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ADVANCEMENTS IN ADDITIVE MANUFACTURING: A REVIEW OF 3D PRINTING PROCESSES

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ABSTRACT

This study aimed to review the transformative technology in pharmaceutical sciences. Additive manufacturing, or 3D printing, is a process of making 3-dimensional objects from a digital file. Charles Hull, who is considered the inventor of 3D printing. This review explores key 3D printing technologies used in pharmaceutical applications, facilitating strategies for drug development, transforming conventional drug development particles, inaugurating new methods for pharmaceutical formulations, and paving the path to creative drug formation techniques and tailored therapy. In this review, we will explore the history of 3D printing and provide an overview of its working principles. The following section discusses the evolution of 3D printing technology, and also operational mechanisms of 3D printing will be presented.

INTRODUCTION

In the past few years, 3D printing in the pharmaceutical field has shown growing interest due to its prospectiveness. Involves the construction of 3D objects by depositing material layer by layer. Following a digital blueprint and guided by computer-associated technologies. In contrast to conventional subtractive manufacturing, which shapes objects by cutting or molding material, 3D printing deposits material precisely where required, reducing waste and enabling the creation of intricate designs.

Several 3D printing techniques are commonly manifested in pharmaceutical

applications. Deposition modeling, selective laser sintering, inkjet printing, and stereolithography.

In fused deposition modeling, heated thermoplastic material is extruded and layered sequentially to form a 3-dimensional form.

Selective laser sintering utilizes a laser to fuse powdered materials, forming a solid object layer by layer without requiring additional support.

The inkjet printing technique involves spraying small amounts of formulation onto a chosen substrate to produce precise pharmaceutical doses.



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Stereolithography uses ultraviolet light to cure liquid resin layer by layer to construct detailed and accurate 3-dimensional structures.

However, the invention of the first 3D printer is generally credited to Charles Hull. Charles Hull was a trailblazer. In additive manufacturing, the stereolithography process is introduced as a groundbreaking layer-by-layer process. The photopolymerization technique and the development of a standard file format of the tessellation language, which remains the industry standard digital model format for 3D printing technologies, are discussed below.

MAIN SECTION

The efficiency and safety of pharmacotherapy in vulnerable populations, particularly pediatric and geriatric patients, have long been critical concerns in clinical pharmacology and personalized medicine [1, 2].

Pediatric patients, who are in dynamic phases of growth and physiological maturation, exhibit heightened pharmacodynamic and pharmacokinetic sensitivity to drug therapies. In contrast, geriatric individuals often experience decreased gastrointestinal absorption, liver metabolism, and renal clearance, compounded by polypharmacy and the prevalence of multiple comorbidities, significantly influencing therapeutic outcomes and safety profiles. [3]

Current pharmaceutical dosing regimens are largely standardized, with limited availability of age- or condition-specific formulations for special populations. In pediatric care, drug administration frequently involves manual tablet splitting

or crushing, a practice that compromises dose precision, alters the physicochemical integrity of the formulation, and may lead to suboptimal therapeutic efficacy or unintended adverse effects [4].

Three-dimensional (3D) printing technology offers exceptional versatility, enabling the fabrication of patient-specific pharmaceuticals by modulating design parameters such as dosage form geometry, dimensions, internal architecture, and infill density to achieve precise therapeutic targeting and controlled drug release profiles. [5]

For geriatric patients with dysphagia, 3D printing technology enables the fabrication of lightweight, porous, and easily disintegrating dosage forms, enhancing swallowability and patient compliance. In cases of polypharmacy, multiple active pharmaceutical ingredients (APIs) can be compartmentalized and integrated into a single polypill, reducing the risk of dosing errors or omissions and thereby improving therapeutic efficacy and medication adherence. Furthermore, 3D printing allows for the creation of uniquely shaped formulations or the incorporation of tactile symbols and visual markers on the tablet surface, offering additional support for patients with visual impairments. [6, 7, 8]

Principle of FDM Technology and Applications in the Pharmaceuticals:

Fused Deposition Modeling (FDM) has become a prominent 3D printing technique in the pharmaceutical field due to its cost-effectiveness, straightforward operational setup, and the ability to produce mechanically robust dosage forms. Utilizing computer-aided design (CAD) software, this technique constructs drug-



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loaded formulations by extruding thermoplastic polymers—infused with active pharmaceutical ingredients—in a layer-by-layer fashion onto a build platform. As illustrated in Figure 2, the drug-loaded polymer filament is fed through dual rollers into a heated nozzle, where it is melted and precisely deposited along the X and Y axes according to digital instructions. Upon completing each layer, the build platform descends or the print head elevates along the Z-axis by an increment equal to the predefined layer height, continuing this process iteratively until the final structure is formed [9, 10].

Currently, three principal methodologies are employed in the fabrication of 3D-printed oral solid dosage forms via Fused Deposition Modeling (FDM).

1. Dipping-Melting Method: This approach involves immersing pharmaceutical-grade polymeric filaments into a solution or suspension containing the active pharmaceutical ingredient (API), facilitating the adsorption or diffusion of the drug into the filament matrix. Upon solvent evaporation, the drug impregnated filaments are thermally processed through the FDM system.

2. Hot-Melt Extrusion Integrated with FDM (HME-FDM): The most prevalent technique, this process entails the incorporation of APIs and pharmaceutical excipients into a hot-melt extrusion unit, where thermal and mechanical energy promote homogeneous mixing and extrusion of drug-loaded filaments. These filaments are subsequently utilized in the FDM process to produce customized drug delivery systems.

3. Filling and Encapsulation Strategy:

In this method, a prefabricated hollow shell is initially printed, followed by the introduction of the API—either manually or through automated filling mechanisms. The shell is then sealed via additional FDM printing, either concurrently or in a staged manner, ensuring containment and stability of the active compound.

Each fabrication route provides distinct advantages with respect to drug-loading capacity, formulation adaptability, thermal stability of the API, and the ability to design tailored release profiles, thereby expanding the scope of personalized and on-demand pharmaceutical manufacturing. [11, 12, 13]

Stereolithography (SLA), originally developed by Charles Hull in 1988, is a vat photopolymerization-based 3D printing technique renowned for its ability to fabricate polymeric components with exceptional dimensional accuracy, fine resolution, and intricate geometric detail through the layer-by-layer photopolymerization of liquid resins using a UV laser. [14, 15]

Stereolithography (SLA) technology is broadly classified into two main modalities: laser-scanning systems, which utilize a focused ultraviolet (UV) laser to selectively cure photopolymer resin point-by-point, and Digital Light Processing (DLP) systems, which employ a digital micromirror device (DMD) to project patterned light, enabling the simultaneous curing of entire resin layers with high precision and throughput [16]

Stereolithography (SLA) is a vat photopolymerization-based additive



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manufacturing technique that constructs three-dimensional structures in a layer-by-layer fashion through the selective solidification of photosensitive resins using a focused ultraviolet (UV) laser. This process is governed by photopolymerization kinetics, wherein liquid monomers or oligomers are cross-linked into solid polymers upon exposure to targeted UV radiation, enabling the formation of complex and high-resolution geometries [97,98].

SLA has gained substantial traction in the biomedical and pharmaceutical sectors due to its precision and material adaptability. Key applications include:

Tissue engineering scaffolds, designed with controlled porosity and architecture to support cellular attachment, proliferation, and tissue regeneration.

Fabrication of implantable medical devices, such as customized prosthetics and anatomical models for pre-surgical planning.

Multidrug-loaded oral dosage forms, allowing precise spatial distribution of active pharmaceutical ingredients (APIs) within a single tablet for personalized therapy

Soft and flexible drug delivery systems, including mucoadhesive patches and bioresorbable implants, which facilitate targeted and controlled drug release

The high resolution and structural complexity achievable with SLA make it a promising platform for next-generation pharmaceutical manufacturing and personalized medicine. [17, 18]

ADVANTAGES

Operational Simplicity: Involves a streamlined process configuration with limited mechanical intricacy, facilitating user-friendly implementation and scalability in routine pharmaceutical manufacturing environments.

Economic Feasibility: Demonstrates high cost-effectiveness through efficient resource utilization, minimized material wastage, and reduced energy consumption, making it suitable for both prototyping and large-scale production.

Extensive Material Applicability: Exhibits compatibility with a wide array of pharmaceutically accepted polymers, excipients, and active pharmaceutical ingredients (APIs), enabling tailored formulation strategies and enhanced drug delivery system design. [19], [20], [21], [22], [23]

DISADVANTAGES

Thermal Instability of APIs: A major limitation is the risk of thermal degradation of heat-sensitive active pharmaceutical ingredients (APIs) during processing, as FDM and related techniques often require elevated extrusion temperatures, which may compromise the chemical stability, bioactivity, or therapeutic efficacy of the incorporated drug compounds. [24], [25]

Limited Printing Resolution: Compared to high-precision additive manufacturing techniques such as stereolithography (SLA), Fused Deposition Modeling (FDM) exhibits relatively lower spatial resolution and surface fidelity, resulting in less intricate microstructural detail and reduced dimensional accuracy in the fabricated dosage forms or medical devices. [26]



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Surface Quality and Mechanical Integrity Constraints: Fused Deposition Modeling (FDM) often yields dosage forms with relatively rough surface morphology and reduced mechanical strength, particularly at interlayer boundaries, which may compromise the structural robustness and aesthetic uniformity of the final product.

Challenges in Drug Release Profiles: The entrapment of active pharmaceutical ingredients (APIs) within the dense polymeric matrix can hinder diffusion and dissolution, potentially resulting in delayed, incomplete, or inconsistent drug release, thereby affecting therapeutic efficacy [27]

APPLICATIONS OF 3D PRINTING IN PHARMACEUTICAL SCIENCES

Fabrication of Solid Oral Dosage Forms (SODFs) via Additive Manufacturing

Among the diverse pharmaceutical applications of three-dimensional (3D) printing, the production of solid oral dosage forms (SODFs)—particularly tablets—remains the most extensively explored. Additive manufacturing enables the precise engineering of tablet geometry, facilitating the customization of physical attributes such as shape, size, internal structure, and surface area. This technological flexibility allows for the modulation of drug release kinetics (e.g., immediate, sustained, or delayed release) and the incorporation of personalized dosages, including polypharmacy systems that integrate multiple active pharmaceutical ingredients (APIs) within a single unit. Such capabilities not only enhance therapeutic efficacy but also support patient-centric drug design, particularly beneficial for

populations requiring tailored pharmacotherapy, such as pediatric and geriatric patients. [28]

Polypills and Multi-API Combinatorial Dosage Forms

The integration of three-dimensional (3D) printing into pharmaceutical manufacturing has facilitated the development of polypills, which are advanced oral dosage forms designed to incorporate multiple active pharmaceutical ingredients (APIs) within a single solid unit. This approach allows for the spatial and temporal separation of APIs, enabling customized drug release profiles tailored to specific therapeutic regimens. By consolidating complex multidrug therapies into a single administration form, 3D-printed polypills enhance patient adherence, reduce the risk of dosing errors, and streamline pharmacological management, particularly in individuals with chronic conditions requiring polypharmacy, such as cardiovascular diseases or diabetes. [29]

Patient specific dosage forms

Three-dimensional printing (3DP) has facilitated the fabrication of oro dispersible formulations that rapidly disintegrate in the oral cavity, enhancing patient adherence and administration convenience, particularly for populations with swallowing difficulties such as pediatric, geriatric, or dysphagic patients. [30], [31]

Pharmaceutical Research and Development

Three-dimensional printing (3DP) has emerged as a powerful tool in pharmaceutical R&D, enabling the rapid prototyping of investigational drug delivery systems and the fabrication of



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customized dosage forms for preclinical evaluation. This technology supports the efficient screening of formulation parameters, optimization of drug release kinetics, and assessment of bioavailability in early-stage development of novel therapeutics. [32]

Challenges in 3D printed drug delivery systems

Despite the significant potential of three-dimensional (3D) printing in pharmaceutical manufacturing, numerous technical, regulatory, and formulation-related barriers must be addressed to facilitate its broader adoption in drug delivery system (DDS) development. Critical challenges include material compatibility, process scalability, API stability under thermal and mechanical stress, and the lack of standardized regulatory frameworks tailored to additive manufacturing in pharmaceuticals. Overcoming these complexities is essential for the successful translation of 3D-printed therapeutics from bench to bedside. [33], [34].

Regulatory Considerations in Pharmaceutical 3D Printing

The regulatory landscape surrounding the use of three-dimensional (3D) printing in pharmaceutical manufacturing is continually evolving. Key concerns involve the authorization pathways, quality assurance standards, and process validation protocols for 3D-printed drug products. Due to the complexity and customization inherent in additive manufacturing, traditional regulatory frameworks may be insufficient to address the unique challenges of this technology. To ensure the safety, efficacy, and consistent quality of 3D-printed

pharmaceuticals, regulatory agencies must establish comprehensive, science-based guidelines encompassing aspects such as Good Manufacturing Practices (GMP), in-process controls, post-production testing, and risk assessment models tailored to additive manufacturing workflows. [35]

Quality Control and Assurance in 3D-Printed Pharmaceuticals:

Ensuring consistent product quality and safety in 3D-printed drug formulations poses significant challenges due to the complexity and variability inherent in the additive manufacturing process. Fluctuations in printing parameters (e.g., temperature, speed, layer height), material characteristics (e.g., polymer viscosity, drug-polymer interaction), and formulation techniques can lead to inconsistencies in dosage uniformity, drug release kinetics, and mechanical integrity of the final product. These deviations may compromise therapeutic performance and negatively impact clinical outcomes. Therefore, the implementation of robust quality control measures, including real-time monitoring, process analytical technologies (PAT), and stringent standard operating procedures (SOPs), is essential to maintain batch-to-batch reproducibility and regulatory compliance in pharmaceutical 3D printing. [36]

Excipient Selection, Cost, and Accessibility Considerations

The selection of suitable excipients for 3D printing in pharmaceutical applications is critical, as they must exhibit appropriate thermal, rheological, and mechanical properties compatible with the chosen printing technique. However, the high cost and limited availability of specialized pharmaceutical-grade materials and 3D



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printing equipment can pose significant financial barriers. These expenses may hinder the adoption of additive manufacturing technologies, particularly for small and medium-sized pharmaceutical enterprises, restricting their ability to compete in the development of advanced, personalized drug delivery systems. [37]

Regulatory Barriers to Implementation

The approval and integration of 3D-printed pharmaceuticals face several regulatory hurdles. A major limitation is the absence of well-defined and specific regulatory frameworks addressing the manufacturing, quality assurance, and post-market surveillance of 3D-printed drug products. While the U.S. Food and Drug Administration (FDA) has established preliminary guide- lines for 3D printing in the context of medical devices and prosthetics, similar comprehensive regulations for pharmaceutical applications remain underdeveloped. This regulatory ambiguity poses challenges to the widespread adoption of 3D printing in drug production, delaying market authorization and limiting its clinical translation. [38]

3D Printing Nanotechnology in Nanomedicine

Nanomedicine encompasses the application of nanotechnology within the biomedical field, aiming to enhance various therapeutic and diagnostic strategies. This includes the reformulation of existing pharmaceuticals for improved efficacy (drug repurposing), targeted drug delivery systems that enable site- specific release at the cellular or molecular level, and the advancement of theranostic platforms—integrated tools that

simultaneously perform diagnostics and deliver therapy, often in real time. These nanoscale interventions leverage materials such as liposomes, dendrimers, quantum dots, and metallic nanoparticles to improve bioavailability, minimize systemic toxicity, and enable precision medicine approaches. [39]

Several branches of medicine stand to gain significantly from the integration of nanomaterials, particularly in areas such as nano diagnostics, targeted nano-therapy, and regenerative pharmacology. Due to their exceptionally high surface area-to-volume ratio, nanomaterials exhibit elevated surface energy and reactivity, making them ideal candidates for a wide array of biomedical applications. Various classes of nanomedicines have been developed, including carbon nanotubes, polymeric micelles, liposomes, nanofibers, and diverse types of nanoparticles. These nano systems can be broadly categorized into organic and inorganic nanomedicines. Organic nanomedicines—most notably liposomal formulations—are widely utilized in clinical settings for the treatment of malignancies and infectious diseases. Prominent examples include Doxil (doxorubicin liposomes), Onivyde (irinotecan liposomes), DepoCyt (cytarabine liposomes), and AmBisome (amphotericin B liposomes). In contrast, inorganic nanomedicines such as NanoHSA, Nanocoll, and superparamagnetic iron oxide nanoparticles (SPIONs) primarily serve diagnostic functions, offering enhanced imaging capabilities for modalities like MRI and nuclear medicine through improved contrast and targeted visualization. Nanomedicine is a rapidly evolving inter disciplinary field that has captured the attention of researchers from



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diverse scientific areas, including nano-materials engineering, molecular biotechnology, clinical pharmacology, and biomedical sciences. Its

groundbreaking potential lies in transforming traditional medical practices through nanoscale engineering, enabling improved therapeutic precision, ultra-sensitive disease detection, and the implementation of personalized treatment strategies. This field supports the innovation of advanced technologies such as nano sensors for real-time monitoring, nanocarrier systems for controlled and site-specific drug release, and hybrid nanodevices that integrate diagnostic and therapeutic functionalities—collectively pushing the boundaries of translational medicine and reshaping the future of healthcare delivery [40].

Nano capsules are nanoscale colloidal carriers with a distinct core-shell architecture, typically exhibiting a spherical morphology. They consist of an inner aqueous or oily core—designed to encapsulate active pharmaceutical ingredients—surrounded by a biocompatible and biodegradable polymeric membrane. These vesicular systems generally range in size from approximately 10 to 1000 nanometers and are engineered to enable controlled drug release, protect labile therapeutic agents from degradation, and enhance targeted delivery through surface modification with specific ligands. Nano capsules are widely employed in drug delivery, gene therapy, and vaccine formulations due to their tunable physicochemical properties and high encapsulation efficiency. [41]

Nano capsules function as intelligent nanocarriers, enhancing pharmacokinetic

profiles by improving bioavailability, minimizing systemic toxicity, and maximizing therapeutic efficacy. Their core-shell nanostructure allows for the simultaneous encapsulation of both hydrophilic and hydrophobic therapeutic agents, enabling combination drug delivery within a single platform. Additionally, their tunable surface properties and sustained release capabilities contribute to optimized drug stability, targeted distribution, and reduced off-target effects, making them highly suitable for precision medicine applications. [42]

In 2020, Rupp and colleagues fabricated nano- and micro-filled polycaprolactone (PCL) composites utilizing two additive manufacturing techniques: fused deposition modeling (FDM) and a liquid inkjet-based printing system. The resulting composites, featuring a core-shell capsule architecture, demonstrated thermal stability up to approximately 176°F (80°C), indicating their potential suitability for applications requiring moderate thermal resistance. [43]

In 2022, a notable advancement in 3D-printed nanomedicine was demonstrated through the successful integration of drug-loaded nano capsules into customized oral delivery systems. This approach involved the nanoencapsulation of bioactive compounds—resveratrol and curcumin—within polymeric nano capsules, followed by their incorporation into a carboxymethyl cellulose (CMC)-based hydrogel matrix. The hydrogel was then processed using 3D printing technology to fabricate solid oral dosage forms. In vitro release studies indicated a sustained and complete release of both therapeutic agents over an 8-hour period, despite their entrapment within the



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nano capsular architecture. This study highlights the potential of combining nanotechnology with additive manufacturing to develop personalized, controlled-release drug delivery systems with improved bioavailability and therapeutic efficiency, particularly for compounds with limited solubility and stability. [44]

Hydrogels are three-dimensional, hydrophilic polymer networks capable of retaining large volumes of water, resulting in highly absorbent, flexible materials. These soft, tissue-like structures exhibit notable properties such as high tensile strength, biocompatibility, and intrinsic self-healing capabilities, making them ideal candidates for biomedical applications. Their tunable mechanical and physicochemical characteristics allow them to mimic the extracellular matrix, supporting cell proliferation and tissue regeneration. Recent advancements in 3D printing technologies have enabled the precise fabrication of hydrogel-based constructs, facilitating their use in applications such as tissue engineering, wound healing, and drug delivery. Below, several current studies involving 3D-printed hydrogels are discussed and critically evaluated. [45]

In 2021, researchers employed extrusion-based 3D bioprinting to develop hybrid hydrogel scaffolds using different concentrations and ratios of gelatin and alginate (3) Scanning electron microscopy (SEM) analysis further confirmed the presence of a well-organized porous network within the printed structures. Such porosity is vital for enabling the diffusion of nutrients, infiltration of cells, and removal of metabolic waste, all of which

are essential features for tissue engineering scaffolds. Additionally, the porous design allowed the scaffolds to effectively encapsulate bioactive compounds, including antioxidant molecules and probiotic microorganisms, illustrating their potential for multifunctional therapeutic applications such as targeted drug delivery and modulation of the gut microbiome.

Moreover, the ability to adjust the gelatin-to-alginate ratio allowed researchers to fine-tune the degradation rate and mechanical behavior of the scaffolds, making them suitable for a wide range of biomedical uses. These include wound healing, soft tissue repair, and site-specific gastrointestinal drug administration. Overall, the study underscores the flexibility of extrusion-based 3D bioprinting as a platform for creating advanced biomaterials with customizable properties tailored to specific therapeutic needs. [46]

CONCLUSION

This review comprehensively analyzes current literature on key three-dimensional (3D) printing technologies employed within the pharmaceutical sector, detailing the underlying operational principles, material compatibility, dosage form adaptability, and emerging technological trajectories. It further explores the commercialization landscape by highlighting pioneering enterprises and research institutions, examining their developmental milestones and notable innovations that are reshaping traditional drug development paradigms. As a disruptive manufacturing platform, 3D printing introduces a novel regulatory landscape, with unique pathways for product registration, patentability, and



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compliance under evolving pharmaceutical governance frameworks. This review aims to present a detailed overview of the technological maturity, industrial evolution, and future directions of pharmaceutical 3D printing. It is intended to serve as a valuable reference for researchers, formulators, and policymakers. With ongoing advancements, 3D printing is anticipated to play a transformative role in enabling intelligent, data-driven, and personalized drug formulation strategies.

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