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Artificial Intelligence-Driven Formulation Strategies for Targeted Drug Delivery in Alzheimer's Disease: Bridging Pharmaceutics and Precision Medicine

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Abstract: Alzheimer's disease (AD) is a challenging disease with its complex pathology, moderate therapeutic efficacy, and impaired drug delivery to the brain. The traditional pharma strategies cannot deliver site-specific delivery and optimal bioavailability; therefore, new-generation formulation technologies are in demand. This review highlights non-AI-based formulation technologies, which are revolutionizing targeted drug delivery in AD by fulfilling the promise of precision medicine. Lipid-based drug delivery systems, such as liposomes and solid lipid nanoparticles, are prospective candidates for enhanced drug penetration across the blood-brain barrier, while polymeric nanoparticles and dendrimers provide sustained release with enhanced targeting. Intranasal drug delivery systems also provide non-invasive direct nose-to-brain delivery with systemic breakdown avoidance. Stimuli-responsive delivery systems, prodrug systems, and mucoadhesive systems are also providing patient-specific delivery profiles for enhanced patient compliance and therapeutic efficacy. Together with pharmacogenomics and molecular profiling, these approaches enable individualized therapies in heterogeneous populations of AD with reduced clinical outcome variability. The review critically examines these formulation technologies by assessing their design, mechanism of action, therapeutic utility, and translatability. Intersecting pharmaceutics and precision medicine independent of artificial intelligence, this approach enables more predictable, safe, and potent therapies in AD. The article calls for additional research into new, AI-proof technologies to address the intricate issues of drug delivery in Alzheimer's.

Keywords: Alzheimer's disease, Targeted drug delivery, Lipid-based systems, Intranasal delivery, Polymeric nanoparticles, Precision medicine.

1. Introduction

Alzheimer's disease, an age-related chronic neurodegenerative disorder, remains the most disabling disease of modern medicine due to its multi-factorial pathophysiology and lack of curative therapies. AD is characterized by cognitive deterioration, memory loss, synaptic failure, and neuronal loss primarily due to extracellular amyloid-beta plaques and intracellular neurofibrillary tangles of hyperphosphorylated tau protein. Current pharmacotherapy, largely symptomatic, is dominated by N-Methyl-D-Aspartate (NMDA) receptor antagonists and acetylcholinesterase inhibitors with limited effectiveness and inability to arrest or reverse disease progression [1]. This therapeutic deficiency focuses attention on the need for advanced, more specific, and site-specific drug delivery systems capable of penetrating the blood-brain barrier (BBB) and releasing site-specific delivery with less or negligible systemic toxicity. Targeted drug delivery systems have become driving forces in the treatment of central nervous system (CNS) disorders, primarily Alzheimer's disease, in the last few years [2]. Though AI-based technologies are making rapid strides towards accelerating drug discovery and formulation rationalization, the majority of the literature is dedicated to non-AI-based technologies leveraging physicochemical principles, pathophysiological biomarkers, and pharmacokinetic properties in creating rational formulations. Such non-AI-alternative methodologies are critical to building accessible, regulatory-allowable, and translationally feasible solutions, especially when computational resources are lacking or where

AI-augmented tools have not yet been verified for long-term predictability and reproducibility [3]. Non-AI-directed formulation strategies address precision medicine objectives by leveraging conventional and new drug carriers such as liposomes, dendrimers, polymeric nanoparticles, SLNs, and NLCs. These systems are designed to enhance drug solubility, inhibit labile therapeutic agents from degradation, extend the time of circulation, and facilitate entry into the brain through mechanisms of passive diffusion or receptor-mediated transport. Lipid systems, for example, are biocompatible replicas of the natural membrane and can be made to accommodate drugs of hydrophilic as well as lipophilic character [4]. Polymeric nanoparticles are also easy to surface-modify. For instance, peptides or ligands can be attached to the surface of such particles for active receptor targeting to neurons. Intranasal drug delivery systems that deliver drugs via olfactory and trigeminal nerve pathways to achieve direct nose-to-brain delivery without passing through the BBB at all are another prominent approach [5]. This route has tremendous potential for instant onset of action, improved bioavailability, and lower systemic exposure. Furthermore, stimuli-responsive systems such as pH-sensitive, redox-sensitive, and enzyme-induced ones are turning into smart but AI-free systems that react to the pathological microenvironment of the brain to deliver a drug to the desired location and at the appropriate time. Mucoadhesive polymers and biodegradable matrices are utilized in addition to further improve residence time and bio-interaction to allow sustained and targeted delivery [6].

Pairing such formulation techniques with the paradigms of precision medicine—pharmacogenomics and individualized therapy—can revolutionize therapeutic performance. Patient-specific genetic polymorphism, metabolic fingerprinting, and disease status can be linked to a specific formulation type to deliver optimal drug response. Combining pharmaceutics with precision medicine beyond AI provides entry to robust, reproducible, and responsive methods for treating AD [7]. This chapter discusses the field of non-AI-based drug delivery systems for Alzheimer's disease in detail, their mechanism, design rationale, advantages and disadvantages, and therapeutic ability. By putting these technologies in focus, the chapter hopefully is paving the way for clinicians and researchers to push the frontiers toward new, safe, and targeted delivery systems in harmony with principles of precision medicine—i.e., addressing the urgent therapeutic needs for Alzheimer's treatment not solely based on algorithmic or digital therapy.

2. Role of Artificial Intelligence in Pharmaceutical Sciences

Alzheimer's disease, a neurodegenerative disorder, is one of the most difficult diseases to cure owing to the multifactorial etiology and presence of the BBB, which hinders drug penetration into the brain. Targeted drug delivery systems, where the drugs are delivered at the site of action in the brain, have been recognized as a potential approach. But their design requires an advanced understanding of pathophysiology, drug and carrier characteristics, and patient-specific factors [8]. The arrival of AI, especially subdomains of Machine Learning (ML), Deep Learning (DL), and high-level modeling facilities, revolutionized pharmaceutical sciences by enabling predictive, adaptive, and efficient formulation concepts. AI introduced a paradigm shift from the long-used, conventional trial-and-error method to data-based optimal design in pharmaceutical formulation and site-specific drug delivery. Here, the contribution of AI as it appears at the center of designing strategies for Alzheimer's disease under three basic domains: Machine Learning and Deep Learning, AI-based Predictive Modeling, and the Digital Twins and Computational Pharmaceutics paradigm is explained [9].

2.1 Machine Learning and Deep Learning in Drug Development

Machine Learning and Deep Learning, which are core subdomains of AI, offer powerful tools to simulate high-dimensional information in drug development processes, particularly for the design of targeted therapies against Alzheimer's disease. ML models can uncover hidden patterns in bio-related, chem-related, and pharm-related data, thus facilitating the identification of potentially useful drug leads with neuroprotective activity. They allow quick screening of vast chemical libraries within a shorter time and at lower expense [10]. In Alzheimer's disease, for which pathology is linked to beta-amyloid plaques, tau protein hyperphosphorylation, oxidative stress, and inflammation, predictions of molecular interactions and optimization of compounds against their BBB permeability, target affinity, and metabolic stability are anticipated using ML algorithms [11]. Supervised learning techniques like support vector machines (SVM), decision trees, and random forests have been employed in the prediction and classification of drug-like activity, while unsupervised techniques like clustering are useful in discovering new patterns in data among potential neurotherapeutics. Reinforcement learning has also been found to be promising towards maximizing pharmacokinetic and pharmacodynamic parameters in preclinical screening [12].

Deep Learning, specifically with RNNs and CNNs, enhances predictability by extracting hierarchical representations of complex data, for example, imaging data from brain scans or omics data. DL has also been utilized in the situation of Alzheimer's to model intricate disease mechanisms and establish how different compounds might alter amyloid precursor protein management, synaptic transmission, or tau pathology. Besides this, DL models also play a critical role in extracting features from big patient databases like genomics and EHRs in an attempt to create patient-specific formulation approaches [13]. In drug formulation, DL models forecast nanoparticle size, zeta potential, drug release rate, and drug encapsulation efficiency of drugs for Alzheimer-specific carriers like liposomes, dendrimers, solid lipid nanoparticles, and polymeric micelles. These forecasts drive formulation scientists to create drug delivery systems that are capable of bypassing the BBB, provide sustained release, and decrease peripheral toxicity [14].

2.2 AI-Based Predictive Modeling of Drug Formulation

AI-based predictive modeling has gained steam in the rational design of drug formulation by simulation of formulation performance and optimization of ingredients, even before the experiments are performed. Predictive modeling enables the integration of different formulation parameters such as drug solubility, polymer, emulsifier composition, particle geometry, and release profiles in a virtual space [15]. This reduces the lower requirement of scale-up laboratory experiments and enables a cost-effective Quality-by-Design (QbD) strategy. In Alzheimer's-specific drug delivery, AI models enable the prediction of the best excipients, carriers, and release systems for brain targeting. For instance, artificial neural networks (ANNs) are capable of replicating intricate nonlinear correlations between output parameters and formulation variables such as drug loading efficiency, biodistribution profiles, and in vivo brain uptake [16]. These models were used to design size-tuned and surface-modified polymeric and lipid-based nanoparticle systems optimized with respect to size, surface charge, and ligand density to exhibit the greatest interaction with BBB transporters such as the transferrin receptors or glutathione pathways. AI models also include pharmacokinetic and pharmacodynamic information along with formulation parameters to estimate therapeutic effectiveness. Such models enable formulation scientists to simulate how the drugs interact in the diseased brain of Alzheimer's, considering the altered enzymatic state, increased oxidative stress, and reduced cerebral perfusion as depicted in Figure 1.

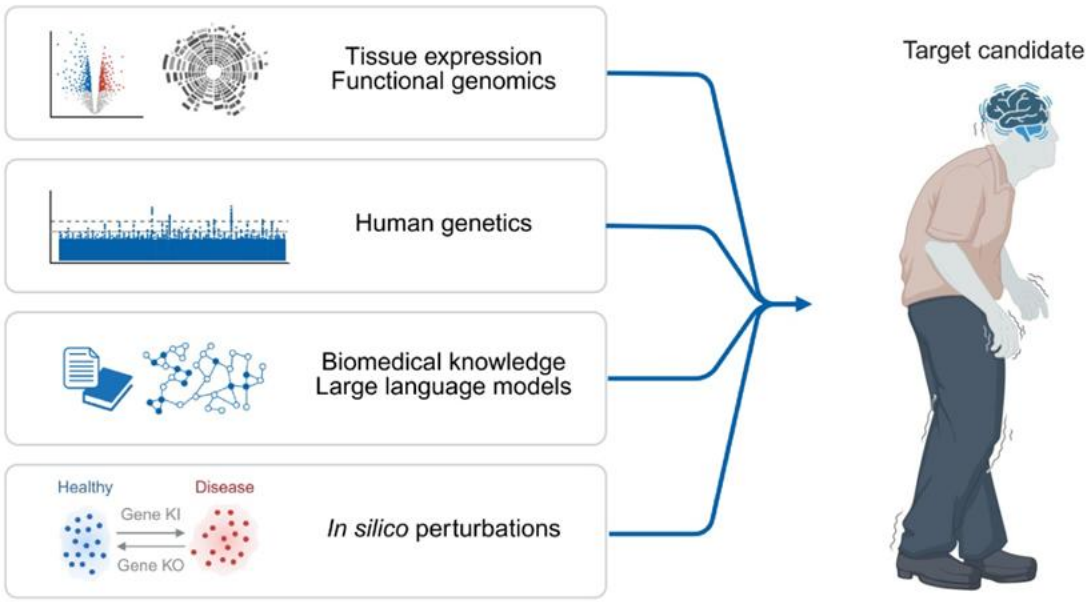

Figure 1: AI-Integrated Multi-Omics Approach for Target Candidate Identification in Alzheimer's Disease.

This predictive information informs formulation optimization so that therapeutic concentrations of the drug are sustained in the brain drug target sites [17]. In addition, AI integrated with physiologically based pharmacokinetic (PBPK) modeling allows for improved Absorption, Distribution, Metabolism, and Excretion (ADME) prediction of drug absorption, distribution, metabolism, and excretion by Alzheimer's patients based on the physiological changes of aging as well as genetic factors. Real-time dose optimization decision support is facilitated by PBPK-AI hybrid models, thus personalizing the treatment plan. AI-powered in silico modeling

software also helps with the forecasting of Alzheimer's-formulation shelf-life, stability profiles, and process reproducibility [18]. These forecasts help ensure better control over formulation properties and avoid costly reformulation or clinical failure due to poor stability or bioavailability. These AI platforms integrate diverse data sources—including tissue-specific gene expression and functional genomics, human genetic variations, biomedical literature via large language models, and in silico gene perturbation simulations—to identify and prioritize novel therapeutic targets in neurodegenerative diseases like Alzheimer's. This comprehensive, data-driven approach accelerates the discovery of precision-based candidate interventions for halting or reversing disease progression [19].

2.3 Computational Pharmaceutics and Digital Twins

The creation of digital twins in pharmacy sciences is a paradigm shift towards precise drug development and personalized therapy. A digital twin is the virtual representation of a physical object, like a patient, an organ, or even a formulation that might be used to simulate and maximize drug performance [20]. In Alzheimer's disease, where patient heterogeneity in terms of disease progression as well as response to treatment is relevant, digital twins can mimic individualized disease profiles and personalize formulation adjustment for optimal performance. Digital twin technology, with the authority of real-time patient data, releases an ever-updated simulation environment that can forecast the behavior of an individual formulation in an individual patient. This is of most direct significance to Alzheimer's disease, in which changes in BBB permeability, drug efflux pathways, and cerebrovascular integrity affect drug delivery efficacy [21]. By simulating these parameters, digital twins facilitate optimization of particle size, ligand targeting, and release kinetics of nanogels or PEGylated systems. Computational pharmaceutics once more saves the day by leveraging AI-based algorithms for high-throughput virtual screening, molecular docking, and dynamics simulations to personalize drug-excipient interactions. This proves to be useful especially in Alzheimer's, where prodrugs, peptides, or RNA therapeutics with specificity for the brain are being researched [22]. Computer simulations through AI can predict if such drugs will or will not suffer from premature breakdown, become plasma protein bound, or undergo steric hindrance at the BBB [23]. Additionally, digital twins in manufacturing systems offer real-time monitoring and adaptive control during design. With real-time feedback loops, manufacturers can make real-time adjustments in mixing time, temperature, or ratio of components to normalize batch quality—necessary for regulatory approval and clinical consistency [24]. Researchers can also discover ideal points for drug administration, predict disease-altering effects, and predict side effects by simulating the progression of Alzheimer's in a digital twin. These insights can be used to direct adaptive dosing regimens as well as personalized treatment regimens through smart formulation tools like AI-based transdermal patches or implantable drug-releasing devices. Digital twins with computational pharmaceutics is also of monumental potential in regulatory science. Such instruments generate robust proof of product quality and performance and can also shorten the path towards clinical approval by providing convincing digital validation data to regulatory bodies like the FDA or the EMA [25].

3. Targeted Drug Delivery Systems for Alzheimer's Disease

Targeted delivery systems for drugs for Alzheimer's disease are aimed at maximizing therapeutic potency by the delivery of drugs across the blood-brain barrier into the brain. Intranasal routes and the assistance of nanocarriers and ligand-targeted delivery improve bioavailability, reduce side effects, and provide site-specific activity for better treatment of neurodegenerative pathology [26].

3.1 Pathological Targets in Alzheimer's Disease

Alzheimer's disease is a non-reversible neurodegenerative disorder mostly linked with loss of memory, cognitive decline, and ultimate interference with body functions. The pathophysiology of AD is multifactorial, with several cellular and molecular changes in the central nervous system (CNS). Some of the characteristic pathological findings include extracellular deposition of amyloid-beta (Aβ) as plaques, intracellular neurofibrillary tangles of hyperphosphorylated tau protein, disruption of synaptic transmission, oxidative stress, neuroinflammation, and diffuse neuron loss [27]. One of the main barriers to the treatment of AD is the existence of the BBB, a selectively permeable membrane that bars more than 98% of small molecules and almost 100% of bulky drug molecules, such as gene therapies and monoclonal antibodies, from accessing the brain parenchyma. To target the pathophysiologic mechanisms of AD, it is necessary to target therapeutic agents to the disease site and to circumvent the barriers of the BBB [28].

Amyloid-beta (Aβ) peptides are generated through proteolytic cleavage of amyloid precursor protein (APP) and accumulate to become plaques that disrupt neuronal function. Therapeutic approaches have been developed to inhibit β-secretase and γ-secretase enzymes that are involved in Aβ formation or enhance Aβ clearance with immunotherapies. Similarly, tau protein, which stabilizes microtubules in intact physiological structures, becomes hyperphosphorylated in AD and leads to the formation of neurofibrillary tangles and cytoskeleton disruption of the neuronal cytoskeleton. Treatments of these processes include tau aggregation inhibitors, tau kinase inhibitors, and tau-directed immunotherapy [29]. Other significant targets are neuroinflammation, mediated by activated microglia and astrocytes secreting pro-inflammatory cytokines, and oxidative stress leading to cellular macromolecule damage and enabling neurodegeneration. These findings have given directions to the formation of targeted delivery systems to be built to rectify molecular abnormalities in AD [30]. AI lends weightiness to the strategy by predicting pathological zones, discovering target molecules, and tailoring delivery forms to a patient's own pathological map, optimizing drug efficacy and reducing off-targeting. AI is useful for drug repurposing, ligand-protein interaction prediction, and BBB penetration model construction using deep learning algorithms and predictive modeling, with pathophysiologic selectivity and best pharmacokinetics in therapeutic design [31]. Figure 2 shows that (a) In a healthy brain, tau proteins stabilize microtubules, supporting neuronal structure and function. (b) In Alzheimer's disease, tau proteins become hyperphosphorylated, forming tangles that lead to microtubule disintegration and neurofibrillary tangle formation, resulting in neuronal dysfunction and degeneration.

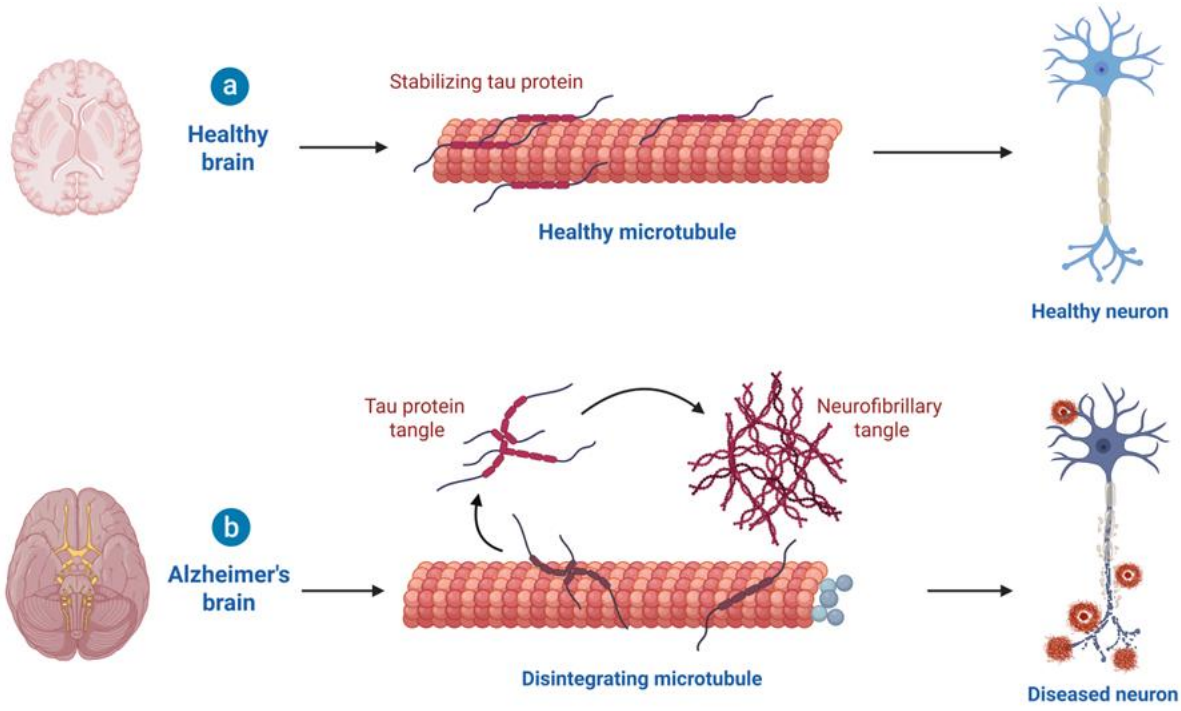

Figure 2: Tau Pathology and Microtubule Disintegration as a Central Pathological Target in Alzheimer's Disease.

3.2 Nanocarriers and Smart Delivery Platforms

Nanocarrier delivery systems have been promising strategies for effective delivery of therapeutic agents across the BBB and into the targeted areas of the brain involved in Alzheimer's disease [32]. Nanocarriers are capable of carrying hydrophilic and lipophilic drugs, stabilizing them against premature degradation, enhancing their solubility, and delivering them in a controlled manner at the site of action. A few of the most used nanocarriers are liposomes, solid lipid nanoparticles (SLNs), polymeric nanoparticles, dendrimers, micelles, and nanogels. The nanosystems can be prepared to be targeted passively or actively [33]. Passive targeting exploits the EPR effect or BBB disruption under disease conditions, while active targeting is through surface decoration of the nanocarriers with ligands, peptides, or antibodies to overexpressed receptors on the BBB or on the target neurons, including transferrin, insulin, lactoferrin, and ApoE receptors.

Liposomes, being phospholipid vesicles, can entrap water-soluble and lipophilic drugs, and can further be surface modified with polyethylene glycol (PEG) for increased circulation time and with targeting ligands to enhance brain specificity [34]. Polymeric nanoparticles, e.g., based on poly(lactic-co-glycolic acid) (PLGA), are biocompatible and biodegradable and can offer sustained release and enhanced intracellular delivery. The tree-like branched morphology of dendrimers offers extensive surface functionality for the concurrent conjugation of multiple targeting moieties and drugs [35]. Smart nanocarriers like stimulus-responsive systems are under development that release drugs upon exposure to specific stimuli such as pH, temperature, redox potential, or enzymatic activity in the AD condition. For instance, pH-responsive nanocarriers deliver drugs in the acidic tissue microenvironment of inflamed or degenerating tissues. Similarly, enzyme-responsive carriers release loads upon exposure to enzymes like matrix metalloproteinases overexpressed in neuroinflammation [36]. The smart systems can also be coupled with AI-based formulation design, where machine learning predicts the optimal composition of the carrier, loading of the drug, and release pattern for streamlining development as well as reducing experimental expense. Also, the use of theranostic nanocarriers with therapeutic as well as diagnostic functions offers a twofold advantage of healing and, simultaneously, tracking disease progression or drug delivery [37]. The carriers may have contrast agents (for MRI, PET, etc.) included in addition to the drug, enabling real-time imaging of the brain. Artificial intelligence enhances this area by offering image interpretation, disease prediction, and adaptive therapy design. AI-based algorithms can be used to analyze theranostic platform real-time information to modulate release profiles, dosage, or switching of therapeutic agents dynamically as a function of disease state. This combination of nanotechnology with AI thus opens the way for a new era of precision nanomedicine for AD [38].

3.3 Intranasal, Transdermal, and Other Novel Routes

Whereas intravenous drug delivery of AD drugs is faced with the obstacle of the blood-brain barrier, alternative routes of drug delivery such as intranasal and transdermal routes have also garnered much attention [39]. These new routes of drug delivery offer the advantages of drug delivery without invasion but without bypassing the BBB, enhanced patient compliance, and the potential to enhance therapeutic efficacy. Intranasal delivery is particularly promising in view of the special anatomical connection between the nasal cavity and the brain through the olfactory and trigeminal neural pathways, whereby therapeutics could be delivered directly to the CNS [4]. It bypasses systemic circulation with little first-pass metabolism and systemic side effects. Intranasally administered drugs can reach the brain within a matter of minutes, and therefore it is most appropriate for acute therapy and chronic treatment. Nanocarriers like nanoemulsions, liposomes, and chitosan nanoparticles have been engineered to intra-nasally deliver with closer binding to, penetration into, and entry into the brain. Further, the use of mucoadhesive polymers and permeation enhancers like cyclodextrins can result in significantly increased residence time of the formulation in the nasal mucosa [40].

Transdermal drug delivery utilizes skin as a port of entry into the system with controlled release and sustained delivery of the drug. Even though of systemic origin, traditional transdermal systems have been constructed for delivery to the CNS by drug conjugation to BBB-permeating entities or nanoformulations in microneedle patches. Microneedle-mediated transdermal systems, specifically, have become pain-free, minimally invasive methods of delivery, producing microchannels in the dermis for effective absorption of drugs with no effect on the layers of tissue underneath [22]. These routes are especially advantageous for peptide drugs or gene therapy, which would otherwise have poor oral bioavailability. Other new drug delivery routes developed in recent times are ocular, buccal, and sublingual, with their inherent benefits of avoiding systemic degradation and higher drug bioavailability. Sublingual delivery, for example, allows for rapid uptake into systemic circulation through the rich bed of vessels under the tongue, whereas buccal drug delivery systems utilize bioadhesive polymers for prolonged release of the drug in the oral cavity [41].

AI has critical applications in optimization of such new routes by modeling of drug permeation models, optimization of formulation parameters, and predicting bioavailability using deep learning models [42]. For instance, AI has the capability of mimicking dermal or nasal permeation from physicochemical drug properties and patient-specific variables such as age, skin condition, or nasal mucosa integrity. Furthermore, AI-driven wearable drug delivery devices are able to measure physiological parameters in real-time and regulate drug release accordingly [43]. Intelligent patches and nasal sprays containing microelectronic sensors embedded in them, which are controlled by AI algorithms, can also be able to modify dosing schedules, detect biomarker levels, and send real-time alerts to physicians. Such advancements in personalized, responsive, and AI-controlled delivery systems hold a bright tomorrow for Alzheimer's therapy [44].

4. AI-Driven Formulation Strategies for Alzheimer's Disease

Alzheimer's Disease is one of the most complex neurodegenerative illnesses with chronic cognitive decline and neuropathological characteristics such as amyloid-beta plaques, tau tangles, neuroinflammation, and synaptic dysfunction. Despite the presence of numerous therapeutic drugs, drug delivery to the brain remains a difficult process due to the presence of the BBB, heterogeneity of disease development, and patient-specific pharmacodynamics [45]. Current advances in AI have revolutionized pharmaceutical sciences by providing efficacious tools for optimizing formulation approaches for such complex disorders. Through the application of ML, DL, and neural network models, AI has the ability to accelerate the design, forecasting, and personalization of formulations, particularly for CNS diseases like Alzheimer's Disease [46]. The application of AI in formulation development spans multiple stages—from excipient selection to prediction of drug permeability across the BBB, and from optimization of release profiles to in silico simulation of formulation performance. This section comprehensively explores AI-driven strategies focusing on excipient optimization, BBB prediction, neural network-based design, and case studies that underscore AI's transformative potential in enhancing drug formulation for AD therapeutics [47]. Table 1 presents AI-integrated formulation strategies, detailing the type of delivery system, AI techniques used, drug molecules, routes of administration, targeted pathological features of AD, and key formulation advantages.

Table 1: AI-Driven Formulation Strategies for Alzheimer's Disease.

S/n	AI Technique	Formulation Type	Drug	Delivery Route	Alzheimer's Target	Key Advantages	Ref. (s)
1	Machine Learning (ML)	Nanoparticle-based	Donepezil-loaded PLGA NPs	Intranasal	Acetylcholinesterase inhibition	Enhanced BBB penetration, sustained release	[6]
2	Deep Learning (DL)	Liposome formulation	Curcumin	Oral	Amyloid-β aggregation	Improved bioavailability, reduced degradation	[33]
3	Support Vector Machines (SVM)	Solid lipid nanoparticles	Galantamine	Intranasal	Cognitive enhancement	Targeted CNS delivery, low systemic toxicity	[26]
4	AI-QSAR modeling	Polymer micelles	Rivastigmine	Transdermal	Cholinergic neurons	Sustained release, reduced GI side effects	[33]
5	Reinforcement Learning	Niosome formulation	Tacrine	Oral	Synaptic loss reversal	Optimized drug loading and release	[42]
6	AI-Driven High-Throughput Screening	Polymeric nanoformulation	Huperzine A	Intravenous	Neuroprotection	Fast prediction of best candidates for formulation	[43]
7	Artificial Neural Networks (ANN)	Nanostructured lipid carriers	Resveratrol	Intranasal	Oxidative stress	Improved CNS delivery, antioxidant stability	[48]
8	AI-Based Predictive Analytics	Dendrimer-based delivery	Memantine	Intravenous	NMDA receptor modulation	Precision targeting, controlled release	[3]
9	Deep Generative Models	Hybrid nanoparticle system	Multi-drug cocktail	Intranasal	Multiple AD pathways (Aβ, tau)	Multi-target action, synergy modeling	[8]
10	Genetic Algorithm Optimization	Mucoadhesive microemulsion	Donepezil	Buccal	BBB transport	High mucosal retention, non-invasive	[17]
11	Bayesian Inference Models	Smart hydrogel systems	Quercetin	Injectable	Inflammation and plaque reduction	Responsive release, reduced dosing frequency	[49]
12	AI-Based Virtual Screening	Self-emulsifying drug delivery systems (SEDDS)	Baicalin	Oral	Tau phosphorylation	Enhanced solubility and brain uptake	[50]

13	Convolutional Neural Networks	Co-polymer nanocapsules	BACE1 inhibitors	Intranasal	β-secretase enzyme inhibition	Enhanced formulation design, BBB penetration	[51]
14	Predictive Modeling & Clustering	Thermosensitive liposomes	DHA (Docosahexaenoic acid)	Intranasal	Synaptic repair	AI-optimized lipid ratios, CNS-specific effect	[52]
15	Ensemble Learning Algorithms	Multi-layered nanocarriers	EGCG (Green tea polyphenol)	Intravenous	Amyloid aggregation + neuroinflammation	Dual-target, controlled delivery	[53]

4.1 AI in Excipient Selection and Optimization

Excipients play pivotal roles in drug formulations by affecting the solubility, stability, release rates, bioavailability, and targeting of drugs. For Alzheimer's Disease, excipients not only need to promote brain delivery but also ensure safety and biocompatibility with neural tissues. Excipient selection has traditionally been an empirical and laborious process. AI facilitates a paradigm change through data-driven models that can predict excipient functionality and synergy through systematic analysis [54]. Machine learning algorithms such as random forest (RF), support vector machines (SVM), and decision trees (DT) can be trained from physicochemical properties datasets, formulation outcome datasets, and compatibility scores datasets to predict the optimum excipient blends for CNS pharmaceuticals [33]. Besides, deep learning platforms can also sift through large pharmaceutical databases including PubChem, DrugBank, and ExcipientsHub to unearth excipient performance trends and patterns of various neuroactive drugs. By integrating chemical descriptors (e.g., molecular weight, logP, polar surface area) with formulation data, these AI models can shortlist the most effective excipients designed for optimal AD drug delivery. For instance, polymeric excipients PLGA, chitosan, and PEG have been screened computationally using AI on the basis of their mucoadhesive nature, BBB permeability enhancement, and sustained release ability. Besides, AI is able to analyze toxicity risks, metabolic liabilities, and immunogenicity profiles of novel excipients, thereby making the process of selection effective as well as safety-oriented. AI application in excipient selection significantly reduces laboratory experiments, minimizes formulation costs, and improves the formulation success rate in producing patient-compatible drug products for Alzheimer's therapy [33, 42, 48].

4.2 Prediction of BBB Penetration and Drug Release Profiles

The blood-brain barrier remains one of the principal obstacles to AD drug delivery due to its selective permeability along with tight endothelial junctions which limit CNS bioavailability. Predicting the capacity of a molecule to cross the BBB is crucial during formulation design, and AI models are growing increasingly significant in this respect [55]. Quantitative structure-activity relationship (QSAR) and quantitative structure–property relationship (QSPR) models in conjunction with machine learning are used widely to make predictions of BBB permeability based on molecular descriptors. Programs like DeepChem, AutoQSAR, and ADMETlab incorporate large libraries of known penetrants and non-penetrants of the BBB to train machines to predict permeability based on lipophilicity, topological polar surface area, hydrogen bond donors/acceptors, and molecular flexibility [56]. Furthermore, convolutional neural networks (CNNs) and recurrent neural networks (RNNs) have been applied to predict on molecular graphs and SMILES strings to improve prediction accuracy. These AI-based models help pharmaceutical scientists screen candidate compounds and eliminate compounds with low brain delivery potential early in the development pipeline [57]. Besides BBB prediction, AI is also used to make drug release kinetic predictions from various formulation vehicles such as nanoparticles, liposomes, hydrogels, and transdermal patches. Algorithms can potentially replicate drug-polymer interactions, diffusion profiles, degradation rate, and encapsulation efficiency for the purpose of forecasting release behavior with respect to time. This information is important in developing pulsatile or long-lasting release systems that match circadian rhythms or specific phases of AD pathology development. Therefore, AI maximizes the rational formulation design of brain-targeted drug delivery systems by exclusively transferring only the molecules with the optimal BBB permeability and desired release pattern [58].

4.3 Neural Network and QSPR Model-Based Formulation Design

The recent development of neural networks, in particular deep neural networks (DNNs) and generative models, has opened up new possibilities for formulation design. These AI tools can handle nonlinear, high-dimensional

data and uncover hidden correlations between formulation variables and therapeutic performance [44]. In AD-specific formulation design, the neural networks also simulate the effects of variability in drug concentration, excipient ratios, and processing conditions on critical quality attributes (CQAs) of final products—e.g., particle size, zeta potential, entrapment efficiency, and drug loading. For example, artificial neural networks (ANNs) have been trained on nanoparticle formulation data of donepezil, galantamine, and memantine to predict encapsulation efficiency and release kinetics [34]. Such models have an advantage over traditional statistical procedures in that they detect hidden interactions and optimize multivariate conditions with a lesser number of experimental trials. GANs are being explored for the purpose of designing novel excipient molecules or the prediction of optimal formulation composition, and RL systems can be used to simulate iterative optimization procedures for formulations [59]. QSPR models, which belong to the category of AI, are applied complementarily by relating molecular structure descriptors to physicochemical and biopharmaceutical characteristics. QSPR models aid in the prediction of solubility, permeability, stability, and aggregation characteristics of APIs and excipients in Alzheimer's medications. Furthermore, they can be used to estimate the interaction energy between drug molecules and excipient carriers, particularly in the formulation of polymer- or lipid-based nanocarriers. In total, these models allow researchers to simulate numerous formulation scenarios in silico, concentrating on the most promising for empirical confirmation, thus significantly accelerating the formulation discovery process for Alzheimer's medicines [60].

4.4 Case Studies: AI-Optimized Formulations for AD

The application of AI in formulation design for Alzheimer's Disease has already been proven to have positive results, as seen in several case studies. An example is the design of optimized SLNs of rivastigmine through artificial neural networks. Researchers input parameters like type of lipid, amount of surfactant, and rate of homogenization into an ANN model that has been trained using experimental data [3]. The reformulated product showed increased brain bioavailability and extended release, as evidenced by pharmacokinetic studies and in vivo models of AD behaviors. Another study employed support vector regression (SVR) models to design the formulation of galantamine hydrobromide in a chitosan-based nasal gel by optimizing its parameters such as viscosity, mucoadhesion, and release rate using AI modeling to identify the optimal combination, resulting in enhanced nasal-to-brain delivery as well as enhanced cognitive outcomes in AD-induced rats. Similarly, deep learning models were employed to formulate donepezil-loaded PLGA nanoparticles, wherein formulation parameters were passed into a deep feed-forward network that was able to predict entrapment efficiency and drug release kinetics precisely [45]. Another recent study also explored the use of reinforcement learning algorithms to discover new excipient combinations for memantine hydrochloride to offer penetration through the BBB and neuroprotection. In this case, the AI model iterated formulation hypotheses through a reward mechanism with ease to converge onto a best nanoparticle design that demonstrated improved memory retention and neuroprotective behavior in preclinical AD models [39]. In another study, graph neural networks (GNNs) were applied to predict BBB penetration and toxicity profiles of co-formulated drugs in combination therapies for AD. The use of GNN enabled the identification of synergistic excipients that not only improved drug delivery but also reduced neuroinflammatory responses—a pivotal player in AD pathophysiology. These case studies illustrate the real-world efficacy of AI in designing effective, brain-targeted drug delivery systems for the treatment of Alzheimer's disease and indicate the potential for these models' scalability for future applications [60].

5. Integration of AI with Precision Medicine in Alzheimer’s Therapy

Alzheimer's disease, a debilitating and progressive neurodegenerative disorder, continues to be among the world's most serious health problems. In spite of significant advances in research, clinical application of therapeutic interventions with established efficacy in AD is not widespread, at least in part because of its etiological heterogeneity with multiple factors involved, interpatient heterogeneity, and the complex interrelationship between environmental and genetic factors. As precision medicine attempts to individualize the therapy of medicine based on patient-specific factors, AI is a game-changing tool that can potentially address large-scale, high-dimensional information to direct targeted therapeutic interventions [61]. AI in combination with precision medicine has the potential to deliver an interesting avenue to tackle disease heterogeneity, establish actionable molecular targets, personalize drug regimens, and improve clinical decision-making in Alzheimer's therapy. This part discusses the significant contributions of pharmacogenomics, dose optimization, and evidence-based strategies to AD treatment's AI-fuelled revolution [62].

5.1 Pharmacogenomics and Stratification of Patients

Pharmacogenomics, or the impact of genes on a person's reaction to medication, is the mainstay of precision medicine, particularly for such neurodegenerative disorders as AD, whose interindividual variation plays a crucial role in defining therapeutic effects. In Alzheimer's disease, a number of genetic biomarkers—e.g., APOE ε4, CLU, PICALM, TREM2, and ABCA7—have been linked to enhanced risk and severity of disease. Not only do the genetic variants affect vulnerability, but they also affect how patients metabolize and respond to drug agents, including cholinesterase inhibitors (e.g., donepezil, rivastigmine) and NMDA receptor antagonists (e.g., memantine) [63]. But to obtain actionable pharmacogenomic signatures from such genomic heterogeneity, computational strategies that can handle big data, reveal concealed relationships, and partition patients into therapeutically relevant subgroups are needed. AI, in the guise of ML and DL algorithms, has unequalled potential in pharmacogenomic analysis and patient stratification. By combining genomic, transcriptomic, proteomic, and metabolomic information, AI may have the potential to identify predictive biomarkers and create patient-specific disease signatures [64]. Methods such as k-means clustering and t-SNE (t-distributed stochastic neighbor embedding) have been used to group AD patients according to genetic profiles as well as endophenotypic characteristics. Supervised models such as support vector machines (SVM), random forests, and neural networks can predict therapeutic response from multi-omic and clinical inputs [57].

In addition, AI-supported stratification enables researchers to determine "responders" and "non-responders" to a treatment even before clinical symptoms fully emerge, thus enabling early intervention. For instance, integrating genomic information with neuroimaging (for instance, PET scans to detect amyloid or tau deposition) and cognition can be used to inform the construction of a durable patient taxonomy informed by disease progression and treatment responsiveness. This also applies to adaptive clinical trial design where patient populations are increasingly revised over time based on response data accrued, making trials more efficient and cheaper. In summary, AI-based pharmacogenomic systems are capable of stratifying Alzheimer's patients better and facilitating the design of genotype-guided therapies and optimize therapy outcomes while reducing side effects [65].

5.2 Personalized Dosage Optimization with AI

Among the largest barriers to the effective treatment of Alzheimer's is the "one-size-fits-all" dosing approach that disregards variability in drug metabolism, receptor sensitivity, comorbidities, and disease stage. Individualized dose optimization aims to fine-tune drug regimens to the specific physiological and pharmacokinetic profile of each patient. Historically, dose adjustment has been empirical and led by trial-and-error approaches that could lead to subtherapeutic effects or toxicity [3]. AI enables data-driven prediction of best dose regimens based on taking into account interindividual variability. Patient-specific information—age, sex, weight, genetic polymorphisms (e.g., CYP2D6 and CYP3A4 enzyme variants), liver and kidney function, and other concomitantly given drugs—can be used by AI programs to forecast how one will metabolize, distribute, and excrete a drug. Reinforcement learning algorithms, for instance, can model multiple dosing regimens and iteratively adjust regimens on the basis of predicted outcomes and side effect profiles. Such systems also can be trained on real-time feedback, adapting doses dynamically in response to changing biomarkers or patient-reported symptoms[61].

Deep networks can also be trained from large-scale electronic health record (EHR) data sets, pharmacokinetic studies, and therapeutic drug monitoring databases to suggest dose changes. Such models can be embedded in clinical decision support systems (CDSS), giving real-time, patient-specific recommendations for doses to clinicians. For example, in a patient who is a carrier of the APOE ε4 allele and presents with rapid cognitive deterioration and failure to respond to conventional cholinesterase inhibitors, AI can suggest a mixture of altered drugs or different doses from past experience in homologous genotypic populations [55]. Secondarily, AI can provide support for optimizing the drug delivery system according to the patient's cognitive state and severity of disease. For instance, the determination of the best formulation (oral, transdermal, intranasal) and frequency of delivery can be offered through neural network-based modeling. In drug repurposing, one of Alzheimer's researchers' go-to strategies, AI can help in finding not only the best drugs but also their best dose for cognitive gain without inducing catastrophic side effects [32]. By adopting AI-powered personalized dosing approaches, physicians can minimize the risks of polypharmacy, maximize patient compliance, and broaden the therapeutic window of Alzheimer's drugs. Ultimately, this serves the most important aspirations of precision medicine: giving the right drug to the right patient at the right dose at the right time [47].

5.3 Data-Driven Decision Making in Clinical Translation

Alzheimer's disease research and drug development have been bedeviled by historical challenges of heterogenous pathologies (amyloid-beta aggregation, tauopathy, neuroinflammation, synapse loss), excessive clinical trial failures, and a paucity of predictive biomarkers for early detection and tracking. Against such background, data-driven decision-making is paramount [36]. AI technology can integrate heterogeneous datasets—genomics, proteomics, imaging data, patient lifestyle data, EHRs, and wearable sensor data—to produce actionable insights that guide each step of clinical translation. Data-based AI models provide more precise patient selection, improved selection of endpoints, and early detection of drug effects of adverse effects, thus boosting the chances of a successful trial [29]. For example, observational data in real-world observational data (RWD) from large population-level registries or EHRs can be analyzed using NLP and ML to detect subtle disease or drug response patterns not apparent under controlled clinical conditions. Outputs can be input into adaptive clinical trial platforms where AI algorithms learn by making iterative modifications to trial parameters like dosage, length of study, or inclusion criteria based on interim results [20]. Additionally, AI enables in silico modeling and virtual simulation, potentially restricting dependence on animal models and justifying preclinical science. Predictive models may model disease pathology and drug response in silico with patient-specific inputs, enabling researchers to select the most effective therapeutic leads prior to investment in expensive human trials. Bayesian inference models and generative adversarial networks (GANs) may be used to further refine trial predictions and reduce risks due to patient dropout or placebo effect. AI has an important role to play in real-time decision-making during the delivery of clinical care. Integrated platforms based on EHRs, genomic information, neuroimaging findings, and patient-reported measures can support clinicians' decisions about the best treatment regimen for individual patients. For instance, when a patient presents with cognitive impairment and elevated levels of neuroinflammation biomarkers, AI can mark this as a candidate for immunomodulation and evidence-based suggestions for certain agents and dosing regimens. Of special interest, ethical issues and data privacy are absolutely critical in clinical decision-making and in the use of AI. Transparency, interpretability, and lack of bias in models are essential to regulatory approval and clinician acceptance. Explainable AI (XAI) methods are being used more and more to make model predictions understandable and trustworthy for patients and clinicians. In summary, AI-driven therapy drives the translation of research to the bedside in the form of clinical intervention more quickly. It makes more evidence-based, timely, and patient-tailored treatment decisions possible, shifting the therapeutic landscape of Alzheimer's disease from broad to highly precise and patient-specific [66].

6. Future Presceptive

The future of formulation design in Alzheimer's disease according to non-AI approaches offers the potential to drive patient-centric, targeted therapies. As our understanding of AD pathology continues to grow, the design of multifunctional, biocompatible, and disease-sensing drug delivery systems will become ever more optimized. New technologies such as stimuli-responsive nanoparticles, hybrid nanocarriers, and intranasal delivery systems will pioneer crossing the blood-brain barrier and improve bioavailability in the brain through such technologies alone, without the help of computational modeling or AI [67]. Additionally, it will be possible to have personalized therapeutic regimens when applied with formulation technologies in consort with precision medicine through patient-specific factors like genetic polymorphisms, biomarker expression, and metabolic profile. Enhanced biomaterials, microfabrication, and release systems promoted by biosensors must be capable of offering smarter and feedback-controlled drug delivery even in AI-independent models. Besides, regulatory harmonization, scale-up manufacturing, and low-cost formulation will drive clinical translation and worldwide availability forward [68]. In the next few years, multidisciplinary research collaborations between neuroscientists, pharmacologists, formulation scientists, and materials engineers will play an important role in circumventing current obstacles [69]. Prioritizing smart yet non-AI formulative design ensures equal innovation that can be embraced even in developing situations. Lastly, non-AI methodology-based formulative strategies will continue to form the bedrock in the provision of accurate, safe, and effective treatments for Alzheimer's disease in various patient populations [70].

7. Conclusion

AD continues to be a persistent global health problem, primarily because it has multifactorial pathophysiology, is a progressive disease, and for which the efficacy of available pharmacotherapies is low. Although the emergence of artificial intelligence has transformed drug discovery and formulation to a great extent, there is

huge value in ongoing research and optimization of non-AI-informed formulation strategies. Based on physicochemical principles, pathophysiology, patient-specific factors, and proven pharmaceutical technology, these methods provide efficient, scalable, and compliant regulatory solutions—particularly useful in low-resource environments. This chapter will highlight the key developments whereby non-AI-based drug delivery systems like liposomes, dendrimers, solid lipid nanoparticles, and polymeric systems are being advanced to fulfill the needs of precision medicine for AD. Technologies such as intranasal drug delivery, mucoadhesive systems, prodrug approaches, and stimulus-responsive systems achieve more effective brain targeting, extended drug release, and patient compliance—without relying on sophisticated computer aids. Furthermore, guided by patient stratification and pharmacogenomics, the systems can be designed for more targeted and predictable therapeutic outcomes. With biocompatibility, ease of production, and clinical utility, non-AI solutions complement high-tech digital developments, making drug-delivery advances equitable and adoptable across settings. Their convergence with advances in molecular diagnostics and personalised medicine could revolutionise therapeutic outcomes in AD. In summary, non-AI formulation technologies remain the necessary link between pharmaceutics and precision medicine. Their fate is one of reflective forethought, clinical proof, and worldwide availability—ultimately leading to safer, smarter, and patient-centred therapies for Alzheimer's disease

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