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Current trends of Artificial intelligence: pharmaceutical for solid oral dosage form

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ABSTRACT :

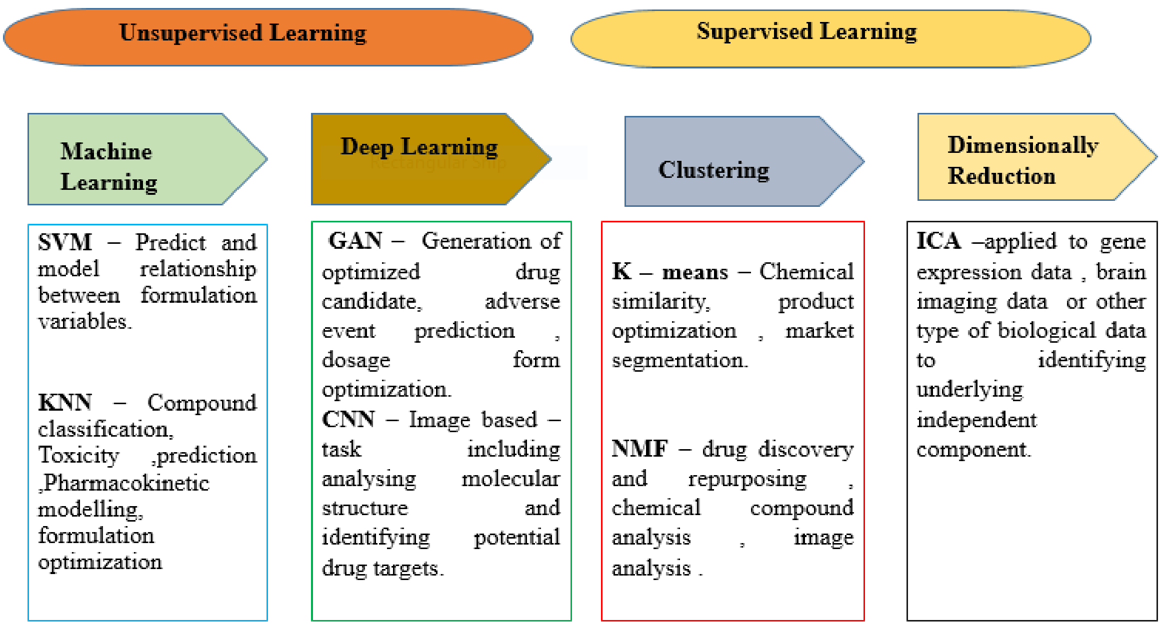
Artificial intelligence (AI) is a promising strategy for enhancing pharmaceutical product development. AI is a versatile tool with various algorithms suitable for various situations, including solid dosage forms like tablets, capsules, powders, etc. The article discusses the importance of evaluating the mechanical properties of solid dosage forms for quality control. AI's network and tools are used in drug discovery, manufacturing, quality control, clinical trial management, and drug delivery. AI is used in both conventional and modified dosage forms, but challenges such as data availability, model interpretability, and regulatory considerations persist. This review provides an overview of AI in pharmaceutical sciences, regulatory guidelines, data processing and preparation methods, and AI algorithms' applications in solid dosage forms. The study concludes by outlining potential applications of AI in drug formulation and development, focusing on precision drug targeting, customized medicine, and quick formulation optimization.

Keywords: Artificial intelligence (AI), algorithms, Regulatory, drug discovery, drug delivery.

1.0 Introduction :

The oral drug delivery allows for easier self-administration, enabling patients to manage their treatments independently. This method also facilitates a broader range of formulations, including tablets, capsules, and liquids, catering to diverse patient needs and preferences [1]. One problem with the oral route is that some medications don't stay stable in the gastrointestinal (GI) tract. Another problem is that hydrophobic agents, which are often used in cancer chemotherapy, are also hard to dissolve [2]. Artificial Intelligence (AI) represents a significant advancement in computer sciences, languages, and statistical modeling, which has been applied to various fields such as biology and healthcare, education, the pharmaceutical industry, drug discovery and development, sales and marketing, business decision-making, and finance, among others [3]. "AI" is a broad term that encompasses research and development from many fields and conceptual approaches. People frequently use it to describe the development of technologies capable of performing tasks that require human-like intelligence [4]. The artificial intelligence (AI) algorithms track and improve industrial processes in real time. AI can anticipate possible deviations and modify parameters to maintain ideal conditions for ongoing data collection and analysis, guaranteeing consistent product quality. This ability is crucial in the manufacturing of biologics, as even little changes in the process can have a big impact on the safety and effectiveness of the final product [5].

Fig no. 1. Different supervised and unsupervised AI learning models/tools for pharmaceutical application



In the field of pharmaceutical research, visual inspection is an important method for identifying and measuring active pharmaceutical ingredients (APIs), excipients, and dosage forms, especially when it comes to solid dosage formulations [6]. Tablets, powders, and granules, as solid dosage forms, are consistently the most widely accepted drug product formats, largely owing to their ability to promote patient compliance and their user-friendly nature [7]. Deep learning algorithms like convolutional neural networks and recurrent neural networks have become more popular in the pharmaceutical sciences over the past few years. These algorithms are used for a variety of tasks, such as creating solid dosage forms and finding flaws in tablets [8]. These algorithms are also utilized for estimating the stability of storage over time and assessing the flow characteristics of particles. Anticipating the release profiles of drug formulations [9] [10] [11].

Artificial intelligence (AI) is expected to revolutionize drug research and formulation, focusing on precision medication targeting, treatment solutions, and rapid formulation innovations [12]. AI has made clinical trials, research, and decision-making more effective, benefiting patients, doctors, insurance companies, and government agencies [13]. AI can replace trial and error by employing rule-based algorithms to determine appropriate excipients based on drug physicochemical properties [14]. A hybrid application combining support vector machines and simulated annealing has improved drug development efficacy and efficiency. The identification of novel enzymes in non-ribosomal peptide synthesis could broaden therapeutic alternatives [15] [16].

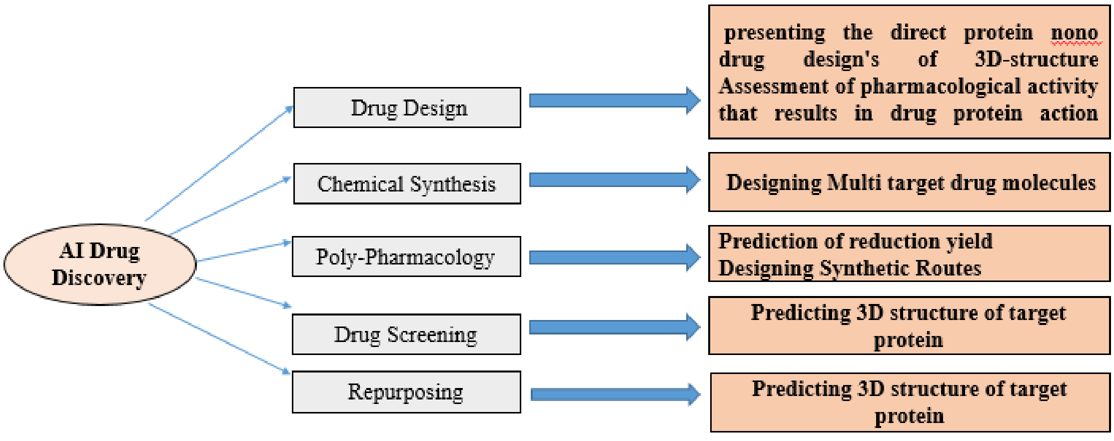
AI-enabled tools and technologies are crucial for efficient drug identification, target confirmation, and structure design optimization [17]. These innovations can significantly benefit the healthcare sector by reducing time and costs associated with new molecule discovery. AI's ability to handle large data volumes through automation supports its increased utilization. AI research has focused on practical solutions to supply chain management issues, with recommendations for future research paths [18]. Implementing innovative technological advancements can help tackle these challenges. The healthcare field requires skilled labor, and continuous education is essential for pharmaceutical sector [19]. Detecting skill shortages in the workplace is crucial for the pharmaceutical sector. While AI can enhance learning analytics, implementing such systems requires extensive data, including sensitive information, raising concerns about privacy and data security [20] [21] [22]. Artificial intelligence aims to create machines and systems capable of performing tasks requiring cognitive abilities similar to humans, such as problem-solving, natural language understanding, pattern recognition, and reasoning. It includes sub-fields like deep learning (DL) and machine learning (ML), which use multi-layered neural networks and iterative practice to improve algorithms [23].

This study examines the use of artificial intelligence in pharmaceuticals to optimize dosage forms for patients, particularly those who struggle with swallowing tablets. The study focuses on the use of AI-generated predictive models to optimize medicine formulations, ensuring efficient delivery of active components to the body [24] [25] [26]. AI algorithms can forecast medication release profiles, enabling controlled-release pharmacological formulations with consistent therapeutic impact over time [27]. The study also examines the implementation of industrial artificial intelligence in practical manufacturing contexts. It introduces a conceptual framework to bridge the gap between academic research and the manufacturing sector, promoting industrial adoption through a digitally oriented and data-driven corporate culture. The framework also highlights challenges and opportunities for future research [28] [29].

Application of AI in Solid Oral Dosage Forms :

The formulation of a stable oral dosage form that meets acceptable standards presents a significant challenge, even for seasoned pharmaceutical chemists. Achieving the necessary criteria for efficacy, safety, stability, and processability necessitates a meticulous consideration and integration of various material, process, analytical, and regulatory factors [30]. The technique of visual inspection is pivotal in pharmaceutical research, particularly for the characterization and quantification of APIs and excipients in solid dosage formulations. With the rise of artificial intelligence, numerous studies have sought to enhance scaffold design and construction through the utilization of neural networks. A specific study analyzed the combined effects of layer thickness, lag time, and pressure direction on the porosity and compressive strength of scaffolds, using an artificial neural network as a methodological tool [31]. In addition to the pressure settings, a neural network technique is leveraged to evaluate the structural characteristics of scaffolds and to identify the most effective mechanical behavior for the regeneration of tendons and ligaments. Recently, a diverse array of AI-driven models has been successfully employed in the development of solid dosage forms in pharmacology. The intersection of computer science, data analytics, and mathematics fosters the advancement of artificial intelligence [32]. A transformative phase of innovation has emerged from the synergy between artificial intelligence (AI) and the development of pioneering drugs, which has significantly impacted various elements of drug discovery and distribution. In the past twenty years, pharmaceutical enterprises have adopted a multitude of AI-centric approaches, encompassing machine learning, deep learning, and other sophisticated computational methods [33].

Fig. no. 2 Different applications of AI in drug discovery



2.1 Developing 3D-Printed Tablets Using AI

Tablets, a primary form of oral solid dosage, are typically produced through compression or molding, combining active pharmaceutical ingredients (APIs) with excipients. Traditional manufacturing methods are labor-intensive, time-consuming, and inflexible, focusing on high-volume production. In contrast, 3D printing enables on-demand manufacturing at the point of care, utilizing cost-effective equipment and streamlined processes. This involves creating a computer-aided design (CAD) file, converting it into a stereolithography format for rapid prototyping, and translating it into machine-specific code for production [34] [35]. This section explores the applications of artificial intelligence (AI) in tablet formulations, particularly in medication release prediction, enhancing manufacturing processes, and identifying tablet defects [36]. AI integration in quality monitoring is crucial for optimizing printing parameters and addressing manufacturing challenges. AI-driven feedback systems, utilizing real-time data, can improve the 3D printing process's scalability, accuracy, and reproducibility. Key manufacturing parameters, such as nozzle temperature and printing speed, significantly influence the quality of the final products and the drugs' release profiles [37]. For instance, Obeid et al. investigated the impact of processing parameters on the drug release of diazepam 3D-printed tablets using an artificial neural network (ANN) model. Additionally, Westphal et al. demonstrated the effectiveness of convolutional neural networks (CNN) in detecting defects in tablets produced via selective laser sintering, showcasing AI's potential for non-destructive quality assurance in 3D printing. The analytical procedures associated with these traditional studies are often protracted and resource-intensive. With the advent of AI technology, scientists are now capable of predicting vital characteristics of drug formulations, thus streamlining the product development process and reducing associated costs and time [38].

2.2 Powders

Powder is a common form of medicinal dosage, composed of finely divided particles within a dry medium. These powders are used in various dosage forms, including pills and capsules. Artificial intelligence technologies have been successfully used to control powder engineering processes, and AI applications in carrier-based dry powder inhalation have shown significant potential [39] [40]. Aerosol performance evaluation is crucial in the development of dry powder inhalation products, with parameters like fine particle fraction (FPF), median mass aerodynamic diameter (MMAD), and geometric standard deviation (GSD) determining performance [41]. These parameters can be precisely measured using next-generation impactors or cascade impactors. Particle size is crucial in pharmaceutical product development, affecting surface area, solubility, porosity, bioavailability, powder flowability, and shelf life. Aerodynamic particle size is essential for pulmonary drug delivery, as powders will be exhaled if too small or cannot reach the lung if too large. Key processing parameters, such as drying temperature, pressure, air flow, and energy input, significantly influence the quality and critical characteristics of the final product. Recent studies have shown that artificial intelligence technologies can be used to monitor the quality and properties of the product during the particle engineering process [42] [43].

2.3 Capsule

Pharmaceutical agents are typically contained in capsules, which are solid dosage forms suitable for oral consumption [44]. Artificial intelligence techniques are increasingly being used in capsule formulation. A study by Zhou et al. demonstrated the use of an advanced Convolutional Neural Network (CNN) to identify capsule defects [45]. The researchers used manually crafted capsules with various defects, such as perforations, concave heads, uncut bodies, oil stains, and shriveled, locked, or nested capsules. The CNN model used L2 regularization and the Adam optimizer to address overfitting. The study also used Support Vector Machine (SVM) and K-Nearest Neighbor (KNN) methodologies. The improved CNN model achieved an accuracy of up to 97.56% in detecting capsule defects [46] [47].

2.4 Granules

Granules are a type of pharmaceutical dosage consisting of powdered particles with active and inactive ingredients. They offer greater stability and are suitable for patients who struggle with swallowing tablets or capsules. Granules in capsule form have enhanced compressibility and flow characteristics. There are various types of granules, including modified-release, coated, effervescent, and gastro-resistant. Wet and dry granulation are the main methods for granule production [48]. Artificial intelligence technologies were used to simulate particle size distribution of final granules [49]. Machine learning strategies were used to estimate drug quantities based on near-infrared spectral data. Three AI frameworks were found to be the best for making prediction models: backpropagation artificial neural networks (ANN), support vector machines (SVM) improved by particle swarm optimization, and genetic algorithms [50].

2.5 Pellets

The first approved modified-release formulation, containing pellets, highlights the importance of pellet technology in the pharmaceutical industry. Pellets offer numerous advantages over traditional solid dosage forms, including enhanced safety and effectiveness of bioactive substances, increased flexibility in dosage form design, and improved absorption of medications [51]. They also help reduce plasma variations and potential side effects, maintain drug bioavailability, and reduce differences in total transit time and gastric emptying rates. Pellets also address the issue of high concentrations of medication in one area, which can cause irritation from active ingredients [52]. The study analyzed the impact of binder content, pellet diameter, and pellet weight on material compressive strength using an artificial neural network (ANN) model [53]. The model's effectiveness was measured using the correlation coefficient (R^2) with 1000 epochs. ANNs, like human cognitive development, can learn from input data and identify features through continuous improvement of connection weights. They are adept at handling large amounts of data and complex nonlinear relationships due to their flexibility and ability to handle parallel processing [54].

2.6 Solid Dispersion

Solid dispersions, composed of drugs and polymers, are crucial for solubilizing solid dosage forms. Amorphous solid dispersion, a subfield, is a homogeneous drug polymer solution formed when an amorphous drug is mixed into a polymer matrix using fusion-based methods like hot-melt extrusion or solvent-based methods like spray-drying and co-precipitation [55]. To overcome phase separation in solid dispersion product development, factors like stability, miscibility, and solubility must be considered. Traditional methods involve pre-formulation, formulation, and characterization stages, which can be time-consuming. High-throughput screening methods like solvent casting can improve efficiency. AI-based techniques have been successfully used to predict characteristics like stability, dissolution rate, and dissolution profile [56].

3.0 Future Prospects :

The utilization of AI models in formulation design is widespread; however, certain areas remain inadequately explored and deserve attention. Specifically, the fields of chemistry and materials science have adopted complex deep learning methodologies, such as graph convolutional networks and generative adversarial networks (GANs) [57]. The optimization of continuous manufacturing processes will be achieved through the real-time monitoring and regulation of essential parameters by AI models. By employing data analysis and feedback mechanisms, AI algorithms will ensure that pharmaceutical manufacturing remains both consistent and efficient. Furthermore, AI will conduct comprehensive data analyses to inform regulatory decisions, thereby assisting regulatory bodies in accelerating the approval of medications and improving their safety profiles [58]. The role of artificial intelligence in clinical settings is poised to enhance the efficiency of healthcare delivery and improve the accuracy of diagnoses. Given the immense investments of time and money in the realm of drug research and development, it is imperative to adopt more innovative strategies and approaches [59].

The future of drug discovery is expected to be significantly influenced by AI-driven methodologies, which will enhance the accuracy of predictions regarding drug-target interactions and provide a more profound understanding of disease physiopathology [60]. The integration of Big Data in the customization of patient treatments will significantly drive the progress of personalized medicine through artificial intelligence. By examining genetic, environmental, and lifestyle data, healthcare systems can develop treatment strategies that are finely tuned to the unique circumstances of each patient [61]. Toxicological issues emerge when Nano-drugs accumulate in unintended tissues. Thus, it is crucial to evaluate the biological distribution of nanoparticles post-systemic injection in the context of clinical research. The prospects of artificial intelligence in the realm of pharmaceutical development and formulation are highly encouraging. As AI technology continues to evolve, it is expected to assume an increasingly significant role in the drug development process, assisting researchers in identifying novel therapeutic targets, understanding medication interactions, and determining patient populations that are most likely to derive benefits from specific treatments [62].

Conclusion :

The development of solid dose formulations and their diverse applications can be significantly enhanced through the integration of artificial intelligence (AI) tools. Research has increasingly demonstrated that AI holds substantial potential in the realm of formulation development, particularly in its ability to revolutionize the drug discovery process. By facilitating rapid and cost-effective predictions, AI-driven strategies can expedite the formulation development timeline, contrasting sharply with traditional methods that rely on labour-intensive trial-and-error approaches. The study also explored the pros and cons of the technologies involved in the creation of 3D printed tablets, namely binder jetting, fused deposition modelling, semi-solid extrusion, selective laser sintering, and stereolithography. An extensive review of the literature has uncovered various applications of 3D printing in paediatric formulations, including Oro-dispersible tablets, modified release systems, biphasic release formulations, gastro-floating tablets, and sustained release tablets. It is important to note that while artificial intelligence and computational research cannot fully replace laboratory experimentation, they are instrumental in enhancing and accelerating the processes of target and drug discovery. Moreover, there is an urgent need for a greater number of researchers who are adept at managing and interpreting data.

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