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Identification and Classification of Risks in the Raw Material Procurement Process in the Pharmaceutical Industry

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Abstract

In the pharmaceutical industry, identifying and managing process-related risks, particularly in the raw material procurement process, is of fundamental importance due to the critical role of these materials in ensuring product quality and production continuity. This study aims to comprehensively identify risks associated with the pharmaceutical raw material supply chain and to propose a process-based classification framework that enables managers and pharmaceutical industry professionals to conduct a structured and practical analysis of risks. This study began with a systematic review of the literature in reputable scientific and industrial databases, through which the risks reported in relevant studies on pharmaceutical raw material procurement were extracted. Subsequently, using a process map of raw material procurement (from inventory review, supplier identification, and supplier evaluation and selection to purchasing, transportation, and delivery to the production department) the identified risks were organized into risk categories associated with each stage of the process. The findings revealed that a considerable variety of operational, financial, logistical, organizational, environmental, and systemic risks can affect the raw material procurement process at different levels. The main outcome of this study is a process-oriented framework that can serve as a basis for developing risk assessment models, prioritizing control measures, and designing more accurate decision-making systems in the pharmaceutical industry. This framework can also provide a foundation for developing quantitative risk assessment models, including Bayesian networks, and for designing strategies to enhance the resilience of the pharmaceutical raw material supply chain in future research.

Keywords: Risk identification, Pharmaceutical supply chain risk, Pharmaceutical supply chain process, Raw materials for production.

1 | Introduction

With the globalization and increasing complexity of supply chain networks, high customer expectations, shorter product and technology life cycles, and an unstable environment, pharmaceutical supply chains today face considerable uncertainties and risks. Uncertainty and risk in supply chains have become major challenges [1–3]. Organizations are under increasing pressure to meet customer expectations by providing high-quality products, rapid delivery, and superior services. Therefore, they must focus their attention on the entire supply

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chain and adopt new strategies to enhance their ability to respond rapidly and cost-effectively to unforeseen events [4]. The critical relationship between pharmaceuticals and public health is one of the main reasons for addressing issues related to pharmaceutical supply chains. Ensuring access to medicines is a major priority, particularly in developing countries; consequently, effective management of pharmaceutical supply chains is of great importance [5]. Due to the critical nature of pharmaceutical products, pharmaceutical supply chains are particularly vulnerable to the consequences of disruptions, as any interruption in the availability of raw materials can directly threaten patients' health [6]. Pharmaceutical raw materials, as the primary inputs to the drug manufacturing process, play a critical role in ensuring the quality and safety of pharmaceutical products. However, the supply chain of pharmaceutical raw materials is exposed to numerous complexities and challenges, including market fluctuations, unexpected events, regulatory changes, and dependence on limited resources. These factors can lead to disruptions in raw material supply, increased costs, production delays, and ultimately, drug shortages and threats to patient health. The flow of the raw material procurement process is influenced by the roles of multiple stakeholders, including procurement, supply chain, production, customer service, and logistics [7]. Furthermore, the importance of risk management has become increasingly critical because pharmaceutical products are highly regulated and subject to stringent controls and restrictions imposed by regulatory authorities [8]. Supply chain risk is a broad concept encompassing events arising from uncertainty or unpredictability that may result in supply chain disruptions and negatively affect supply chain performance [9]. These risks originate from numerous sources, including offshore production, terrorism, political instability, natural disasters, economic cycles, demand fluctuations, infectious diseases, infrastructure failures, manufactured disasters, currency fluctuations, price risks, information system risks, quality risks, theft, lean supply chain strategies, outsourcing and single sourcing, forecasting, intellectual property theft, customer payment issues, inventory policies, capacity constraints, and delays caused by disruptions [10], [11]. Given the wide range of potential risk sources, pharmaceutical raw material supply chains require systematic approaches to risk identification and management. The increasing complexity of supply chains has made their management more challenging, particularly because identifying process details and effectively controlling interconnected activities have become more difficult. Therefore, proactively identifying and assessing risks is essential for ensuring business continuity and preventing significant losses [12]. Risk identification also enables managers to better understand potential future uncertainties within supply chain processes, thereby allowing these uncertainties to be appropriately managed by considering potential risks in advance [13]. A comprehensive understanding of supply chain processes and their associated risks enables manufacturers to effectively manage and control their activities [14].Given the considerable number and diversity of risks affecting the pharmaceutical industry, organizing these risks into meaningful categories based on the procurement process is essential for facilitating their systematic analysis and effective management. Accordingly, this study aims to comprehensively identify the risks associated with the supply chain of raw materials used in pharmaceutical production and develop a process-based framework for classifying these risks. To this end, the raw material procurement process is examined through a systematic review of the relevant literature, and the identified risks are organized according to the different stages of the procurement process. The proposed framework is intended to provide a structured basis for understanding the sources and types of risks affecting pharmaceutical raw material procurement and to support future risk assessment, prioritization, and management efforts in this critical sector.

2|Supply Chain Risk Management

According to the International Organization for Standardization (ISO), risk is defined as the "effect of uncertainty on objectives." Risk assessment is a key component of the risk management process and consists of three main elements: Risk identification, risk analysis, and risk evaluation (ISO 31000). The first stage in any risk assessment model, and one of the critical steps affecting the success of risk management, is risk identification. Risk identification can have either positive or negative effects on the performance of supply chains [15]. Moreover, risk identification helps managers better understand future uncertainties within processes; consequently, these uncertainties can be appropriately managed by taking potential risks into

account [13]. Risk management is a process of identifying, analyzing, and controlling risks associated with any activity or operation within an organization [16]. Supply chain risk management is a combination of the concepts of supply chain management and risk management [17].

3 | Pharmaceutical Supply Chain Risk

The pharmaceutical supply chain is a complex system comprising multiple phases, each of which presents unique challenges and vulnerabilities. Each phase, from raw material procurement to product distribution, involves distinct threats and opportunities. Understanding these risks enables organizations to strategically allocate resources and implement proactive mitigation measures [18]. Throughout the procurement process, various risk events and risk factors may arise, affecting the smooth performance of procurement activities both internally and externally to the organization [7]. In fact, beyond considering only the processes within the supply chain, it is also important to consider the classification of the products themselves when identifying risks in the pharmaceutical supply chain [19]. Risk identification is the first step in risk assessment and involves searching for, determining, and defining potential risks. This step can be conducted using various approaches, including geographic mapping or supply chain mapping, reviewing historical problems, investigating industry trends, brainstorming sessions with experts, assessment surveys, site visits, literature reviews, qualitative methods, checklists, and cause-and-effect diagrams [20]. Risk classification is one of the critical stages of risk management in supply chains. The main reason is that the key risk factors associated with each risk to be classified must first be identified, and precautionary measures must be taken to ensure that risks overlap as little as possible [12]. Chu et al. [21] classified global supply chain risks into seven categories, each comprising several potential risk factors. These categories include political, environmental, financial, supply and demand, logistics, systemic, and operational risks. Based on a review of various studies, each of these categories is described as follows.

3.1 | Financial Risks

Financial risks in the pharmaceutical supply chain include cash flow problems affecting pharmaceutical companies' ability to purchase raw materials, insecurity in international money transfers (particularly under sanctions), increases in transportation and insurance costs, domestic financial constraints, domestic inflation and economic recession, suppliers' credit risk, bankruptcy of business partners, depreciation of the national currency and its impact on imports, cash flow difficulties, loss of customers due to poor performance, and insecurity in digital money-transfer channels. The latter has increased the incidence of fraudulent transactions, theft, and other forms of financial crime through hacking, thereby contributing to a lack of trust among pharmaceutical supply chain partners [18]. According to Kara and Fırat [22], financial risk also encompasses the economic environment, cost and price risks, cash flow risks, currency fluctuations, economic recession, Gross Domestic Product (GDP) stability, and tax-related risks.

3.2 | Supply and Demand Risks

Supply and demand risks in the pharmaceutical supply chain refer to a set of challenges arising from instability in supply sources and fluctuations in demand patterns, which can directly affect production continuity, product quality, and financial performance. From the supply perspective, factors such as poor raw material quality, supplier shutdowns caused by unforeseen events, and fluctuations in material costs can disrupt the inflow of critical materials, resulting in delays, product shortages, and instability in profitability [12]. On the demand side, factors such as a decline in the company's reputation, demand forecasting errors, and the bullwhip effect can lead to excess or insufficient inventory, reduced sales, and inappropriate operational decision-making. Overall, this category of risk represents one of the most critical areas in the pharmaceutical industry and requires close monitoring, reliable forecasting, and proactive management to maintain supply chain stability [18].

3.3 | Political Risks

Political risks are less frequently represented in the literature; however, they are critical due to their potential impact on supply chain operations through trade policies, geopolitical instability, and regulatory compliance [19]. Regulatory and policy instability can create uncertainty, making long-term planning and investment more difficult. International sanctions can also disrupt the import and export of pharmaceutical products and raw materials, thereby negatively affecting the efficiency of healthcare systems. In addition, government pharmaceutical pricing policies, by imposing price restrictions, can reduce manufacturers' profit margins and may even lead to the discontinuation of production of certain essential medicines. These factors are considered part of the political risk category [18].

3.4 | Operational Risks

Operational risks are frequently identified in the literature, highlighting the need for adequate infrastructure, technology, and effective organizational processes across all phases of the pharmaceutical supply chain [19]. The factors associated with this category of risk mainly include planning, scheduling, and forecasting errors [15]. Poor service performance, which can lead to customer dissatisfaction, particularly during critical periods such as pandemics, and product quality problems arising from weaknesses in manufacturing processes or quality infrastructure (which may have serious consequences for patient health) are also considered operational risks. In addition, inefficient operational planning can reduce production efficiency and impair the coordination of activities such as procurement, distribution, and sourcing, making it a major operational challenge [18].

3.5 | Logistics Risks

Logistics risks include the lack of cold-chain infrastructure, which can compromise the quality and efficacy of pharmaceuticals that are sensitive to environmental conditions, as well as the risk of counterfeit medicines, which threatens patient safety and the reputation of the pharmaceutical industry and represents one of the major global challenges in pharmaceutical logistics. In addition, untimely delivery is considered a significant logistics risk because, given the critical nature of pharmaceutical products, delivery delays can disrupt the provision of healthcare services and result in serious consequences [18]. Other risks in this category include transportation disruptions, the adaptability or flexibility of transportation systems, delivery delays, adverse weather conditions, inadequate packaging, and human errors in transportation operations [22].

3.6 | Environmental Risks

Environmental risks may arise from interactions between the supply chain network and its external environment. Khan and Burns [23] stated that economic, political, and social developments and events increase the risk of supply chain disruptions, which have become more complex due to the increasing length and complexity of supply chains. Punniyamoorthy et al. [24] identified policy, macroeconomic, social, natural disaster, and manufactured disaster factors as key elements of environmental risk. Environmental risk can also be defined as an uncontrollable external event involving variable conditions arising from interactions between the supply chain and its surrounding environment. This category includes natural disasters, terrorism and war, political instability in a region, changing regulations, strikes, and the unavailability of qualified personnel [24], [25].

3.7 | Systemic Risks

Systemic risks include threats arising from deficiencies in information infrastructure, insufficient data transparency, disruptions in communication networks, and inter-organizational processes. These risks can result in uncoordinated information flows, reduced decision-making efficiency, and increased vulnerability of the pharmaceutical supply chain as a whole to shocks and fluctuations [21].

3.7.1|Literature review

Table 1 provides an overview of previous studies on supply chain risks in pharmaceutical production.

Table 1. Review of studies on risks in the pharmaceutical production supply chain.

Author	Objective	Research Method/Model	Supply Chain Stage	Case Study	Key Findings/Conclusions
Jaberidoost et al. [5]	To investigate pharmaceutical supply chain risks from the perspective of manufacturing companies	Systematic literature review	Supplier; manufacturer; distributor; consumer	Pharmaceutical supply chain	Fifty major risks were identified in the pharmaceutical supply chain based on the findings of previous studies.
Jaberidoost et al. [26]	To assess risks in the Iranian pharmaceutical industry by considering process, risk, and risk probability priorities	Analytic Hierarchy Process (AHP) and Simple Additive Weighting (SAW)	Manufacturer; distributor; retailer; raw material supplier; consumer	Iranian pharmaceutical industry	Eighty-six major risks were identified from the perspective of pharmaceutical companies and classified into 11 classes.
Brako [27]	To investigate risks in the pharmaceutical supply chain in Ghana	Descriptive analysis; questionnaire-based data collection	Supplier; manufacturer; distributor; retailer; consumer	Ghanaian pharmaceutical supply chain	Drug shortages, theft, and drug expiration were identified as major risks associated with the pharmaceutical supply chain.
Enyinda [28]	To model Enterprise Risk Management (ERM) in the operations and supply chain of a pharmaceutical company	Multi-Criteria Decision-Making (MCDM) methods	Supplier; manufacturer; distributor; retailer; consumer	Pharmaceutical company	Regulatory/legal, operational, and reputational risks were identified as highly important, with risk mitigation/reduction identified as the preferred strategy.
Handayani [17]	To identify, assess, and mitigate supplier–buyer relationship risks in the raw material purchasing process to improve supply chain performance	Integrated SCOR–FMEA–TOPSIS–SRM model	Raw material procurement	Indonesian carton manufacturing company	The most important risks in the purchasing process were identified, and strategies for addressing and mitigating these risks were proposed.
Moktadir et al. [29]	To assess and prioritize risks in the pharmaceutical supply chain using an AHP-based approach	AHP	Supplier; manufacturer; consumer	Pharmaceutical supply chain	Financial, demand, operational, and other risks were prioritized.
Akter et al. [30]	To assess risk factors associated with disruptions in the supply chain of essential medicines using the Grey DEMATEL approach	Grey DEMATEL	Consumer; manufacturer; consumer	Essential medicines supply chain	Disruption risk factors were identified and assessed, highlighting the need for a systematic approach to risk management.
Khan et al. [31]	To assess the impact of supply chain performance factors in the pharmaceutical industry using a hybrid MCDM approach	Hybrid MCDM approach	Supplier; consumer	Pharmaceutical industry	Critical factors affecting supply chain performance were identified, and their interdependencies were analyzed.

Table 1. Continued.

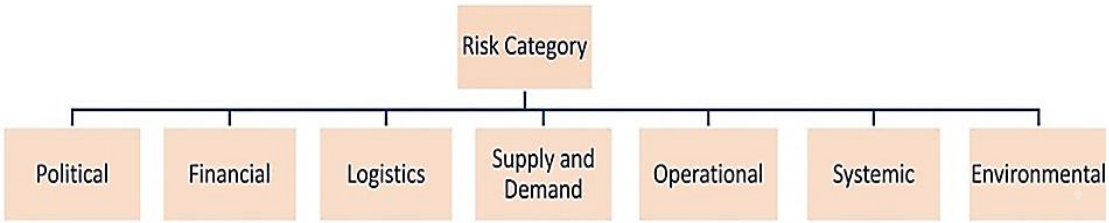
Author	Objective	Research Method/Model	Supply Chain Stage	Case Study	Key Findings/Conclusions
Kilic et al.[12]	To develop an integrated method for identifying, assessing, and prioritizing supply chain risks to reduce potential losses	Hybrid FMEA–IF-AHP–RPN model	All stages	Consumer goods industry supply chain	Risks were identified based on a classification framework and subsequently assessed and prioritized.
Sharma et al. [18]	To identify and prioritize pharmaceutical supply chain risks to enhance resilience	Systematic literature review, Delphi, and AHP	Entire supply chain	Indian pharmaceutical industry	Sixty-seven risks were identified and prioritized, and critical risks were determined.
Ostadi et al. [32]	To identify quality-related hazards associated with the pharmaceutical industry, focusing on ophthalmic drop products	Interviews, questionnaire, and validation	Production; filling; packaging; warehousing	Pharmaceutical company	A comprehensive list of quality-related hazards associated with pharmaceutical products was developed.
Goswami et al. [33]	To develop an integrated framework for modeling disruptions in pharmaceutical supply chains and identifying risk mitigation strategies	Process mapping and disruption modeling	All stages	Pharmaceutical supply chain	Disruptions were classified, pre- and post-disruption mitigation strategies were proposed, and their effectiveness in reducing risks was evaluated.
Yoseph & Sunitiyoso [19]	To classify risks based on a global risk management framework and identify existing research gaps	Bibliometric mapping based on 257 Scopus-indexed articles (2015–2024) and systematic review of highly cited studies	Raw material imports and foreign suppliers; entire supply chain	Iranian pharmaceutical company	A three-dimensional framework for risk classification was proposed.
Ciceri et al. [34]	To comprehensively map and prioritize risks in pharmaceutical supply chains from a multi-stakeholder perspective in European and North American countries	Systematic literature review and AHP	All stages	Pharmaceutical supply chains in Europe and North America	Eighty-four risks were identified, 15 critical risks were prioritized, and differences among stakeholders in risk prioritization were demonstrated.

The systematic literature review indicates that although existing studies have identified a broad range of pharmaceutical supply chain risks, nearly all of these studies have classified risks according to their thematic nature, such as financial, operational, logistics, supply and demand, political, environmental, and systemic risks. However, relatively limited attention has been paid to classifying risks based on the actual stages of the pharmaceutical raw material procurement process. Although some studies, such as those focusing on purchasing processes or supplier quality management, have addressed specific parts of the supply chain process, these process-oriented perspectives have not yet led to the development of a structured framework for classifying risks at the level of the operational steps of the supply chain.

4 | Research Methodology

This study was conducted using a structured literature review approach to identify and classify risks associated with the raw material procurement process in the pharmaceutical industry. To this end, studies addressing pharmaceutical supply chain risks, raw material procurement processes, and risk management were searched, reviewed, and analyzed. The objective was not only to identify the risks reported in the literature but also to

organize them according to the actual stages of the pharmaceutical raw material procurement process. To collect the relevant sources, searches were conducted in the scientific databases Scopus, Google Scholar, and Civilica. The search strategy employed keywords such as "supply chain risk," "pharmaceutical supply chain," "pharmaceutical raw materials," "raw material procurement process," "pharmaceutical production supply chain process," and "risk management," along with their English equivalents. Following the screening of relevant sources, more than 40 articles addressing risk identification, risk management, raw material procurement processes, and supply chains in the pharmaceutical industry were selected for information extraction. In the next step, the stages and activities involved in the pharmaceutical raw material procurement process were extracted from reference studies, including Handayani [17], as well as other relevant articles, and were compared and consolidated to develop a comprehensive process map of the raw material procurement process. This process comprises the following stages: inventory review, supplier identification, supplier capacity assessment and selection, supplier approval, raw material purchasing, transportation, shipment receipt, quality control inspection and testing, storage, and transfer of raw materials to the production department. Subsequently, the risks reported in the selected studies were extracted and mapped onto the different stages of the procurement process based on their nature and point of occurrence. Accordingly, each



risk was classified under the process stage with which it had the strongest association and organized within a process-oriented framework. The final structure of this classification is presented in *Fig. 1* and served as the basis for extracting the identified risks presented in *Table 2*.

Fig. 1. Classification of supply chain risks in pharmaceutical raw material procurement [21].

4.1 | Finding

By reviewing numerous studies in the field of challenges, risks, and disruptions in the pharmaceutical raw material supply chain, 49 risks were identified. These risks were categorized by considering the processes involved in pharmaceutical raw material procurement and by reviewing studies in the field of supply chain management. The research process is presented in *Fig. 2*.

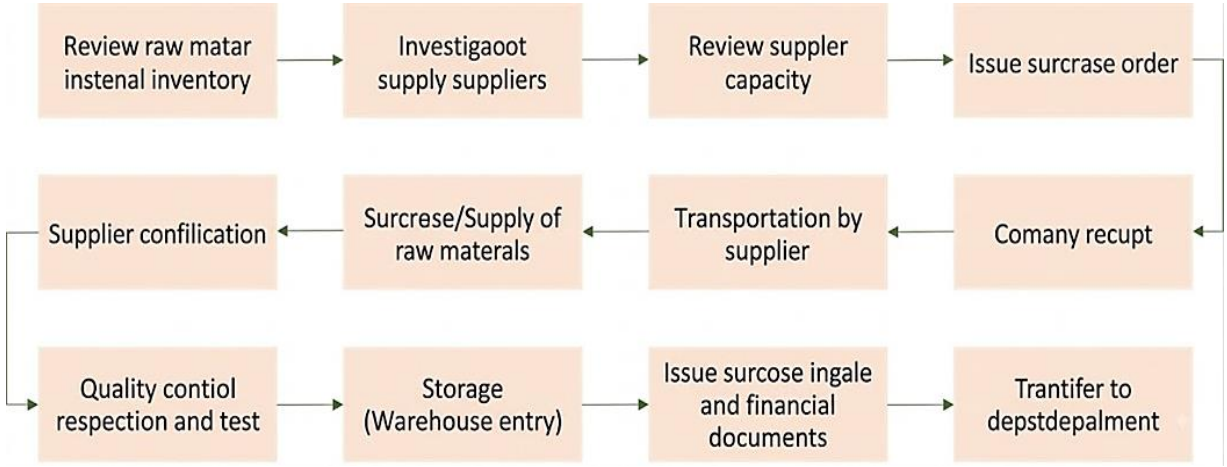


Fig. 2. Pharmaceutical raw material supply chain process [35–38].

The pharmaceutical raw material supply chain process begins with reviewing inventory levels and forecasting production requirements. Once a shortage is identified, comprehensive research is conducted to identify

qualified external suppliers. After evaluating their capacity and ability to comply with the stringent standards of the pharmaceutical industry, the best supplier is selected, and following final approval, a purchase order is issued. The purchasing and procurement stage involves reaching an agreement on all terms and conditions, including price and technical specifications. After the contract is concluded, the raw materials are transported by the supplier to the company and received at the customs office or at the company's premises. The shipment is immediately subjected to thorough inspection and quality control testing to ensure compliance with safety and efficacy standards. Once quality approval is obtained, the materials are stored in designated warehouses under standard storage conditions. Finally, after the invoice is issued and the financial documentation is completed, the raw materials are transferred to the production department to enter the pharmaceutical manufacturing cycle. The identified risks are presented in *Table 2*.

Table 2. Identified risks based on the pharmaceutical supply chain process.

Process Stage	Risk Group	Number	Risk	Source
Raw material inventory review	Supply and demand risk	1	Shortage of raw materials	[27]
		2	Poor inventory management	[27]
		3	Inaccurate demand forecasting or unpredictable and unstable demand	[34]
Research on foreign suppliers	Supply and demand risk	4	Limited number of suppliers	[26]
		5	Dependence on specific importers	[39]
	Logistics risk	6	Lack of easy and rapid access to suppliers	[40]
	Political risk	7	Cancellation of contracts with foreign suppliers	[28]
	Operational risk Operational risk	8	Inappropriate supplier selection and evaluation	[31]
		9	Supplier technology failure	[26]
		10	Supplier's lack of GMP certification	[5]
	Systemic risk	11	Cultural, language, or geographical location issues	[5]
		12	Lack of transparency and access to supplier information	[5]
		13	Supplier fraud	[27]
		14	Misalignment of objectives with the supplier	[17]
Supplier capacity assessment	Supply and demand risk	15	Inability of the key supplier to meet requirements	[29]
		16	Supplier inflexibility (delivery quantity/time)	[26]
	Systemic risk	17	Supplier non-compliance with commitments	[26]
	Operational risk	18	Supplier technology failure	[26]
Purchase order issuance	Systemic risk	19	Loss of reputation	[34]
		20	Lack of information exchange among supply chain stakeholders	[29]
		21	Coordination problems and disruptions in normal activities	[17]
	Operational risk	22	Fluctuations or delays in the order cycle	[5]
	Financial risk	23	Cash flow problems	[26]
Supplier approval	Political risk	24	Changes in customs regulations	[26]
		25	Changes in contract terms	[5]
		26	Changes in regulations (changes in import policies, tariffs, or gmp standards)	[28]
	Operational risk	27	Approval timelines (lengthy permit and regulatory approval processes)	[34]
	Financial risk	28	High cost of raw materials	[27]

Purchase/procurement of raw materials		29	Fluctuations in raw material prices (inflation, exchange rate)	[34]
	Logistics risk	30	Theft	[27]
	Political risk	31	Political turmoil / political disputes	[41]
		32	Sanctions	[34]
		33	Conflicts and wars	[34]
	Environmental risk	34	Natural disasters	[30]
		35	Epidemic diseases	[30]
		36	Spillage of raw materials during transportation	[32]
		37	Seasonal logistics	[12]
	Financial risk	38	Increase in transportation costs	[29]
Order receipt	Operational risk	39	Absence or shortage of personnel in the purchasing or warehouse department	[7]
		40	Coordination problems and disruptions in normal activities	[17]
Inspection and quality control testing	Operational risk	41	Poor quality of raw materials	[27]
		42	Human Error	[34]
		43	Lack of an evaluation process for received raw materials	[42]
		44	Risk of contamination of received raw materials	[42]
Storage (warehousing)	Logistics risk	45	Inappropriate storage conditions for raw materials (cooling, lack of space)	[32]
		46	Disruptions in warehouse processes and raw material storage areas	[32]
		47	Expiration of raw materials	[27]
Purchase invoice issuance	Financial risk	48	Problems with bank transfers	[26]
Transfer to the production department	Operational risk	49	Absence or shortage of personnel in the purchasing or warehouse department	[7]

6 | Conclusion

This study aimed to identify and categorize process-related risks in the pharmaceutical industry and its supply sector by conducting a comprehensive systematic review of relevant studies and extracting the risks reported in reputable sources. The findings indicate that existing literature predominantly classifies risks into thematic, financial, operational, or organizational categories, while a process-oriented perspective focusing on the actual stage involved in raw material procurement has received comparatively limited attention. In comparison with previous studies, the framework proposed in this article focuses on the procurement process map, encompassing activities from inventory assessment and demand forecasting to supplier identification, evaluation and selection, purchasing, and transportation. This approach enables the risks dispersed throughout the literature to be organized and represented according to the actual stages of operations. Compared with non-process-oriented approaches adopted in previous research, the proposed framework provides a more structured and practically applicable perspective on risk analysis in the pharmaceutical raw material supply chain.

Based on the findings of this systematic review and the proposed process-based categorization, future research should focus on developing quantitative risk assessment models based on this process structure to enable more accurate measurement and prioritization of risks. Furthermore, pharmaceutical industries are encouraged to employ this framework as a basis for designing risk management systems, reassessing their interactions with suppliers, and developing strategies to enhance supply chain resilience. Extending the proposed model to areas such as scenario analysis, Bayesian network modeling, and risk-specific approaches provides promising directions for further research.

Authors' Contributions

All aspects of the research and manuscript preparation were carried out by the author. The author has read and approved the final version of the manuscript.

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Data Availability

All data supporting the reported findings in this research paper are provided within the manuscript.

Conflict of Interest

The author declares that they do not have any conflict of interest.

Consent for Publication

The author confirms consent for the publication of this work.

Ethics Approval and Consent to Participate

This article does not contain any studies with human participants performed by the author.

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