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ROLE OF ARTIFICIAL INTELLIGENCE IN IMPROVING LIQUID DOSAGE FORMULATION AND DEVELOPMENT

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ABSTRACT

In formulation development, formulation tactics are essential, and conventional trial-and-error methods are ineffective. In line with Industry 5.0 principles, this publication investigates how Artificial Intelligence (AI) might improve medicine formulation. AI facilitates data-driven decision-making, which enhances workflow efficiency, productivity, process monitoring, human-centric automation, and product quality. Solvent selection, compatibility with excipients, crystallinity, salt formation, permeability, and stability are important developmental design elements. While AI and Process Analytical Technology (PAT) are used together, they speed up decision-making and guarantee consistency while producing different liquid dosage forms. In order to improve the development of liquid dosage formulations, the review highlights research gaps, difficulties, and future directions in addition to identifying current applications of AI in manufacturing.

KEYWORDS: Artificial intelligence, Fluid flow, Manufacturing, Pharma 5.0, Process

analytical technology.

INTRODUCTION

By turning scientific knowledge into new drug products, artificial intelligence (AI) is completely changing the pharma product development process. Through the integration of several data sources, AI improves several phases of the drug development pipeline, leading to increased drug discovery success rates and efficiency. Systems may learn from data thanks to machine learning (ML), a branch of artificial intelligence that includes supervised learning, unsupervised learning, and reinforcement learning. Furthermore, ANNs, a deep learning technique, are sophisticated instruments for data processing in drug discovery that use neural architectures modeled after biological neurons to guide choices.[1,2]

Two important supervised machine learning tasks targeted at various data sources are classification and regression. Using methods like logistic regression, decision trees, random forests, support vector machines (SVM), k-nearest neighbors (k-NN), and neural networks (ANNs), classification makes predictions about discrete categories. Predicting continuous values is the main goal of regression, and methods like decision trees and random forests can also be used. ANNs are especially good at modeling intricate relationships, and by reducing prediction mistakes, they can learn to improve performance. In order to improve the quality and safety of pharmaceutical products, they are used in drug development to forecast efficacy, optimize procedures, and identify side effects. In this context, SVM, random forests, and XGBoost are often used algorithms for modeling complex input-output functions.[3,4]

Depending on the demands of the patient, dosage forms such pills, capsules, and liquids are made for various routes of administration. To guarantee safety and effectiveness, liquid formulations made up of excipients (such as solvents and preservatives) and active pharmaceutical ingredients (APIs) necessitate a thorough understanding of physicochemical characteristics, pharmacokinetics, and pharmacodynamics. Maintaining regulatory compliance while attaining the best possible solubility, stability, and bioavailability requires controlling the interaction between APIs and excipients. Pre-formulation and manufacturing phases are part of the development process, with an emphasis on variables like stability, viscosity, and solubility that have a big impact on manufacturing performance, particularly when non-Newtonian fluids affect pump and impeller operation.[5]

By processing massive information and connecting formulation properties to processing

factors, artificial intelligence (AI) integration in manufacturing is revolutionizing operational efficiency. In addition to streamlining processes and providing a competitive advantage, it improves productivity, product quality, problem detection, and cost savings. A network of interconnected machinery that keeps an eye on equipment conditions and guarantees product uniformity is made possible by combining AI with IoT devices. Additionally, by automating documentation and record-keeping, AI streamlines regulatory compliance in pharmaceutical manufacturing. This procedure is aided by Artificial Neural Networks (ANN), which identify patterns and produce predictions for improved output analysis.[6]

Industry 5.0 signifies a transformative phase in the industrial revolution, combining human-machine interactions through Augmented Intelligence (AuI) and collaborative robots (cobots). AuI enhances decision-making and operational efficiencies by merging AI's data processing capabilities with human intelligence. Innovations driven by robotic process automation have led to significant ecosystem benefits, including increased control and reduced errors. Cobots, designed for safe interaction with humans, utilize advanced sensing technologies and algorithms to work alongside people with precision in dynamic environments.[7]

The integration of AuI and cobots is driving the shift from Pharma 4.0 to Pharma 5.0, improving automation's efficacy, speed, and accuracy in the pharmaceutical sector. This change optimizes operations, increases productivity and product quality, and encourages sustainable behaviors. By using data analytics and machine learning to anticipate equipment failures, minimize downtime, and improve operational efficiency and asset longevity, artificial intelligence (AI) is crucial in the transition of maintenance from reactive and preventative to predictive maintenance. In spite of earlier usage of machine learning in drug development and solid dosage forms, the current work focuses on the real-time application of AI in liquid dosage form manufacturing with the goal of investigating tools and strategies for process monitoring and correction.[8]

LIQUID DOSAGE FORM – A BRIEF

Pharmaceutical formulations containing one or more active pharmaceutical ingredients (APIs) and excipients in a solvent are known as liquid dosage forms. They serve groups that struggle with solid forms or require rapid treatment effects. Increased market demand has resulted from their compliance and ease of use, especially for items like acetaminophen syrups and suspensions. These formulations are in ready-to-use liquid or reconstitution

powder form and can be delivered orally, parenterally, nasally, ophthalmically, otically, inhaled, or topically. Parenteral versions must adhere to sterility standards based on clinical criteria, whereas oral forms are not.

Monophasic Liquid Dosage Forms

Monophasic liquids absorb quickly and effectively because they are a single-phase solution with the API and excipients completely dissolved. Examples include external formulations like lotions and liniments, as well as oral ones like mixes, elixirs, and syrups. Additionally, they are used in injections, eye and ear drops, and mouthwashes. The Quality Target Product Profile (QTPP), which takes into account pharmacokinetics, dosage strength, and administration route, serves as a guide for the formulation of these liquids.[9] Solubility, stability, and compatibility are important qualities, while sterilization, efficient mixing, and pH control are crucial characteristics. Strict process control is required for the safety and effectiveness of parenteral products.[10]

Biphasic Liquid Dosage Forms

Emulsions and suspensions are examples of biphasic systems, which consist of two immiscible phases. While emulsions, which are categorized as either water-in-oil (W/O) or oil-in-water (O/W), combine water and oil stabilized by emulsifying agents, suspensions use suspending agents to disperse insoluble active pharmaceutical ingredients (APIs) in a liquid media. These formulations improve the stability and solubility of medications that are not very soluble. For example, Diprivan is an emulsion for intravenous anesthesia, and Pepto Bismol is a suspension for gastrointestinal problems. Critical quality characteristics are different for emulsions and suspensions. Emulsions need consistent droplet size, while suspensions concentrate on particle size distribution. In addition to requiring sterile conditions and appropriate packaging for product safety and stability, the development process must regulate mixing and emulsification to avoid degradation or phase separation.[11]

Understanding the physicochemical characteristics of the active pharmaceutical ingredient and how it interacts with excipients—which act as solubilizers, viscosity modifiers, preservatives, and stabilizers—is essential when creating monophasic and biphasic systems in the pharmaceutical industry. For efficient drug administration and stability, important properties like shape, particle size, surface chemistry, and wettability need to be examined. In order to ensure batch homogeneity and shelf stability, the API and excipients must be dissolved in solvents or dispersed in oil/water phases during manufacturing. Formulations are

greatly influenced by rheological characteristics, which classify fluids as Newtonian or non-Newtonian; they have an impact on flow behavior and administration. Furthermore, droplet interactions in emulsions and particle size and zeta potential in suspensions are important for defining viscosity, flow properties, and product appearance, particularly in injectable formulations.[12]

Reactor stress and fluid dynamics are simulated by process monitoring technologies such as computational fluid dynamics (CFD). Heat flux, entropy, and internal energy must all be continuously monitored throughout formulation and scale-up. Ampoules, vials, and bottles are examples of primary packaging components that guarantee correct delivery and shield formulas from contamination.[13] Stability studies assess how formulations and packaging materials interact. The flexibility of traditional large-batch pharmaceutical manufacturing is constrained, and it faces challenges from shifting market and regulatory conditions. By incorporating AI into the production of liquid dosage forms, the Pharma 5.0 framework improves automation, real-time monitoring, and predictive analytics for increased productivity and compliance. AI eliminates the need for human involvement in risky tasks and helps with formulation optimization. By integrating process design, development, and quality assurance, this smart manufacturing strategy promotes innovation and shortens the time to market for pharmaceutical liquids.[14]

Pre-Formulation Challenges

To guarantee that the active pharmaceutical ingredient (API) is soluble and stable across a range of circumstances, including pH and temperature, monophasic liquid formulations need to carefully choose their solvents. Precipitation can be caused by problems like inadequate solubility, while degradation can be caused by chemical instability. Because elements like buffers and preservatives can alter bioavailability and cause deterioration, compatibility with excipients is essential. Additionally, because of hygroscopicity issues, compositions need packaging that is resistant to moisture. Controlling droplet size, which affects stability, is difficult for biphasic formulations, and if viscosity is out of balance, sedimentation could occur. Shear stress or temperature variations during manufacturing might cause phase separation, hence carefully chosen excipients are required. To improve performance, stability, and manufacturability, comprehensive pre-formulation research and cutting-edge techniques are necessary.[15]

APPLICATION OF AI IN LIQUID DOSAGE FORMS

From conception to scale-up, the creation of liquid dosage formulations follows a standardized framework. The first step is to identify the target market while taking legal and patent restrictions into account. Critical Quality Attributes (CQAs) for product efficiency and compliance are defined as a result of formulation objectives. In order to maximize stability and bioavailability, pre-formulation studies evaluate the physicochemical characteristics of Active Pharmaceutical Ingredients (API), such as solubility. In order to ensure uniformity in large-scale production, the development phase employs trial-and-error techniques with an emphasis on mixing, filtration, and homogenization. By improving process efficiency and dependability, data from earlier formulations help refine scale-up techniques. In order to guarantee process stability, batch performance assessments and real-time monitoring are part of the prototype finalization process.[16]

Prioritizing formulation optimization through experimental research and retrospective analysis for quality and compliance comes before large-scale manufacturing in conventional approaches. This procedure is enhanced by Artificial Neural Networks (ANN), which reduce trial-and-error experimentation, optimize settings, and speed up data analysis. AI models improve reproducibility and robustness by using large datasets to predict formulation results. This automation lowers expenses, increases accuracy, and enables effective scale-up in pharmaceutical manufacturing.

Table 1: AI-powered softwares used in liquid dosage formulation development.

Software	Key Features	Application
ZoomLab	Formulation screening and predictive modelling.	Helps to identify the optimal excipient combinations and how APIs and solvents interact.[17]
SuperPro Designer	AI to optimize resource allocation and assess alternate manufacturing paths. Cost estimation and process modelling.	Batch design and scale-up.[18]
PAT Solutions	Real-time quality monitoring and predictive maintenance.	Critical Quality Attributes are maintained through the process.[19]
Aspen Plus	Software for process optimization and modeling. AI-powered simulation for efficiency and scale-up.	Aids in the scale-up of liquid formulation processes and optimizing constituent quantities.[20]
LabDCT	Platform for digital twins for process and laboratory testing. Uses modelling driven by AI to replicate manufacturing settings.	Virtual testing of formulations.[21]

AI in Preformulation

AI's incorporation into pre-formulation research transforms how problems with liquid dosage forms are approached. Artificial intelligence (AI) methods like artificial neural networks (ANNs) improve the prediction of the solubility of active medicinal ingredients in monophasic formulations, reducing the need for conventional experimental labour. In order to screen excipients and detect reactive agents, statistical models such as Principal Component Analysis (PCA) help understand spectrum data from Fourier-transform infrared spectroscopy and differential scanning calorimetry. Multivariate models also assess hygroscopicity to help with packaging choices. Controlling droplet size is essential in biphasic formulations to avoid instability, and this is backed by machine learning models that mimic homogenization conditions and computational fluid dynamics. In order to improve physical stability forecasts and optimize emulsifier concentrations to avoid problems like coalescence and viscosity-induced settling, ANN models correlate rheological data with sedimentation.

PharmDE and FormulationAI

Pharmaceutical excipients like solvents, surfactants, and preservatives are used to package APIs into dosage forms for reliable administration. Quality and performance depend on an understanding of how APIs and excipients interact. PharmDE, an expert system that assesses the risk of drug-excipient incompatibility using a comprehensive database of 532 data points from 228 trials, and FormulationAI are platforms that support pharmaceutical formulation. It offers methods and resources for evaluating formulation risks and drug compatibility.[22]

In order to improve medication formulation development, PharmDE evaluates drug-excipient incompatibility concerns using logical reasoning with RDKit and Python. Access to compatibility information and risk evaluations is made easier by an intuitive website. FormulationAI, in contrast, uses sophisticated machine learning models to forecast formulation parameters such as stability and solubility for various drug delivery systems. It also has an easy-to-use interface for real-time design. FormulationAI improves formulation optimization, whereas PharmDE concentrates on early-stage risk assessment using literature and mechanistic rules. When combined, they enhance the creation of liquid dosage forms, although problems with transparency, data coverage, and regulatory integration still exist.[3]

Drug-Excipient Compatability

Studies using a variety of machine learning (ML) techniques use the DE-INTERACT model

as a reference standard because of its excellent accuracy in predicting drug-excipient incompatibility. In contrast to resource-intensive conventional approaches like chromatographic techniques, FTIR, and DSC, DE-Interact use artificial neural networks (ANNs) and machine learning to detect incompatibilities using PubChem molecular fingerprints. With a validation precision of up to 99.6% using multiple ANN models, DE-Interact classified combinations as either "compatible" or "incompatible" after being trained on more than 3,500 drug-excipient combinations using an optimized input feature set of 1762 bits.[23]

Analytical tests verified the DE-Interact tool's prediction that vanillin and paracetamol are incompatible. While FTIR spectra revealed the loss of distinctive NH peaks, indicating chemical interaction, DSC studies revealed thermal instability. The breakdown of paracetamol in the presence of vanillin was further validated by HPTLC and HPLC. The validation of the DE-Interact model highlights how useful it is for early formulation screening to prevent expensive failures. When it came to recognizing drug-excipient incompatibility, a staking model fared better than DE-Interact, identifying 10 out of 12 cases, whereas DE-Interact only identified 3 out of 12. According to recent studies, AI models such as DE-Interact (ANN) are effective; they can achieve up to 99.6% validation precision, outperforming more conventional techniques like FTIR and DSC, and they also match experimental solubility predictions well.

Solvent Selection and Solubility

In order to help choose a solvent for liquid dosage forms, the study addresses the application of Artificial Neural Networks (ANNs) to forecast the solubility of drug-like molecules. The ANN model used 10 physio-chemical descriptors and demonstrated high predictive accuracy across several test datasets after being trained on a sample of 270 compounds with known log S values. Furthermore, the model outperformed conventional techniques in forecasting the stability of esomeprazole under various pH conditions. The study underlined how crucial it is to keep the pH between 10.4 and 10.6 for maximum stability, and how the MLP network might improve the lyophilization process to achieve a 36-month shelf life.

Crystallization

The production of liquid dosage forms depends heavily on crystallization, which affects medication stability and bioavailability through characteristics like size distribution, shape, and purity. A study that used a Multi-Layer Perceptron (MLP) network to predict drug

crystallinity from experimental data was able to predict liquid crystalline behavior with a mean absolute percentage error of less than 7.22%. The physical and crystallographic characteristics of the medication were enhanced by the combination of MLP and genetic algorithms. Control over crystallization processes has improved thanks to developments in Process Analytical Technology (PAT) sensors, which allow for real-time monitoring of crucial parameters such particle size and shape. Furthermore, by examining component interactions, advances in deep learning and computational modeling aid in the design of taste-masked pediatric formulations. Although encouraging, extensive datasets and clinical validation are required before this field may be widely used.

Interindividual variability is a challenge for tacrolimus, an immunosuppressant that requires precise dose in pediatric renal transplants. Using pharmacokinetic data from 21 pediatric patients, this study used machine learning (ML) to develop a dosage prediction system. With an R2 of 0.8, the Extra Trees Regressor (ETR) was the most accurate of the nine assessed machine learning models. Predictions were significantly impacted by important parameters like AUC and time, and external validation verified the model's resilience across several pediatric cohorts. The algorithm's effectiveness shows how AI may be used to customize dosage for medications with limited therapeutic indices, improving pediatric precision medicine.[24]

Formulation Development

In material science, generative intelligence (GI) makes use of physical characteristics to improve the prediction of target material data and the creation of new materials. By incorporating physical laws, advances in physics-informed GI models, like diffusion models and neural operators, increase predictive accuracy. According to Unni et al., the significance of multimodal architectures and large-scale datasets fills in the gaps in conventional machine learning and domain-specific limitations. AI also improves Failure Mode and Effects Analysis (FMEA) by providing real-time monitoring for dynamic updates and evaluating past failure data for accurate forecasts. By using AI-driven predictive analytics and automated data processes, this leads to proactive risk management and well-informed decision-making.[25]

In a case study, FMEA was used to identify hazards and provide remedial actions while evaluating the dependability of subsystems in a man-machine system. Through ongoing monitoring, AI integration improves reliability; machine learning algorithms spot biases that

conventional approaches might overlook, and natural language processing (NLP) technologies examine user input to boost risk assessments. By simulating possible failures, AI-driven simulations provide risk anticipation. GI improves the detection of CMAs by helping to alter input descriptors for precise target sample creation. Despite difficulties in integrating DoE with ML in liquid dosage forms, the DoE technique supports systematic experimentation that yield solid insights for product creation. Significant opportunities and insights are being revealed by ongoing research into these integrations, especially when using ANNs to analyze DoE data in regression tasks.[26,27]

AI APPLICATIONS IN MANUFACTURE OF SPECIFIC DOSAGE FORMS

Solution

Pharmaceuticals frequently employ solutions because of their quick start of action and flexible dosage, but their production necessitates close attention to a number of crucial factors, including tank size, mixing speed, and filtration properties. Manufacturing performance is improved by modifying these parameters using Artificial Neural Networks (ANN). Mixing times, which differ greatly between laminar and turbulent flows, are influenced by variables such as fluid characteristics and system geometry. Mixing times were predicted using a Machine Learning Perceptron (MLP) model, highlighting the significance of impeller placement and design. The FDA advises using automated image analysis and high-speed photography for spray characterization in order to precisely assess important spray properties. Spraying patterns were predicted using a Deep Neural Network (DNN), which significantly decreased the number of experimental trials and improved prediction accuracy, enhancing the investigation's resource efficiency.[28,29]

To guarantee that they are devoid of visible particles, pyrogenic chemicals, and viable microbes, parenteral medication products must meet strict criteria. According to the United States Pharmacopeia (USP) < 71 >, sterility tests show the absence of contaminants but do not ensure complete sterility.[30] Because of their long incubation periods, culture media such as Soybean-Casein Digest Medium are utilized in sterility testing, which calls for specific protocols. Dierks et al.'s study suggests an automated deep learning method for sterility testing that achieves excellent accuracy in identifying microbial growth. The design of clean rooms, which are necessary for producing sterile goods, is based on effective filtration and airflow control. HEPA-equipped air handling units (AHUs) are essential for maintaining air quality. The creation of an aptamer-based biosensor that makes use of machine learning to

enhance the efficacy and precision of endotoxin detection is another new development in pyrogen detection.[31]

Suspension

Important factors that affect quality qualities including viscosity and dissolving profile during suspension manufacturing include granulator type, impeller design, product temperature, and filtration parameters. Nanosuspension particle size and polydispersity index (PDI) have been predicted using machine learning algorithms, specifically Keras and LightGBM. With some techniques, these algorithms have demonstrated strong predictive performance for PDI, but due to data limitations, predictions for antisolvent precipitation (ASP) were less accurate. Variables including pH, temperature, and material characteristics determine the ideal microfluidization settings; higher passes can intensify results. Controlling the temperature is essential to prevent thermal deterioration, and the choice of solvent has a big impact on how materials interact.[32]

Adjusting pH can optimize microfluidization properties, including protein water-holding ability, particularly in acidic environments. By automating trials and rapidly gathering data on suspension behavior, machine learning (ML) greatly improves high-throughput screening, speeding up the optimization process and enhancing result dependability. By combining machine learning with mechanistic models, hybrid techniques that combine scientific principles with data-driven insights are made possible, improving predictions of particle behavior in microfluidization. Understanding hydrodynamics, where interphase forces like drag and turbulence are taken into account using computational fluid dynamics (CFD) models, is essential to the operational effectiveness of mechanically stirred tanks. Based on the density and viscosity of the slurry, these models are able to forecast power number trends.[33]

Using techniques like artificial neural networks and rheology-informed neural networks, recent developments in machine learning for rheology show promise for forecasting nano emulsion stability by linking formulation parameters with stability outcomes. Furthermore, fast picture acquisition and quantitative measurement of suspension stability are made possible by high-resolution imaging in conjunction with ultrasonic agitation, which is useful in a variety of industries using multiphase systems.[34]

Emulsion

Although instability results from the thermodynamic incompatibility of water and oil in emulsions, micro- and nano-emulsions offer benefits including increased stability and bioavailability. Limitations on particle size and viscosity occur, although minimizing the usage of surfactants and optimizing doses of poorly soluble drugs are crucial. Artificial Neural Networks (ANNs) use formulation inputs to predict particle size outcomes and emulsion characteristics and microemulsion structures. With a 90% prediction accuracy, the DSC-based ANN helped to clarify the architectures of microemulsions. In order to minimize cytotoxicity, optimal nano emulsion formulations rely on preserving specific surfactant ratios while lowering oil content.[35,36]

AI helps with QSPR model creation and microemulsion design for drug solubility in SEDDS. ANNs are used in conjunction with mechanical techniques such as high-pressure homogenization and ultrasound to maximize the generation of nano emulsions. Ternary phase diagrams show the stability of three-component systems, and machine learning techniques in software such as Pandat improve calculation performance. Potential industrial applications were demonstrated by a study on emulsified liquid membranes that used artificial neural networks (ANN) to maximize stability and achieve optimal parameters for low rupture rates.[37]

CONCLUSION

This article compares AI methodologies to conventional labor-intensive procedures in order to discuss the usage of AI tools in the development of liquid dosage formulations. It highlights how AI can speed up the formulation process and produce forecasts at a reasonable cost. Along with advice on model selection, a variety of AI algorithms for various purposes are reviewed. The conclusion highlights the restricted use of AI in real-time and suggests that productivity can be increased by additional automation. It suggests that AI could result in intelligent, self-sufficient pharmaceutical manufacturing and recommends future research possibilities. In order to maximize therapeutic efficacy, increase production speed, lower costs, and lessen environmental effects, the evaluation also recommends combining AI with PK/PD models.

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