

Research Article

Artificial Intelligence in the Pharmaceutical Galenic Field: A Useful Tool with Associated Risks

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Abstract

The integration of artificial intelligence (AI) technology into various fields, particularly healthcare, has demonstrated considerable potential in improving efficiency and accuracy. However, the potential risks associated with unprofessional or inappropriate use of AI cannot be overlooked. The current landscape of healthcare demonstrates a growing reliance on AI tools, which is expected to expand in the future. The existing literature highlights the effectiveness of various AI applications, including chatbots, in specific medical domains. This study aims to review relevant literature in the pharmaceutical and galenic fields while evaluating a prominent AI chatbot provider. Based on the findings, this article presents critical considerations for researchers and practitioners. A thorough assessment of the benefits and risks associated with AI technologies is essential as these tools become increasingly prevalent in pharmaceutical practices.

More Information

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Submitted: April 17, 2025 **Approved:** April 23, 2025 **Published:** April 24, 2025

How to cite this article: Luisetto M, Ferraiuolo A, Fiazza C, Cabianca L, Edbey K, Mashori GR, et al. Artificial Intelligence in the Pharmaceutical Galenic Field: A Useful Tool with Associated Risks. Arch Pharm Pharma Sci. 2025; 9(1): 014-020. Available from:

https://dx.doi.org/10.29328/journal.apps.1001066

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Keywords: Al; Artificial Intelligence; Chatbot; Pharmaceutical galenic; Risk management; Toxicology; Risks; Benefits; Accuracy





Introduction

Artificial Intelligence (AI) encompasses a range of technologies designed to enable systems to analyze data, learn from experiences, and make informed decisions, all guided by human input (ISO, 2023).

As stated by Kufel, et al. [1], AI includes subsets such as Machine Learning (ML), artificial neural networks (ANNs), and deep learning (DL), which have gained traction in recent years. These technologies are increasingly applied in the medical field to enhance the speed and efficacy of disease diagnosis and treatment.

The impact of AI on pharmaceutical laboratories is profound. AI applications are revolutionizing analytical processes, regulatory compliance, and quality control, thereby improving automation, data interpretation, and

compliance monitoring. Regulatory authorities have begun emphasizing the importance of aligning AI innovations with Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) guidelines (Figure 1).

According to the FIP International Pharmaceutical Federation, the FIP Development Goals launched in September 2020 aim to transform the pharmacy profession globally by 2030. These goals emphasize the significance of digital health, focusing on education, workforce development, practice, and science (Figure 2).

The wide-ranging applications of AI in drug discovery, dosage form design, process optimization, and pharmacokinetics/pharmacodynamics studies are further explored by Lalitkumar K. Vora, et al. [3]. AI technologies, including deep learning, natural language processing, and



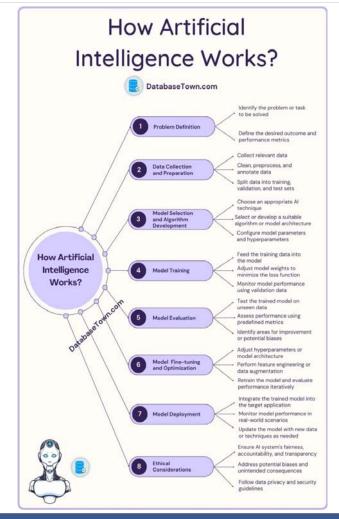


Figure 1: Adapted from Database Town.com How it work artificial intellience?

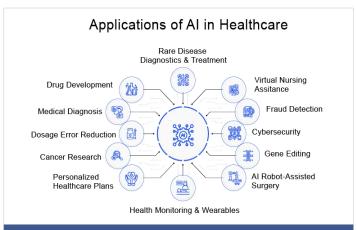


Figure 2: Adapted from Applications of Artificial Intelligence (AI) in Healthcare Segment [2].

computer vision, are driving advancements in telemedicine, diagnosis, drug development, and personalized treatment. In contrast to other scientific fields, pharmaceutical sciences can cause delays in data codification and standardisation. Data accumulation and standardisation are essential for effectively training AI in the former (Figure 3).

While the benefits of AI in healthcare are substantial—such

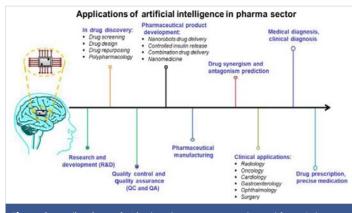


Figure 3: Applications of Al in the pharma sector adapted from Sultana A, et al. [4].

as time savings, improved diagnostic accuracy, and enhanced data management—significant risks also accompany these advancements.

As noted by the Royal Pharmaceutical Society and other experts, it is crucial for pharmacists to develop an understanding of AI technologies to navigate the associated benefits and risks effectively. This research aims to explore these dynamics within the pharmaceutical galenic field, assessing both the transformative potential of AI and the imperative for risk management in its deployment [5,6].

- The search for weaknesses or causes of errors is known as "root cause analysis." The goal of such an analysis in practice is to:Reduce or avoid downtime in production
- Minimize quality defects in manufactured products
- Identify unknown causal relationships and subsequently use them to optimize production plants and processes

Root cause analysis is a continuous task and a part of the continuous improvement process of a company, given the ever-increasing demands for quality and optimization (Figure 4) errors in these large data sets.

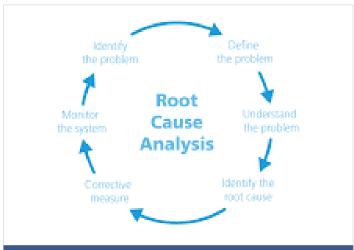


Figure 4: Adapted from Al-based root cause analysis of Hans-Ulrich Kobialka 2022 [7].



Materials and methods

This study employed an observational approach to review scientific literature pertinent to the integration of Artificial Intelligence (AI) in the pharmaceutical and galenic fields. Relevant articles were identified and analyzed to understand the current landscape of AI applications and their implications for pharmacy practice. Figures 1-5 illustrate the core concepts discussed in the manuscript.

Additionally, a practical component was incorporated into the study, wherein a series of queries—ranging from simple to complex—were submitted to a well-known AI chatbot. The chatbot's responses were documented and evaluated for accuracy and relevance to pharmaceutical practice. This practical experience aimed to provide insights into the capabilities and limitations of AI technology in addressing specific pharmaceutical inquiries.

Following the literature review and practical experience, a comprehensive conclusion was drawn to summarize the findings and implications for researchers and practitioners in the field.

Results

Key findings from literature review

1. Cognitive limitations in medicine: Aliasghar Karimi, et al. noted that the human mind faces numerous obstacles in recalling and applying vast amounts of medical information. The proliferation of medical knowledge makes it impractical for clinicians to analyze extensive literature, leading to diagnostic errors primarily attributed to cognitive biases among healthcare workers. Medical errors continue to be a major contributor to patient morbidity and mortality in the United States, often linked to human error [8].

Summary (Galenic Lab Semi-Automatic Mixer):

Type of Blend	Minimum Time	Notes
Simple, high-dose API	5-10 minutes	Similar particle size, good flow
Low-dose/ potent API	10-15 minutes	Use geometric dilution
Difficult/ cohesive powders	15-20 minutes	May need intensificati on
Visual/ manual mixing	Add 2-3 min	Common in small batches

Figure 5: Response from an Al Chat bot.

- **2. AI in pharmacy practice:** Sri Harsha Chalasani, et al. highlighted AI as a transformative technology capable of enhancing medication management and patient care. By leveraging AI algorithms and machine learning, pharmacists can analyze extensive patient data, improving the identification of drug interactions and informing tailored recommendations [9].
- **3. Personalized medicine:** As reported by Vora, et al. emphasized that AI can facilitate personalized medicine through the analysis of real-world patient data, leading to improved treatment outcomes and adherence [10].
- **4. Streamlining clinical decisions:** Kelsee Tignor, et al. discussed how AI, referred to as pharmacointelligence, can assist clinical pharmacists in making evidence-based decisions by analyzing large volumes of patient data [11].
- **5. Enhancing patient safety:** Rayn Oswalt noted that pharmacists are concerned about patient safety and that AI can help detect and prevent medication errors, thereby reducing adverse events and hospital readmissions [12].
- **6. Applications in dosage form development:** Praveen Halagali, et al. reviewed Al's applications in developing solid dosage forms, optimizing formulation processes, and assessing drug toxicity profiles, which streamline the path from pilot studies to market [13].
- **7. Excipient compatibility:** Ashutosh Kumar, et al. pointed out that AI can significantly enhance the assessment of excipient compatibility, improving pharmaceutical development [14].
- **8. Predicting drug toxicity:** Mahroza Kanwal Khan, et al. highlighted the advantages of using AI to predict drug toxicity, which allows for a deeper understanding of drug interactions with biological systems [15].
- **9. Formulation optimization:** Negar Mottaghi, et al. discussed how AI algorithms evaluate data to enhance the stability and compatibility of pharmaceutical ingredients, leading to improved formulations [16].
- 10. Pediatric dosing: Andreea-Alexandra Mocrii, et al. aimed to assist pediatricians in determining appropriate treatment doses for children based on various parameters [17].
- 11. Education on AI in pharmacy: Muhammad Ahmer Raza, et al. advocated for pharmacy education to incorporate AI and data science, emphasizing the need for pharmacists to develop skills that promote AI integration in practice [18].
- 12. Systematic review of AI in healthcare: Margaret Chustecki reported a systematic review yielding 8796 articles, which narrowed down to 44 studies. The review highlighted AI's potential in healthcare, such as improving diagnoses and personalized treatment plans, while also addressing concerns about biases and data privacy [19].



- **13. Risk prevention in clinical practice:** Michela Ferrara, et al. emphasized the usefulness of AI in risk prevention and incident reporting in clinical settings [20].
- **14. Advancing toxicology:** Nicole Kleinstreuer, et al. noted that AI could advance toxicology into a more predictive discipline, safeguarding human and environmental wellbeing [21].
- **15. Risks associated with AI:** Mateusz LASKA, et al. identified human error as a significant risk in AI applications, emphasizing the need for understanding and managing these technologies [22].
- **16. Ethical considerations:** Mitul Harishbhai Tilala, et al. discussed the multifaceted ethical considerations surrounding AI in healthcare, including privacy, bias, and accountability [23].
- 17. 3D Printing in pharmaceutical development: Timothy Tracy, et al. highlighted the versatility of 3D printing technology in creating customized dosage forms, which accelerates formulation development [24].
- **18. Prescription monitoring:** Cinzia Barberini, et al. described a system that interconnects prescription-related aspects, enhancing stock monitoring and preparation checks [25].
- **19. AI system failures:** Sasanka Sekhar Chanda, et al. identified potential failure points in AI systems, including input errors and processing deficiencies, which can lead to inappropriate outputs [26].
- **20. Risks of AI in medicine:** Karim Lekadir, et al. outlined seven main risks of AI in healthcare, including patient harm, misuse of tools, and gaps in accountability [27].
- **21. Chatbot accuracy in healthcare:** Stefanie Beck, et al. evaluated the accuracy of ChatGPT versions 3.5 and 4 in healthcare contexts, revealing discrepancies in adherence to established guidelines [28].
- **22. Variability in chatbot responses:** Meron W. Shiferaw, et al. noted inconsistencies in ChatGPT's responses, highlighting errors that could result in clinical harm [29].
- **23.** Performance comparison of ChatGPT versions: Ronald Chow, et al. reported varying performance levels between ChatGPT versions, emphasizing the need for further development to enhance reliability in medical training and decision-making [30].

These findings underscore the transformative potential of AI in pharmacy and healthcare while also highlighting the associated risks and ethical considerations that must be addressed to ensure safe and effective implementation.

Experimental project

In this section, a series of queries—ranging from simple to

complex—were submitted to a widely recognized AI chatbot accessible for free on the web. The responses received are documented below:

1. Is digoxin water-soluble?

Response: It is poorly soluble in water and more soluble in alcohol.

2. What is the molecular weight of NaCl?

Response: 58.44 g/mol.

3. Must Collyria be sterile?

Response: Yes, it is fundamental to avoid eye infections.

4. Is propranolol compatible with microcrystalline cellulose?

Response: Yes.

5. Is omeprazole acid-sensitive?

Response: Yes, it is inactivated in the acidic environment of the stomach.

6. What is the chemical structure of citric acid monohydrate?

Response: (The chatbot did not provide a specific right structure).

7. Is lidocaine hydrochloride considered a poison by the Italian Pharmacopoeia No. 3?

Response: Yes.

8. Is acetone flammable?

Response: Yes.

9. What is the galenic use of NIPAGIN?

Response: Preservative.

10. What is the water solubility of amoxicillin?

Response: The water solubility is not extremely high, so specific formulations are needed to improve body absorption.

11. How can the solubility of water-insoluble active principles in galenic oral drops be increased?

Response: Various strategies include using cosolvents like ethanol, glycerin, and propylene glycol; employing surfactants; utilizing cyclodextrin complexation; applying solubility enhancers (e.g., PEG); adjusting pH; and formulating suspensions.

12. How can the solubilization of a solute in a solution be increased?



Response: Increase temperature, use a suitable solvent, apply agitation, increase the surface area of the solute, employ surfactants, adjust the pH, use co-solvents, apply pressure (for gases), and utilize complexants.

- 13. How many grams of KOH are needed to prepare a 100 ml solution at 30%? Response: Dissolve 30 grams in a total volume of 100 ml of solution.
- 14. How should medications be administered to children with difficulty swallowing?

Response: Liquid suspensions, chewable tablets, dissolvable forms, powders, orally disintegrating tablets, other liquid forms, or suppositories.

15. What is the time needed to adequately mix APIs and excipients in the galenic field using a semi-automatic powder mixer to prepare capsules?

Response: The chatbot provide answer as reported in the Figure 5.

Discussion

The applications of AI in the galenic field are diverse, ranging from robotic systems in oncology laboratories to software for laboratory management, algorithms for verifying incompatibilities, and assessing posology or toxicity. As with other disciplines such as medicine and technology, AI tools are increasingly integrated to support healthcare professionals, including those in the pharmaceutical sector. By incorporating AI into clinical practice, health care professionals can augment their decision-making processes and provide patients with personalized care. AI allows for greater collaboration between different healthcare services provided to a single patient [31,32].

In pharmaceuticals, adherence to regulatory and safety standards is paramount. Consequently, it is crucial to evaluate the results obtained from various AI instruments—be they robots, software, chatbots, or other technologies. Pharmaceutical manufacturing prioritizes precision and consistency in formulation and safety assessments, while AI, by its nature, operates on probabilities and approximations. Although AI systems leverage large datasets and processing power available, AI systems operate probabilistically and may not yield deterministic outcomes, underscoring the importance of human oversight, AI tools are trained on historical datasets, and their predictive outputs are contingent upon the quality and representativeness of the input data [33-35].

It is essential to understand the underlying algorithms and quantify the error rates associated with this emerging technology. Key healthcare priorities include ongoing professional development, digital competence, and technological innovation, digital competencies, and innovation. According to the FIP, integrating AI in pharmacy requires

pharmacists to grasp not only the capabilities of these new technologies but also their limitations, data quality, regulatory compliance, ethical considerations, and the infrastructural investments necessary for successful implementation [36].

The responses generated by the AI in the experimental project were generally straight forward, differing from traditional search engines that yield multiple viewpoints from various sources. In this project, out of 15 scientific and technical questions posed, 14 responses were deemed acceptable, with one notable exception regarding the chemical structure of citric acid monohydrate, where the AI failed to provide the correct formula featuring three carboxylic acid groups [37,38].

The limitations of Al include

- Lack of transparency and explainability, making it difficult for users to understand AI and deep learning models.
- Potential biases in training data, which can lead to unequal treatment or misdiagnosis of certain demographic groups.
- New regulatory and legal challenges that complicate compliance with existing frameworks.
- Risks of manipulation through AI algorithms and increased control systems (e.g., facial recognition).
- Concerns regarding data privacy, particularly in the absence of explicit protective laws.
- Erosion of human influence in decision-making processes.
- Interoperability issues between existing healthcare systems and new data platforms.
- Accountability challenges in identifying responsibility for errors.
- Resistance from healthcare professionals towards adopting AI technologies.
- Agenerallackoftrustin AI-generated recommendations.
- High costs associated with developing and implementing AI solutions.
- Absence of emotional intelligence and creativity in AI systems.
- Risks of diminishing critical thinking and judgment among healthcare professionals.
- Ethical dilemmas arising from AI decisions that may conflict with patient or family preferences.
- Data quality issues stemming from incomplete or inaccurate information.



• Potential cybersecurity threats, including ransomware, malware, data breaches, and privacy violations.

Conclusion

This study demonstrates that AI tools can be beneficial in guiding practices within the galenic field. However, the findings from the chatbot queries should be rigorously validated against established pharmaceutical standards. Of the 15 queries posed, 14 responses were found acceptable, resulting in a notable 6.7% rate of unacceptable responses. Because galenic formulations must meet stringent regulatory standards and prioritize patient safety, it is imperative that all AI-generated outputs undergo professional verification to ensure clinical accuracy in the current landscape of pharmaceutical practice.

As AI becomes increasingly embedded in pharmaceutical practices, it is vital for professionals in the field to maintain a critical perspective, ensuring that their implementation must enhance, rather than compromise, patient care and medication safety.

Disclaimer

Some figures and tabulated data in this manuscript (Figure 5) were generated with the assistance of the ChatGPT AI tool developed by OpenAI. All content has been reviewed and validated by the authors to ensure scientific accuracy and relevance.

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