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Novel Dosage Forms: Current Trends, Challenges, and Future Perspectives in Pharmaceutical Sciences

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Abstract

Conventional drug delivery systems face significant limitations such as poor bioavailability, variable absorption, and lack of patient compliance, which have driven the development of novel dosage forms to enhance therapeutic outcomes. This review provides an in-depth analysis of current trends, technological advancements, and future directions in novel dosage forms. A systematic literature search was focusing on innovations in formulation design, evaluation, and clinical applications. Key developments include orodispersible films, floating drug delivery systems, mucoadhesive formulations, nanoemulsions, microneedle-based transdermal patches, and 3D-printed personalized dosage forms, supported by nanotechnology, smart polymers, and artificial intelligence to achieve targeted and controlled release. These advancements represent a paradigm shift toward patient-centric and personalized therapy. Future perspectives emphasize integration with digital health technologies, large-scale manufacturing strategies, and regulatory harmonization to accelerate clinical translation and commercialization.

Keywords: Novel dosage forms, controlled release, personalized drug delivery, orodispersible films, transdermal systems, 3D printing.

I. Introduction

The development of effective drug delivery systems is a cornerstone of modern pharmaceutics, as it ensures therapeutic efficacy and patient compliance. Conventional dosage forms such as tablets, capsules, and injections, although widely used, present several limitations including poor bioavailability, dose dumping, frequent administration, and systemic side effects [1,2]. These drawbacks have driven the pharmaceutical industry to innovate and explore advanced drug delivery systems that can provide controlled, targeted, and patient-friendly therapeutic outcomes [3]. Novel dosage forms, such as nanoparticles, liposomes, transdermal patches, and oral thin films, have emerged as promising alternatives to overcome the challenges of conventional formulations [4,5]. These systems not only enhance drug solubility and permeability but also enable site-specific delivery, minimizing systemic toxicity [6].

The need for novel dosage forms is further emphasized by the increasing prevalence of chronic diseases requiring long-term therapy, personalized medicine approaches, and the growing demand for non-invasive delivery routes [7]. For instance, transdermal drug delivery systems (TDDS) and mucoadhesive formulations have gained significant attention for improving patient adherence and reducing gastrointestinal irritation [8]. Similarly, nanocarrier-based systems have revolutionized oncology and CNS drug delivery by improving bioavailability and enabling targeted action at diseased sites [9,10].

This review aims to comprehensively explore the current trends in novel dosage forms, including their design strategies, technological advancements, and therapeutic applications, while addressing the key challenges and limitations associated with their development [11]. Furthermore, the article highlights regulatory considerations and future prospects for integrating these innovations into clinical practice [12-15].

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II. Classification of Novel Dosage Forms

2.1 Solid Oral Novel Dosage Forms

Orodispersible Films (ODFs)

Orodispersible films are ultra-thin polymeric strips designed to disintegrate rapidly on the tongue without water, improving adherence in pediatrics, geriatrics, dysphagia, and on-the-go administration [16–18]. Modern ODFs leverage hydrophilic film formers (e.g., HPMC, pullulan), plasticizers (glycerol, PEG), and superdisintegrants to achieve sub-30-second disintegration while maintaining tensile integrity for packaging and handling [16,17]. Drug loading is enabled via solution casting, hot-melt extrusion, or inkjet printing for dose personalization and combination therapy; permeation enhancers and taste-masking ion-exchange resins improve palatability and mucosal uptake [16–19]. Advances include nano-enabled ODFs (drug nanocrystals, polymeric nanoparticles, cyclodextrin inclusion) to elevate dissolution/supersaturation windows for BCS II–IV drugs and biologic actives (vaccines/enzymes) when stabilized with sugars and proteins [17–19]. Critical challenges are dose uniformity for potent drugs, moisture sensitivity, and scale-up rheology control; quality endpoints (disintegration, content uniformity, mechanical properties, residual solvents) are now well-standardized across pharmacopeial drafts and ICH-aligned QbD frameworks [16–18].

Floating Drug Delivery Systems (FDDS; gastro-retentive)

FDDS increase gastric residence time by reducing system density (<1 g cm^{-3}) to remain buoyant on gastric fluid, thereby enhancing proximal-gut absorption for narrow-window drugs (e.g., riboflavin, levodopa), improving local treatment (H. pylori), and mitigating variability from rapid GI transit [20–22]. Formats include effervescent matrices (CO_2 generation from citric acid/sodium bicarbonate) and non-effervescent swellable/hydrodynamically balanced systems using gel-forming polymers (HPMC, carbomer) and oils [20,22]. Design relies on buoyancy lag time, total buoyancy (>8–12 h), in-vitro–in-vivo correlation (IVIVC) of gastric retention (gamma-scintigraphy), and control of food effects and posture [20–23]. Evolving gastro-retentive strategiesexpandable/shape-memoryand bioadhesive platforms—are increasingly combined with floating for robust retention under fed/fasted conditions [21,23]. Limitations include interpatient variability in motility (MMC phase III), risk of dose-dumping with alcohol/acidic co-ingestion, and swallowability of larger systems [20–22].

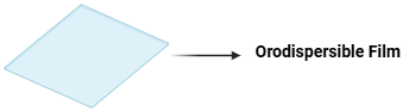

Figure 1. Orodispersible Film

Effervescent Tablets

Effervescent tablets incorporate organic acids (citric, tartaric) and carbonates/bicarbonates to generate CO_2 on reconstitution, yielding fast dispersion, improved palatability, and high-dose delivery with reduced GI irritation for actives like NSAIDs and vitamins [24–26]. Process-critical aspects are moisture control (anhydrous processing, low-RH environments), granular flow, and rapid dissolution without insoluble residues; twin-screw continuous granulation and PAT have modernized manufacturability and robustness [26]. Clinically, effervescence can enhance onset via transient micro-mixing and favorable gastric emptying profiles; however, sodium load and dental enamel exposure require labeling and risk mitigation [24,25].

2.2 Liquid Novel Dosage Forms

Nanoemulsions

Nanoemulsions (20–200 nm) are kinetically stable O/W or W/O dispersions stabilized by surfactant/co-surfactant systems (e.g., SMEDDS/SEDDS variants), delivering poorly soluble drugs with improved dissolution, lymphatic uptake, and reduced first-pass metabolism [27–31]. High-energy (high-pressure homogenization, ultrasonication) and low-energy (phase inversion, spontaneous emulsification) methods are selected based on API solubility, interfacial curvature, and scalability constraints [27–29]. Contemporary work emphasizes biological fate (protein corona, mucus

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transport), in-situ gelling nanoemulsions for mucosa/ocular routes, and transdermal/follicular targeting via droplet deformability [29–31]. Key CMC/QbD levers include droplet size/PDI, interfacial tension, Ostwald ripening control (oil selection, ripening inhibitors), and digestion-informed in-vitro lipolysis tests to predict oral bioavailability [28,29].

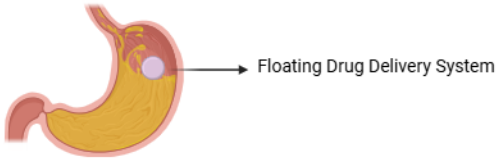

Figure 2. Floating Drug Delivery Systems

Lipid-Based Systems (LBDDS; SLN/NLC, SEDDS/SMEDDS, liposomes)

LBDDS encompass colloidal carriers and self-emulsifying systems that solubilize lipophilic APIs in digestible oils/surfactants to enhance intestinal solubilization and promote lymphatic transport [28,32–34]. Solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC) provide solid/semi-solid lipid matrices enabling controlled release, chemical protection, and high physical stability; however, crystallinity and polymorphic transitions can expel drugs—addressed by mixing solid/liquid lipids (NLC) and using functional surfactants [32–34]. For oral SEDDS/SMEDDS, digestion-dependent supersaturation and precipitation inhibition (polymer precipitation inhibitors) are pivotal to translation; biorelevant lipolysis assays coupled with in-silico PBPK models are now standard for developability assessment [28,33]. Emerging directions include surface-engineered LNPs for tissue targeting and mRNA/protein delivery, bridging pharmaceutics with nanomedicine [35].

2.3 Semi-Solid Novel Dosage Forms

Gels and Hydrogels

Hydrogels are 3D hydrophilic networks (covalent or physical crosslinks) with high water content that enable local depot formation, sustained release, and stimuli-responsive delivery (pH, temperature, enzymes, redox) [36–39]. In situ-forming systems (thermo-gelation of poloxamers/PLGA-PEG-PLGA; ion-activated alginate; solvent-exchange NMP/PLGA implants) provide minimally invasive administration and conformal filling of complex anatomical spaces [38,40]. Release mechanisms are governed by swelling-controlled diffusion, mesh size, and degradation kinetics; for bioactives (proteins/cells), mild gelation and affinity interactions (heparin-mimetic, host–guest cyclodextrin) maintain stability and spatiotemporal control [36–39]. Clinical translation focuses on post-surgical local therapy, ocular/periodontal depots, and intra-articular disease modifiers, with attention to injectability, sterilization resilience, and extractables/leachables [39,40].

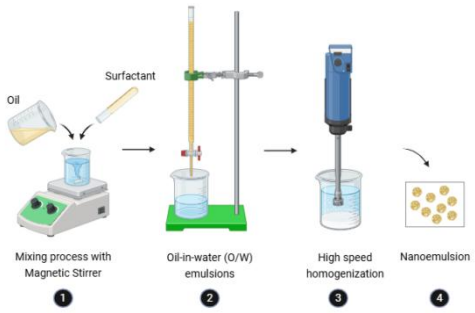

Figure 3. Preparation of Nanoemulsion

Mucoadhesive Formulations

Mucoadhesive dosage forms (buccal, nasal, vaginal, ocular, GI) prolong residence time via interfacial interactions (hydrogen bonding, electrostatics, interpenetration) between polymers (carbomers, chitosan, thiomers) and mucins, improving absorption of short-window and labile drugs [41–45]. Modern design integrates rheology-based adhesion metrics, mucin–polymer complexation, and particle engineering (mucoadhesive vs mucopenetrating surfaces) to balance retention with permeation [41–43]. Buccal films/tablets and ocular inserts exemplify successful translation; limitations include mucus turnover, variability in mucin glycosylation, and potential irritation with cationic polymers—addressed through degree-of-deacetylation control and thiolation strategies [41–45].

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2.4 Transdermal Systems

Patches

Transdermal patches deliver drugs across the stratum corneum to the systemic circulation, offering steady plasma profiles, bypass of first-pass metabolism, and improved adherence for chronic therapy [46–49]. Contemporary designs include drug-in-adhesive matrices, reservoir and multilayer systems with permeation enhancers (fatty acids, terpenes, iontophoresis/thermal ablation adjuncts) while managing adhesive cold-flow, crystallization risk, and dose dumping [46–48]. Regulatory expectations emphasize adhesive performance (peel/tack/shear), in vitro skin permeation (human/porcine), in vivo PK bioequivalence, and extractable/leachable safety of acrylate/silicone backings [47–49]. New directions pair patches with digital adherence sensing and on-skin microheaters to modulate flux on demand [46,49].

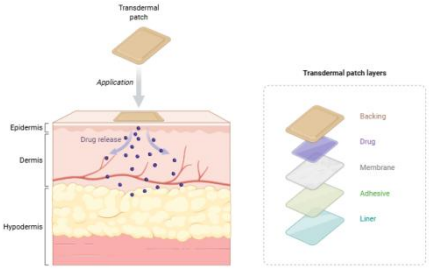

Figure 4. Transdermal Drug Delivery

Microneedle-Based Delivery

Microneedles (solid, coated, dissolving, hollow) create transient microchannels to painlessly traverse the stratum corneum, enabling delivery of small molecules, biologics, and vaccines with reduced cold-chain burden and potential for self-administration [46,50–52]. Materials span metals, silicon, and dissolving polymers (PVP, PVA, carboxymethylcellulose, hyaluronate) that can stabilize sensitive cargos; performance hinges on insertion force, tip sharpness, mechanical robustness, and rapid dissolution kinetics [50–52]. Clinical progress includes influenza, measles-rubella, and COVID-19 vaccine candidates, as well as systemic delivery of small molecules and peptides; challenges include dose loading limits, scalable manufacturing (molding/3D printing), and reproducible skin insertion across demographics [50–52].

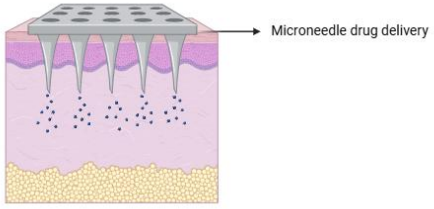

Figure 5. Microneedle Based Drug Delivery

III. Recent Technological Advancements

3.1 3D Printing for Personalized Dosage Forms

Three-dimensional (3D) printing, also known as additive manufacturing, has revolutionized pharmaceutical manufacturing by enabling the fabrication of personalized dosage forms with high precision. Unlike conventional manufacturing methods, 3D printing allows layer-by-layer deposition of materials to create drug products with customized shapes, sizes, and drug release profiles. Techniques such as Fused Deposition Modeling (FDM), Inkjet Printing, and Stereolithography (SLA) are widely employed in drug formulation. These technologies facilitate patient-specific dosing, multi-drug combination in a single unit, and controlled drug release. The first FDA-approved 3D-printed drug, *Spritam® (levetiracetam)*, demonstrated the feasibility of this approach for rapid disintegration and high-dose loading [53,54].

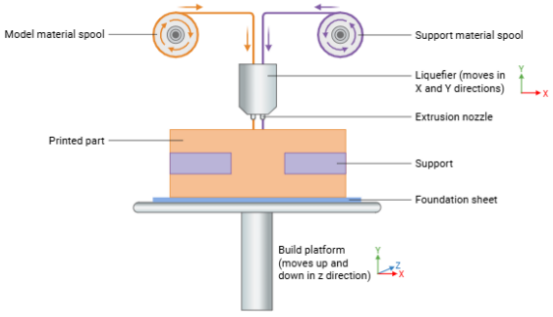

Figure 6. Fused Deposition Method of 3D Printing

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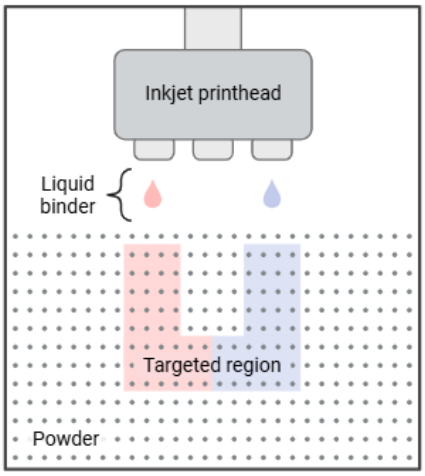

Figure 7. Inkjet Method 3D of Printing

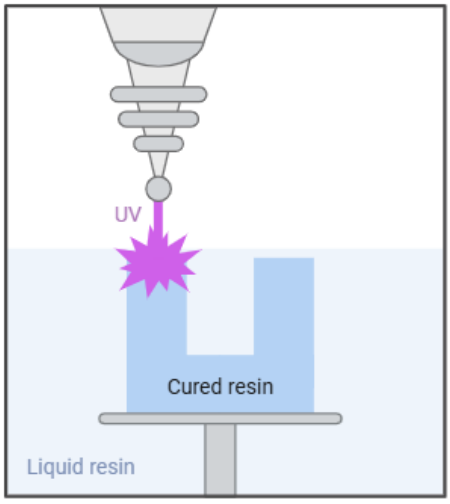

Figure 8. Stereolithography Method of 3D Printing

Recent studies focus on improving printable pharmaceutical-grade polymers, temperature-sensitive materials, and bio-based excipients to enhance stability and biocompatibility. Furthermore, advancements in 3D printing have introduced 4D printing, which incorporates smart materials that respond to environmental triggers like temperature, pH, and moisture, adding a dynamic aspect to drug delivery [55–57].

3.2 Smart Drug Delivery Systems (pH-sensitive, Temperature-responsive)

Smart drug delivery systems have emerged as a significant advancement in targeted drug delivery. These systems respond to specific physiological stimuli, such as pH, temperature, enzymes, or redox conditions, to release drugs at the desired site, thereby improving therapeutic efficacy and reducing systemic side effects. pH-sensitive polymers (e.g., Eudragit®, poly(methacrylic acid)) are widely used in oral delivery systems for targeting the gastrointestinal tract, particularly for colon-specific drug release [58,59].

Temperature-responsive hydrogels, such as those based on poly(N-isopropylacrylamide) (PNIPAAm), exhibit sol-gel transitions triggered by temperature variations, enabling controlled and sustained drug delivery. Recent developments include dual-stimuli-responsive systems (pH and temperature combined), which offer greater precision in drug targeting for cancer therapy and chronic inflammatory diseases [60,61].

3.3 Use of AI and Machine Learning in Formulation Development

Artificial Intelligence (AI) and Machine Learning (ML) have transformed pharmaceutical formulation development by enabling predictive modeling, process optimization, and virtual screening of excipients. These technologies significantly reduce the time and cost associated with drug development. AI algorithms such as neural networks, decision trees, and support vector machines are employed to predict critical formulation parameters, such as dissolution rate, stability, and bioavailability, based on experimental and historical data [62,63].

AI-driven platforms assist in designing patient-specific dosage forms, optimizing polymer ratios, and predicting drug-excipient compatibility, which accelerates formulation screening and minimizes experimental trials. Furthermore, machine learning models integrated with real-time manufacturing data enable continuous process optimization in continuous manufacturing systems, ensuring quality by design (QbD) compliance [64,65].

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IV. Challenges in Development

The development of novel dosage forms faces several challenges that limit their large-scale implementation despite their therapeutic benefits. One of the primary concerns is stability issues, which significantly affect the shelf life and bioavailability of the final product. Formulations involving biologics, nanoparticles, or hydrophilic polymers often exhibit physical and chemical instability during storage due to moisture absorption, crystallization, or degradation of active pharmaceutical ingredients (APIs) [66]. For instance, lipid-based drug delivery systems are highly prone to oxidative degradation, leading to reduced drug efficacy [67]. Additionally, protein and peptide formulations often require stringent storage conditions, such as cold chain logistics, to maintain their integrity [68].

Another critical challenge is manufacturing scalability. Although technologies like 3D printing and microfabrication have shown great promise in personalized medicine, their application in large-scale production remains limited [69]. The complexity of producing precise structures for controlled drug release at an industrial scale introduces high production costs and extended processing times [70]. Furthermore, maintaining batch-to-batch consistency in novel systems such as nanoparticles or microneedle arrays is difficult due to the intricate processing parameters involved [71]. Such limitations pose a significant barrier to commercialization and widespread clinical adoption.

Regulatory hurdles represent another major challenge in the development of novel dosage forms. Current regulatory frameworks are primarily designed for conventional dosage forms, and therefore lack standardized guidelines for emerging technologies such as 3D printing, nanomedicine, and smart drug delivery systems [72]. Developers must conduct extensive preclinical and clinical evaluations to demonstrate safety, efficacy, and quality, which increases time and financial investment [73]. Additionally, novel excipients and advanced manufacturing processes require comprehensive toxicological and stability data before approval, further delaying market entry [74]. Harmonizing global regulatory requirements for advanced drug delivery systems is essential to accelerate innovation while ensuring patient safety [75].

V. Clinical Applications and Market Trends

5.1 Recent FDA/EMA Approvals of Novel Dosage Forms

The regulatory landscape for novel dosage forms has evolved considerably in recent years, emphasizing patient-centric designs, enhanced compliance, and improved clinical outcomes. Regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have granted approvals for various innovative formulations that address limitations of conventional dosage forms.

Intranasal Delivery Systems
One of the most notable approvals is the epinephrine nasal spray (neffy®), which provides a needle-free alternative for the management of anaphylaxis. Approved by the FDA in 2024, this formulation improves patient convenience and compliance, especially for needle-phobic individuals. Intranasal systems bypass first-pass metabolism and ensure rapid absorption through the nasal mucosa, making them ideal for emergency therapies (76).

Self-administered Vaccines
The FDA has also expanded approval for at-home administration of influenza vaccines (FluMist®), marking a paradigm shift in vaccine delivery. This strategy not only enhances accessibility but also aligns with public health goals for mass immunization and pandemic preparedness (77).

Subcutaneous (SC) Formulations of Monoclonal Antibodies
The trend toward subcutaneous administration of drugs traditionally given intravenously (IV) continues to gain traction. For instance, nivolumab (Opdivo®) received FDA approval for a fixed-dose SC formulation in late 2024. Similarly, atezolizumab (Tecentriq®) was approved by the EMA for SC use in oncology indications, significantly reducing infusion times and healthcare resource utilization (78, 79).

Long-Acting Injectables (LAIs)
The EMA granted a positive opinion for lenacapavir, a twice-yearly injectable for HIV pre-exposure prophylaxis (PrEP), representing a major advancement in adherence-driven therapy (80).

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Such LAIs reduce dosing frequency from daily to biannual intervals, addressing non-adherence issues in chronic disease management.

5.2 Global Market Analysis

The market for novel dosage forms is experiencing robust growth, driven by technological innovation, patient convenience, and the need for personalized medicine.

Long-Acting Injectables
The global LAI market was valued at approximately USD 26.3 billion in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 12–13% through 2030. This growth is primarily attributed to the expanding application of LAIs in psychiatry, endocrinology, and infectious disease prevention (81).

Intranasal Drug Delivery
The demand for intranasal formulations is increasing, with projections indicating significant growth due to rising approvals of needle-free emergency medications and vaccines. The global intranasal drug delivery market is expected to grow steadily, driven by patient preference and the ability to bypass hepatic metabolism (82).

3D-Printed Dosage Forms
The adoption of 3D printing in pharmaceuticals remains in the early stages but shows promising growth potential, particularly for personalized therapies. The global market for 3D-printed drugs is estimated to reach USD 0.43–0.79 billion by 2035, with mid-teen CAGR forecasts, fueled by advancements in additive manufacturing technologies and regulatory acceptance post-Spritam® approval (83, 84).

VI. Future Perspectives

Integration with Digital Health Technologies

The integration of novel dosage forms with digital health technologies is anticipated to transform patient care by enabling precision medicine and real-time therapeutic monitoring. Smart drug delivery systems embedded with sensors and wireless communication tools allow continuous monitoring of physiological parameters and medication adherence. Digital pills, approved by the FDA for psychiatric disorders, are an example of such integration, combining pharmacotherapy with ingestible sensors that transmit adherence data to mobile applications (85,86). Wearable devices connected to controlled-release systems enable dose optimization based on patient-specific needs, reducing adverse effects and enhancing efficacy. Furthermore, cloud-based platforms and AI algorithms are being employed to interpret patient data collected via these systems, facilitating data-driven decision-making and personalized treatment strategies (87,88). This convergence of pharmaceuticals and digital health aligns with the growing demand for telemedicine and remote patient management, particularly after the COVID-19 pandemic (89,90).

Role of 4D Printing and Nanotechnology

4D printing, an evolution of 3D printing, introduces smart materials capable of transforming shape, properties, or functionality over time in response to external stimuli such as temperature, pH, or light (91). In drug delivery, 4D-printed dosage forms can adapt their release kinetics based on physiological conditions, ensuring precise therapeutic outcomes (92,93). For instance, shape-shifting oral tablets have been designed to provide site-specific release and controlled drug delivery, significantly improving patient compliance (94). Nanotechnology further complements these advances by enabling targeted and controlled drug delivery through nanoparticles, nanomicelles, and dendrimers, which improve solubility, stability, and bioavailability of poorly soluble drugs (95,96). Combined with 4D printing, nanotechnology can produce intelligent drug delivery systems capable of responding to environmental stimuli and delivering therapeutics with unprecedented precision (97). These innovations are expected to dominate the future landscape of personalized medicine, regenerative therapies, and chronic disease management (98,99). Regulatory frameworks and scalable manufacturing strategies will be critical for successful commercialization and widespread clinical adoption of these futuristic dosage forms (100).

VII. Conclusion

The evolution of novel dosage forms has significantly transformed pharmaceutical sciences by enhancing drug efficacy, improving patient compliance, and enabling personalized medicine.

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These advanced systems, including controlled-release formulations, orally disintegrating tablets, transdermal patches, 3D/4D printed dosage forms, and nanotechnology-based platforms, address critical limitations associated with conventional dosage forms such as poor bioavailability, patient inconvenience, and inconsistent therapeutic outcomes. Despite these benefits, several challenges remain, including high manufacturing costs, complex regulatory pathways, stability concerns, and limited scalability for large-scale production. Furthermore, safety and long-term efficacy of innovative technologies such as nanocarriers, smart polymers, and bioprinted dosage forms require rigorous clinical validation.

Future directions in this domain emphasize the integration of digital health technologies, smart sensors, and connected devices for real-time monitoring of drug therapy, along with the adoption of 4D printing and nanotechnology for precision medicine. Collaborative efforts among researchers, regulatory agencies, and industry stakeholders will be essential to overcome existing barriers and accelerate clinical translation of these technologies. In conclusion, while novel dosage forms present unprecedented opportunities to revolutionize drug delivery and patient-centric care, achieving their full potential will require harmonized regulatory frameworks, technological advancements, and cost-effective manufacturing strategies.

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