2025 – 2026, each informant completed one semi-structured in-depth interview. The guide covered definitions of halal critical points; material origin and manufacturer identity; animal-derived and dual-source materials; ethanol and solvents; microbial cultures, media, and downstream aids; formula alternatives and dosage forms; shared facilities and cleaning; supplier evidence; traceability; and laboratory testing. Data were captured as contemporaneous written field notes and

expanded immediately after each session into a structured summary for analysis. Because no audio recordings were made, the summaries were treated as analytic records, not verbatim transcripts.

Regulatory and scientific documents were then used for data triangulation. The regulatory corpus included the national halal product assurance framework; rules for good manufacturing practice, registration, safety and quality, labeling, stability, probiotic products, and raw-material risk assessment; and fatwas relevant to microbial products, shellac, and ethanol in medicines (Indonesian Ulama Council, 2012, 2013, 2018). Scientific literature was identified through PubMed, publisher databases, and backward reference checking using combinations of halal pharmaceutical, traditional medicine, natural medicine, health supplement, animal-derived excipient, gelatin, capsule, fermentation media, ethanol, traceability, and authentication. Documents were included when they provided traceable evidence about source, process, facility, formulation, audit, or analytical verification.

For reporting transparency, a retrospective inventory of the revised bibliography classified 42 cited sources into 18 substantive journal articles, 20 official documents, and four methodological or reporting references. The 38 substantive sources provide the documentary support for the framework. This inventory describes the cited corpus, not the number of records originally retrieved from databases.

Figure 1 presents a PRISMA-informed account of this documentary corpus, following the principle of transparent source reporting (Page et al., 2021). The available records do not establish the original search yields, duplicate-removal totals, title/abstract screening decisions, or full-text exclusions. These stages are therefore identified as unavailable rather than assigned estimated counts. The figure is a retrospective source-classification flow, not a completed PRISMA 2020 systematic-review flow diagram. Journal articles and official documents served as triangulation sources; neither replaced the interview data.

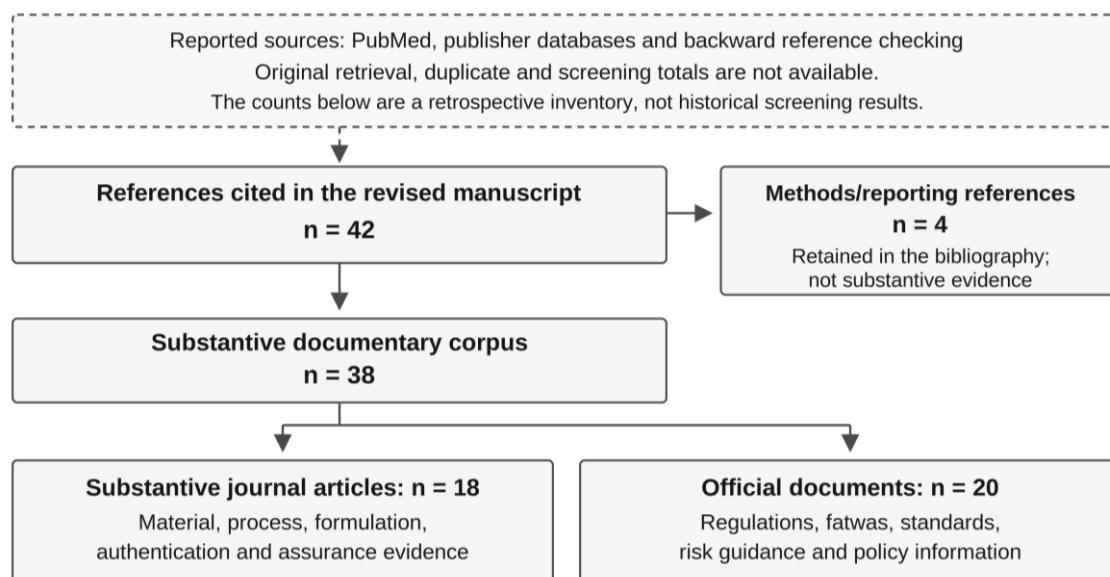


Figure 1. PRISMA-informed account of the reported documentary corpus.

Informant selection

Five experts were recruited through purposive expert sampling supplemented by snowball referral. Initial selection was based on senior experience in halal inspection and assurance, regulation of natural medicines and health supplements, or national halal product assurance; referrals sought complementary expertise. Participants comprised three halal inspection and assurance specialists, one national medicines regulatory specialist, and one national halal product-assurance specialist. Institutional and personal identities are withheld to maintain confidentiality. Table 1 presents the non-identifying profile.

Table 1. Non-identifying profile of expert informants.

Expertise group	Number	Relevant experience	Role in the inquiry
Halal inspection and assurance specialists	3	Materials, manufacturing processes, facilities, audit evidence, and traceability.	Identification of halal critical points and verification logic
National medicines regulatory specialist	1	Ingredient evaluation, product registration, safety, quality, and labeling.	Boundary between medicines regulation and halal evidence
National halal product-assurance specialist	1	Halal product-assurance governance and certification requirements.	Policy interpretation and system-level assurance

Source: Authors' anonymized interview records.

Data Analysis

Interview material was organized using reflexive thematic analysis: familiarization, initial coding, candidate-theme construction, theme review, definition and naming, and analytical reporting (Braun & Clarke, 2019, 2021). Coding combined deductive categories derived from the product life cycle with inductive attention to issues emphasized by informants. Regulatory and scientific documents served as triangulation sources rather than substitutes for interview data. Negative or limiting evidence was retained, particularly where laboratory testing could not resolve a supplier-document gap. The resulting framework was reviewed for internal consistency across materials, processes, formulations, facilities, and evidence.

The author team coded the structured interview summaries. All authors collectively reviewed the supporting evidence, compared themes with the documentary corpus, refined them through discussion, and approved the final structure. An audit trail linked field-note summaries, codes, themes, and analytical outputs. Source triangulation, limiting evidence, and collective review strengthened trustworthiness. The study followed principles of voluntary participation, confidentiality, and data protection. Before each interview, informants were told the study purpose, use of anonymized findings, and their right to decline or withdraw; documented informed consent was obtained.

RESULT AND DISCUSSION

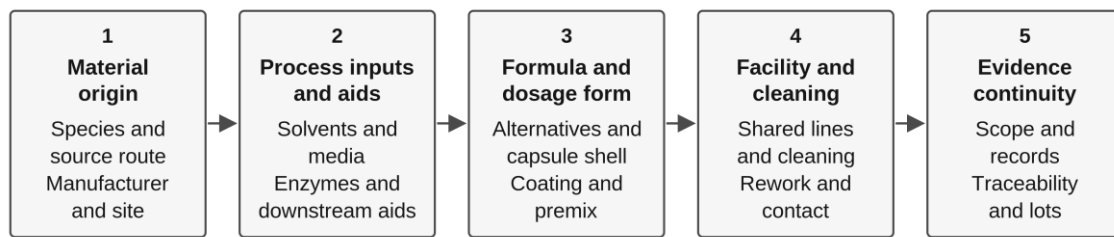
Five interconnected domains of halal criticality

The interview synthesis produced five interconnected domains: material origin; process inputs and processing aids; formula and dosage form; facility and cleaning control; and evidence continuity and traceability. Informants did not treat these domains as an additive checklist. Instead, they described a chain in which uncertainty at an early stage propagates into later decisions. A material with a permissible theoretical source may remain unapprovable when the actual manufacturer or production site is unknown. Conversely, a material with high inherent criticality may be controlled when its source, process, certification scope, segregation, and batch traceability are consistently verified.

Table 2 provides an anonymized data display for each theme. The evidence statements were paraphrased from the expanded field-note summaries and are not presented as verbatim quotations because the interviews were documented through written notes rather than audio recordings.

This distinction supports two levels of priority. Inherent priority is determined before controls are considered and reflects source ambiguity, animal or microbial involvement, ethanol or multi-source pathways, process complexity, and potential contact with prohibited materials. Residual priority is assessed after controls are verified. It reflects the remaining uncertainty following supplier approval, document review, facility segregation, cleaning, change control, and traceability. The distinction prevents a certificate from being treated as a universal risk eraser while also avoiding the assumption that every animal- or fermentation-derived material is automatically non-compliant. Figure 2 integrates the five verification domains with the sequence from inherent priority through verification of controls to residual priority.

(A) Verification domains



(B) Risk prioritization

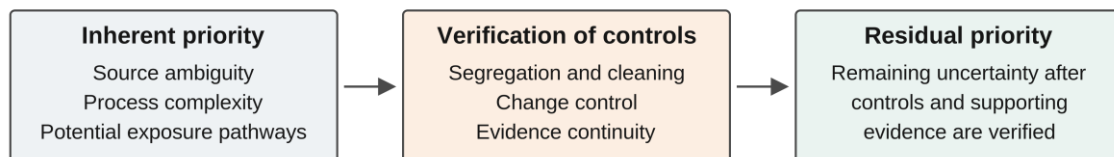


Figure 2. Expert-informed framework for identifying and verifying halal critical points.

Table 2. Anonymized data display supporting the five analytical themes.

Theme	Critical-point indicators	Primary verification evidence	Paraphrased field-note evidence
Material origin	Species, source route, manufacturer, production site, and multi-source identity.	Source declaration, current certificate where applicable, process flow, and manufacturer-site match.	Material names alone were considered insufficient when the same ingredient could follow different source routes or be made at different sites.
Process inputs	Solvents, enzymes, fermentation media, antifoam, purification aids, carriers, and stabilizers.	Full process map and disclosed input materials at each critical stage.	Media, solvents, enzymes, and downstream aids required review even when they were not declared on the finished-product label.
Formula and dosage form	Capsule shell, coating, flavor, premix, lubricant, glazing, and alternative materials.	Complete master formula, approved alternatives, specifications, and change-control records	Alternative suppliers and proprietary compound inputs were described as frequent sources of undocumented formula change.
Facility and cleaning	Shared lines, storage, weighing, rework, incidental-contact materials, and cleaning	Facility map, production history, segregation, cleaning evidence, and plant observation	A compliant formula could lose integrity through shared equipment, rework, or inadequately controlled cleaning and production changeovers.
Evidence continuity	Alignment among approval, purchase, receipt, storage, weighing, production, and release.	Two-way lot traceability and reconciliation of formula, supplier, and batch records	Certificates, purchasing records, formula data, and batch traceability had to refer to the same material-manufacturer-site combination.

Source: Authors' synthesis of anonymized written field notes, triangulated with regulations and scientific literature.

Material origin as the first decision point

Animal-derived and dual-source materials

Animal-derived materials were consistently prioritized because permissibility depends on species, slaughter status where relevant, processing, and segregation. Gelatin and collagen are prominent examples because they can be used as capsule shells, gelling agents, stabilizers, binders, or

coating components. Authentication studies show that species-related evidence can be generated through DNA- or peptide-based methods, but test performance depends on processing intensity, matrix, marker selection, and sample preparation (Ali et al., 2018; Hameed et al., 2018; Jumiono, 2022; Rohman et al., 2020). Informants therefore placed analytical testing after documentary and traceability review rather than before it.

The same logic applies to dual-source ingredients such as glycerol, stearic acid, magnesium stearate, mono- and diglycerides, and certain carriers. Their chemical names do not reveal whether the source was plant, animal, or synthetic. Expert judgment focused on the manufacturer and site that produced the material, not merely the distributor that sold it. This distinction is operationally important because one internal material code may cover several approved or unapproved manufacturers. The literature similarly cautions that animal-derived excipients may be invisible to patients and downstream users when labeling identifies function but not biological origin (Herdiana et al., 2026; Lababidi et al., 2025; Wang et al., 2025).

Botanical materials, extracts, and ethanol

Unprocessed botanical materials generally present lower inherent halal priority than multi-stage extracts, but the description 'plant-based' does not close the assessment. Extract production can involve ethanol, glycerol, enzymes, antifoam, activated carbon, resin, precipitation agents, and spray-drying carriers. Risk increases when the trader cannot identify the actual manufacturing site or when a specification describes the final extract without its extraction and purification history. Earlier material-focused analysis reached a similar conclusion: processing can convert an initially low-priority botanical source into a critical derivative (Jumiono et al., 2023).

Ethanol requires source- and use-specific analysis. Fatwa Number 40 of 2018 differentiates ethanol originating from the khamr industry from non-khamr ethanol and evaluates its use in medicines in relation to source, purpose, and safety (Indonesian Ulema Council, 2018). Interview findings rejected the use of one concentration threshold as a universal shortcut. Verification must identify the ethanol manufacturer, production route, stage and function of use, recovery process, and relevant residue specification. A safety limit for residual solvent addresses a different question from whether the solvent source and use satisfy halal requirements.

Microbial and fermentation-derived materials

For probiotics, enzymes, vitamins, amino acids, and microbial metabolites, the microorganism name was considered only the entry point. Criticality extends to preservation of the master culture, refreshing media, inoculum media, production media, antifoam, pH-control agents, harvesting, purification, concentration, cryoprotectants, carriers, and final stabilization. Peptones, animal extracts, trypsin, lactose, and dairy-derived ingredients may enter at different stages and may not remain detectable in the finished product. The six-stage structure of culture, refreshing, inoculum, production, harvesting or purification, and stabilization provides an auditable sequence for reviewing these inputs (Ermis, 2017; Indonesian Ulema Council, 2012; Jumiono et al., 2024; Karahalil, 2020).

This finding has a practical implication for confidential supplier formulations. A statement that the product is 'microbial' or 'fermentation-derived' is insufficient if the supplier withholds culture-media or downstream-input information. Confidentiality can be managed through a controlled third-party review or a direct assessment of the manufacturer, but it cannot be interpreted as evidence of compliance. The updated national guideline for probiotic health supplements strengthens safety and quality evaluation, while halal verification still requires source transparency for media and processing aids (Indonesian Food and Drug Authority, 2025b). Table 3 consolidates these material- and process-specific critical questions, required evidence, and verification boundaries.

Table 3. High-priority material and process critical points.

Material/process	Critical questions	Core evidence	Verification boundary
Gelatin and collagen	Species, slaughter status where relevant, mixing, manufacturer and site.	Certificate-scope match, source evidence, process flow, lot identity.	PCR or LC-MS only for a defined unresolved question.
Glycerol, stearates, emulsifiers	Plant, animal, or synthetic route; alternative supplier	Origin statement, starting materials, manufacturer and change control.	Chemical identity alone cannot establish biological source.
Enzymes	Animal, plant, or microbial production; carrier and stabilizer.	Source organism, media where microbial, formulation, and production flow.	Species testing may be unsuitable when the target is degraded or absent.
Botanical extracts	Solvent, resin, activated carbon, antifoam, carrier, and actual site.	Extraction and purification flow, solvent source, carrier specification.	Botanical origin does not eliminate process-related criticality.
Ethanol	Industrial origin, function, stage of use, recovery and residue.	Manufacturer, production route, process balance and use justification.	Do not determine halal status from concentration alone.
Fermentation products and probiotics	Culture preservation, media, antifoam, purification and stabilization.	Composition at each stage, downstream aids, supplier verification.	Escalate when proprietary media prevent adequate review.
Flavor, color and encapsulated premix	Carrier, solvent, coating, minor components and sub-supplier.	Complete composition or adequate manufacturer declaration.	Trade name and 'natural' claim are insufficient.

Source: Authors' synthesis; analytical limitations discussed by Dewi et al. (2023), Grundy et al. (2016), and Nikzad et al. (2017).

Formula and dosage form change the risk profile.

The interviews indicated that halal approval must be attached to the complete master formula and its authorized alternatives. Reviewing a sample of formulas cannot demonstrate that every marketed product and every approved alternative has been evaluated. Risk-based sampling remains useful for physical inventory, transaction records, and batch evidence, but the formula population itself should be reconciled comprehensively. Particular attention is required for premixes, capsule-shell formulas, coatings, printing inks, glazing agents, rework, and materials administratively classified as processing aids rather than label ingredients.

Dosage form determines where hidden criticality concentrates. Hard capsules focus attention on shell polymer, color, opacifier, and printing ink; soft capsules add plasticizers and sealing systems. Tablets may use stearates, binders, antifoam, coating premixes, and polishing agents. Liquids can involve ethanol, glycerol, solubilizers, preservatives, and compound flavors. Gummies combine gelling systems, coatings, glazing, emulsifiers, and flavors. Probiotics introduce the entire fermentation chain plus cryoprotection and encapsulation. A generic list of risky ingredients is therefore less useful than a dosage-form-specific map linked to the actual formula.

Plant-derived or synthetic substitution can reduce animal-source dependency but introduces technological trade-offs. Hydroxypropyl methylcellulose, starch, carrageenan, and pectin-based capsule or gelling systems differ from gelatin in moisture behavior, oxygen permeability, machinability, compatibility with the fill, stability, cost, and supply availability (Fauzi et al., 2021; Herdiana et al., 2024). Halal-by-design should therefore integrate substitution with stability, dissolution, performance, and consumer requirements. A halal improvement that creates unacceptable quality or clinical

performance is not a complete product solution. Table 4 maps the priority components and verification focus for each dosage form.

Table 4. Dosage-form-specific critical points and verification focus.

Dosage form	Priority components	Verification focus
Hard capsule	Shell polymer or gelatin, color, opacifier, printing ink	Shell formula, manufacturer-site identity, certification or origin evidence, lot reconciliation
Soft capsule	Gelatin, glycerol or sorbitol, color, sealing aid	Complete shell formula, plasticizer source, production facility and supplier alternatives
Tablet or caplet	Stearates, binder, antifoam, coating, glazing and flavor	Premix composition, complete formula, alternative-supplier approval and batch record
Liquid or syrup	Ethanol, glycerol, flavor, solubilizer, and preservative	Solvent origin and function, compound-flavor evidence and mixing record
Powder or granule	Spray-dry carrier, anticaking agent, flavor, and premix	Drying-site process flow, premix composition and manufacturer identity
Gummy or jelly	Gelatin or alternative gelling agent, glazing, emulsifier, and flavor	Gelling-agent origin, coating system and validated formulation change
Probiotic	Culture media, antifoam, cryoprotectant, and encapsulation matrix	Media at every stage, downstream process, stabilizer and supplier audit evidence

Source: Authors' thematic synthesis and supporting literature.

Facility, cleaning, and change control

A compliant ingredient list does not guarantee a compliant production run. Informants identified shared storage, weighing, processing, transfer, filling, and packaging equipment as points where status can be compromised. Plant observation should therefore test whether the documented flow matches actual practice. The observation scope includes open transfer points, dedicated or shared utensils, sampling devices, production sequencing, returned materials, rework, lubricants, maintenance materials, cleaning chemicals, and contractor activities. Documentary review without observation may miss informal practices; observation without historical records cannot demonstrate consistency across time.

Cleaning verification must be proportionate to the prior material and the applicable religious and certification requirements. A generic sanitation statement is not sufficient when a line has handled prohibited or impure material or when its previous-use history is uncertain. At the same time, halal cleaning and pharmaceutical cleaning validation should not be merged carelessly. They can share equipment maps, procedures, residues, and records, but the acceptance logic may differ. Integration is strongest when the quality system provides the record infrastructure and the halal system supplies explicit approval criteria.

Alternative materials and emergency suppliers were repeatedly identified as a practical blind spot. Supply disruption can cause an approved trade name to be sourced from a different manufacturer or site without a visible change in the internal material description. Halal evaluation must therefore be a prerequisite in change control for supplier, manufacturer, site, raw-material source, process aid, fermentation medium, formula, shared facility, cleaning method, primary packaging, and contract manufacturer changes. Good manufacturing practice requirements provide a suitable management backbone for this integration (Indonesian Food and Drug Authority, 2021).

Evidence continuity and risk-proportional verification

The strongest cross-cutting theme was evidence continuity. A certificate is strong evidence only when its scope matches the material name, manufacturer, production site, and relevant period. A distributor's statement cannot correct a mismatch in the manufacturer identity. When formal certification is unavailable or not applicable, a combination of source declarations, specifications, starting-material lists, process flows, facility statements, and supplier assessment may be needed. The amount of evidence should increase with source ambiguity and process complexity, consistent with risk-management principles that align effort, formality, and documentation with risk ([International Council for Harmonisation, 2023](#); [International Organization for Standardization, 2018](#)).

Traceability must operate in both directions. A finished-product lot should be traceable to each material lot, supplier, manufacturer, and production site, while a received material lot should be traceable forward to every product batch in which it was used. Reconciliation should connect the approved formula to purchasing, receipt, storage, weighing, batch production, rework, and release. Digital table matching can help identify duplicate codes, alternative suppliers, and materials that appear in transactions but not in the approved master data. The principle is consistent with earlier work showing that audits and laboratory analysis perform complementary rather than interchangeable roles in halal assurance ([van der Spiegel et al., 2012](#)).

Laboratory testing should begin with a precise question. Species-specific PCR can support the detection of porcine DNA in gelatin under validated conditions, but DNA degradation and matrix effects can produce non-detection that does not prove a complete source history. Peptide-based LC-MS can provide complementary species evidence, yet performance depends on extraction, digestion, marker specificity, instrumentation, and data processing ([Dewi et al., 2023](#); [Grundy et al., 2016](#); [Nikzad et al., 2017](#)). Therefore, a negative test result cannot repair missing supplier transparency. Testing is most defensible when documentary review identifies a defined uncertainty that the selected method is capable of resolving.

Implications for audit practice and policy

For manufacturers, the recommended unit of control is the material-manufacturer-site combination, linked to every approved formula and alternative. This approach detects situations in which a trade name remains constant while the source route or manufacturing site changes. The material master should include document status, validity date, source classification, process complexity, authorized suppliers, and change triggers. High-priority items should receive deeper supplier review and more frequent verification; lower-priority items can be managed through standard approval and change monitoring.

For auditors, comprehensive formula reconciliation should precede risk-based transaction sampling. Sampling is then directed toward the highest-risk lots, alternative suppliers, fermentation materials, shared lines, and periods of supply disruption. ISO 19011:2026 provides updated general guidance for auditing management systems, but sector-specific competence remains necessary to interpret pharmaceutical ingredients, microbial processes, and analytical limitations ([International Organization for Standardization, 2026](#)). The five-domain framework can structure an audit plan without pretending to replace religious rulings or certification decisions.

For policy and certification practice, harmonized data requests could reduce unnecessary duplication between halal, safety, quality, and registration assessments. The same process diagram, supplier identity, stability information, or manufacturing-site record may support more than one assessment, provided that each decision retains its own criteria. OIC/SMIIC 50-1:2022 similarly frames halal pharmaceutical requirements across the product chain rather than at the finished-product label alone ([Standards and Metrology Institute for Islamic Countries, 2022](#)). The main policy risk is to mistake integrated data for merged decisions. Integration should connect evidence and change control, not erase the distinction between halal permissibility and pharmaceutical quality.

The proposed framework remains an expert-informed model rather than a validated predictive instrument. It does not estimate the prevalence of non-compliance, and the informant composition may emphasize Indonesian regulatory and certification practice. Future research should validate domain definitions through a larger Delphi panel, assess inter-auditor agreement, and compare priority

classifications with actual audit findings. Case studies involving ethanol extracts, probiotic products, capsules, gummies, and multi-site contract manufacturing would test whether the framework is sufficiently sensitive to different technologies. The targeted documentary component and unavailable historical screening counts limit reproducibility and assessment of document-selection bias. The retrospective inventory improves transparency but does not establish exhaustive retrieval or compliance with a systematic-review protocol.

CONCLUSION

Halal criticality in traditional medicines and health supplements is produced by the relationship among material origin, process inputs, formula and dosage form, facility control, and evidence continuity. The highest audit priority occurs when animal, microbial, ethanol, or multi-source pathways intersect with opaque processes, uncontrolled alternatives, shared facilities, or inconsistent documents. Certificates, production records, plant observation, and laboratory tests answer different questions and must be assembled into a continuous chain of evidence. The expert-informed framework distinguishes inherent from residual priority and directs verification toward gaps that could alter halal status. Its practical value lies in integrating halal-by-design with supplier approval, change control, and two-way batch traceability while keeping halal decisions distinct from safety and quality assessment. Further validation is required before the framework is used as a standardized scoring or certification instrument.

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