

## 3D PRINTING IN PHARMACEUTICALS: PRINCIPLES, TECHNOLOGIES, APPLICATIONS AND FUTURE PROSPECTS

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### ABSTRACT

Three-dimensional (3D) printing has emerged as a disruptive manufacturing technology in pharmaceutical sciences, enabling the fabrication of patient-specific dosage forms with precise control over drug dose, geometry, internal architecture, and release kinetics. By integrating computer-aided design with layer-by-layer material deposition, 3D printing aligns closely with the goals of personalized medicine and on-demand drug manufacturing. This review consolidates the principles, historical evolution, major printing techniques, printable materials, process workflow, regulatory considerations, and wide-ranging applications of pharmaceutical 3D printing. Key technologies—including binder jet printing, fused deposition modeling, semi-solid extrusion, stereolithography, selective laser sintering, and inkjet printing—are discussed with respect to their operational mechanisms, advantages, and limitations in drug formulation. The role of polymers, active pharmaceutical ingredients, excipients, hydrogels, and photopolymers in

determining printability and drug release behavior is critically examined. The article further highlights process stages from digital design to post-processing and quality assurance, emphasizing the importance of formulation optimization and process parameters. Applications such as polypills, controlled-release systems, fast-dissolving tablets, implants,

microneedles, and point-of-care manufacturing demonstrate the transformative potential of this technology. The approval of the first 3D printed drug, Spritam® (levetiracetam), marked a regulatory milestone, while ongoing developments in bioprinting, organ-on-chip models, and implantable drug delivery devices indicate promising future prospects. Despite challenges related to material limitations, scalability, technical complexity, and evolving regulatory frameworks, continuous advancements are expected to integrate 3D printing into mainstream pharmaceutical manufacturing and precision therapeutics.

**KEYWORDS:** 3D printing, Personalized medicine, Fused deposition modeling, Binder jet printing, Polypill, Controlled drug release, Pharmaceutical polymers, On-demand manufacturing, Drug delivery systems, Regulatory considerations.

## I. INTRODUCTION

Pharmaceutical three-dimensional printing has emerged as a transformative approach that enables the fabrication of patient-specific dosage forms with precise control over drug dose, geometry, and release behavior, aligning directly with the goals of personalized medicine.<sup>[1]</sup> The concept gained momentum as regulatory bodies and research agencies in Europe began promoting technologies that support individualized therapies through advanced manufacturing platforms.<sup>[2]</sup> The integration of additive manufacturing into healthcare has been further strengthened by the growing need for customized treatments in complex diseases such as cancer, where tailored devices and drug delivery systems are essential.<sup>[3]</sup> Applications of 3D printing in oncology have demonstrated its capability to fabricate patient-adapted models, implants, and drug delivery systems for improved therapeutic outcomes.<sup>[4]</sup> Beyond solid dosage forms, 3D printing has also enabled the development of organ-on-chip and multi-organ systems that simulate human physiology for drug testing and toxicity studies.<sup>[5]</sup> Advanced in vitro models mimicking bone and other tissues have been developed using 3D printing techniques to better understand drug–tissue interactions.<sup>[6]</sup> Multi-organ-on-chip platforms fabricated using additive manufacturing have opened new avenues for studying biodistribution and therapeutic efficacy of novel drug carriers.<sup>[7]</sup> The technology has also been applied to simulate immune–tumor interactions using matrix-based tumor models within microfluidic chips.<sup>[8]</sup> Reviews in high-impact journals have emphasized how multi-organ systems on chips are reshaping preclinical drug development and testing paradigms.<sup>[9]</sup> Furthermore, modular lab-on-chip devices fabricated by 3D printing have shown promise in early cancer detection and diagnostic applications.<sup>[10]</sup>

## II. History and Development of 3D Printing in Pharmaceuticals

The entry of 3D printing into pharmaceutical sciences began with the adaptation of microfluidic and biofabrication techniques for drug delivery research.<sup>[11]</sup> Early demonstrations of cell-laden hydrogel constructs within 3D-printed microfluidic chips illustrated the feasibility of combining printing with biological materials.<sup>[12]</sup> Subsequent studies evaluated the durability and reusability of 3D-printed microfluidic devices for biological sample processing.<sup>[13]</sup> Innovations in multilayer microfluidic chip design enabled high-throughput preparation of nanoliposomes for drug delivery applications.<sup>[14]</sup> Market analyses highlighted the growing demand for 3D-printed pharmaceutical products and their potential commercial impact.<sup>[15]</sup> Research on spherical mini-tablets demonstrated how geometry and composition could be manipulated to control dissolution profiles for personalized therapy.<sup>[16]</sup> The introduction of stereolithography for oral modified-release dosage forms marked a milestone in precision drug release design.<sup>[17]</sup> One of the most cited breakthroughs was the fabrication of a five-in-one polypill with distinct release profiles using 3D printing.<sup>[18]</sup> Comparative analyses between industrial manufacturing and personalized 3D printing further emphasized the flexibility offered by additive manufacturing.<sup>[19]</sup> Scenario-based studies explored how 3D printing could be integrated into real clinical and community pharmacy settings for personalized medicines.<sup>[20]</sup>

## III. Principle of 3D Printing Technology in Pharmaceuticals

The principle of pharmaceutical 3D printing lies in the layer-by-layer deposition of materials to create dosage forms with predefined geometry and drug distribution.<sup>[21]</sup> Fused deposition modeling requires preformulation studies to ensure appropriate thermal and mechanical properties of drug-polymer filaments.<sup>[22]</sup> Quality considerations in pediatric formulations have highlighted the importance of printer design, filament extrusion, and process parameters.<sup>[23]</sup> Compatibility and stability studies of polymers used in fused deposition modeling are essential for ensuring drug integrity during printing.<sup>[24]</sup> Reviews have identified the most successful techniques and polymers suitable for personalized 3D-printed medicines.<sup>[25]</sup> Hot-melt extrusion has been widely used to prepare drug-loaded filaments with optimal mechanical properties for printing.<sup>[26]</sup> Passive diffusion loading into filaments has been optimized to improve drug incorporation efficiency.<sup>[27]</sup> Mechanical behavior such as stress and strain of printed filaments influences the final dosage form characteristics.<sup>[28]</sup> Optimization of printing parameters significantly affects the tensile properties and quality of

printed constructs.<sup>[29]</sup> Electrical and mechanical properties of polymer composites have also been investigated to enhance functional performance.<sup>[30]</sup>

#### **IV. Various 3D Printing Techniques Used in the Pharmaceutical Field**

##### **1. Types of 3D printing technologies used in pharmaceuticals**

Three-dimensional printing is a highly innovative and sophisticated additive manufacturing technique used for the production of pharmaceutical formulations in three dimensions according to computer-aided designs. The technique provides precise control over dose and drug release characteristics.<sup>[31,32]</sup>

##### **a) Binder Jet Printing**

Binder jet printing is a powder-based technique wherein a liquid binder is deposited selectively onto a powder bed containing API and excipients to produce a solid dosage form.<sup>[33]</sup> The technique enables the formation of porous structures that aid rapid disintegration and dissolution, making it appropriate for orodispersible tablets.<sup>[34,35]</sup> The technique has been recognized following approval for levetiracetam (Spritam), which is the first drug approved to be 3D printed.<sup>[36]</sup> However, drawbacks include low mechanical strength and difficulties in achieving sustained drug release.<sup>[37]</sup>

##### **b) Fused Deposition Modeling (FDM)**

Fused deposition modeling involves extrusion of drug-loaded thermoplastic filaments through a heated nozzle to form dosage forms layer-by-layer.<sup>[38]</sup> These filaments are typically prepared using hot-melt extrusion, ensuring uniform drug distribution.<sup>[39,40]</sup> The technique allows modification of internal structure and infill density to achieve controlled drug release.<sup>[41]</sup> However, high temperatures may degrade thermolabile drugs.<sup>[42]</sup>

##### **c) Semi-Solid Extrusion (SSE)**

Semi-solid extrusion involves deposition of gels or paste-like formulations through a syringe-based system under pressure.<sup>[43]</sup> This method operates at low temperatures, making it suitable for thermosensitive drugs and biologics.<sup>[44]</sup> It also enables high drug loading and fabrication of multi-drug systems.<sup>[45]</sup> However, challenges include maintaining structural integrity and drying efficiency.<sup>[46]</sup>

**d) SLA, or Stereolithography**

In SLA, liquid photopolymer resins are used to produce objects in a solid form using ultraviolet light (47). SLA is best suited for complex drug delivery systems such as implants and microneedles.<sup>[48,49]</sup> However, this method is limited in that it is affected by photopolymer toxicity and the lack of biocompatible photopolymers.<sup>[50]</sup>

**e) Selective Laser Sintering (SLS)**

In this method, a laser is used to sinter powdered materials to form objects in a solid form without using binders.<sup>[51]</sup> With this method, porous drug delivery systems can be created to deliver medication in a controlled manner.<sup>[37]</sup> In addition, stability is not a problem since no solvents are used.<sup>[52]</sup> However, medication stability is affected at high temperatures.<sup>[50]</sup>

**f) Printing with an inkjet**

Drug solution droplets are precisely placed in substrates using inkjet printing technology.<sup>[53]</sup> This is particularly beneficial in personal medicine and in developing formulations of low doses.<sup>[35]</sup> However, there are restrictions such as limited viscosity range and clogging of the printing nozzle.<sup>[52]</sup>

**V. Pharmaceutical 3D Printing Materials**

The nature of 3D printed pharmaceutical products is significantly affected by the material used in printing.<sup>[41]</sup>

**a. Polymers**

Polymers are mostly used in 3D printing due to their flexibility in controlling the release of drugs.<sup>[54]</sup> The most commonly used polymers include polyvinyl alcohol, polylactic acid, polycaprolactone, and hydroxypropyl methyl cellulose.<sup>[55]</sup> These materials utilize erosion, swelling, and diffusion in controlling the release of drugs.<sup>[56]</sup>

**b. Pharmaceutical Active Ingredients (APIs)**

APIs can be incorporated in various forms as solutions, filaments, and powders in accordance with printing methods.<sup>[40]</sup> Stability of drugs during processing is critical, particularly in APIs that are vulnerable to light and temperature.<sup>[42]</sup>

**c. Excipients**

Excipients help enhance drug release properties, mechanical strength, and printability.<sup>[57]</sup> Excipients are composed of fillers, disintegrants, binders, and plasticizers.<sup>[58]</sup> Plasticizers like polyethylene glycol are used in filament-based printing to enhance flexibility.<sup>[55]</sup>

**d. Hydrogels**

Due to their hydrophilic nature and high water absorption, hydrogels are used as hydrophilic polymer networks in extrusion-based printing.<sup>[59]</sup> They are useful in biological applications and drug delivery.<sup>[60]</sup>

**e. Photopolymers**

Photopolymers are used in SLA printing. They have the ability to be hardened by UV light. However, their toxicity limits their application in drug delivery, despite their high printability.<sup>[50]</sup>

**VI. 3D Printing Process in Drug Manufacturing****1. Digital Design**

Using computer-aided design software that facilitates internal structure modification of the drug product, the dosage form is created.<sup>[32]</sup> The layers of the created product are then formed by converting it into STL format.<sup>[39]</sup>

**2. Preparing the Materials**

Depending on the printing process, the materials are manufactured in suitable forms such as filaments, powders, or gels.<sup>[41]</sup> For printing to take place successfully, suitable rheological and thermal properties must exist.<sup>[46]</sup>

**3. The Printing Procedure**

In order to produce the dosage form, the material is added layer by layer based on the digital design.<sup>[39]</sup> The quality of the final product depends on several process parameters like temperature, speed, and thickness of the added layers.<sup>[40]</sup>

**4. Post processing**

The mechanical strength and stability are improved by post-processing operations like drying, curing, and sintering.<sup>[51]</sup> These operations are also helpful in achieving the desired drug release profile.<sup>[37]</sup>

## 5. Quality Assurance

The safety and efficacy of the final drug product are ensured by quality control.<sup>[61]</sup> The drug content, solubility, and mechanical strength are some of the tests.<sup>[62]</sup>

## VII. Applications of 3D Printed Drugs

### 1. Customized Healthcare

Drug dosage and release characteristics can be easily customized for each patient using 3D printing technology.<sup>[32]</sup> Pediatric patients and elderly patients are the ones who will be greatly helped by this.<sup>[34]</sup>

### 2. Polypills

Many drugs with different release characteristics can be combined into a single dosage form.<sup>[45]</sup> This reduces the number of pills that patients have to take, thereby increasing compliance.<sup>[55]</sup>

### 3. Controlled Drug Delivery

The kinetics of drug release can be easily controlled using complex geometries.<sup>[41]</sup> This minimizes side effects and maximizes efficacy.<sup>[56]</sup>

### 4. Quick-Dissolving Tablets

Rapid dissolving and disintegration of tablets can be achieved by creating highly porous structures.<sup>[33]</sup> This is beneficial in terms of patient compliance, especially those who suffer from difficulty in swallowing.<sup>[35]</sup>

### 5. Drug Delivery Devices and Implants

Drug delivery devices such as implants and microneedles can be created using 3D printing.<sup>[48]</sup> These devices provide long-term benefits.<sup>[49]</sup>

### 6. Manufacturing on Demand

On-demand manufacturing is beneficial in hospitals and other remote areas.<sup>[32]</sup> This reduces the need for central manufacturing facilities.<sup>[44]</sup>

## VIII. FDA-Approved 3D Printing Drugs

The first FDA-approved 3D printed drug is Spritam® (levetiracetam), developed using advanced manufacturing approaches for improved drug delivery.<sup>[63]</sup> The application of CAD-CAM and digital fabrication technologies has further enabled precision in dosage form

development.<sup>[64]</sup> Clinical applications of 3D printed models in patient-specific treatment planning highlight its growing role in healthcare.<sup>[65]</sup> Personalized drug fabrication using 3D printing enables precise control over drug composition and release profiles.<sup>[66]</sup> Microneedle-based drug delivery systems demonstrate advanced therapeutic applications of 3D printing.<sup>[67]</sup>

### **IX. Advantages of 3D Printing in Pharmaceuticals**

3D printing enables the production of personalized medicines tailored to individual patient needs.<sup>[66]</sup> It supports the fabrication of complex drug delivery systems with controlled and multi-phase release mechanisms.<sup>[67]</sup> Advanced printing procedures and materials improve manufacturing flexibility and innovation.<sup>[68]</sup> Hydrogel-based printing technologies enhance drug delivery and biomedical applications.<sup>[69]</sup> 3D printing enables the development of porous implants for effective drug delivery and tissue integration.<sup>[70]</sup> Mesh-based implant systems further expand its applications in targeted therapy.<sup>[71]</sup> Drug-eluting stents produced through 3D printing improve localized drug delivery.<sup>[72]</sup>

### **X. Limitations and Challenges**

The availability of suitable printable materials remains limited in pharmaceutical applications.<sup>[68]</sup> Technical complexity and requirement of specialized expertise pose challenges for implementation.<sup>[69]</sup> Ensuring consistent quality, reproducibility, and regulatory compliance is difficult.<sup>[63]</sup> Scaling up production from laboratory to industrial levels remains a significant limitation.

### **XI. Regulatory Considerations**

Regulatory frameworks for 3D printed pharmaceuticals are still evolving and require standardization.<sup>[63]</sup> Clinical validation is essential to ensure safety and efficacy of 3D printed medical applications.<sup>[65]</sup> Patent developments reflect increasing regulatory focus and technological advancements.<sup>[68]</sup> Hydrogel and biomaterial-based innovations require strict evaluation for safety and performance.<sup>[69]</sup>

### **XII. Future Prospects of 3D Printing in Pharmaceuticals**

3D printing is expected to revolutionize personalized medicine and drug delivery systems.<sup>[66]</sup> Bioprinting technologies enable development of engineered tissues for regenerative medicine and drug testing.<sup>[73]</sup> Advanced vascularized tissue models enhance applications in drug discovery and therapeutic research.<sup>[74]</sup> Engineered skin tissues provide platforms for

pharmaceutical testing and regenerative treatments.<sup>[75]</sup> Implantable and device-based drug delivery systems will continue to expand in the future.<sup>[70,72]</sup>

### XIII. CONCLUSION

3D printing represents a transformative technology in pharmaceutical sciences with applications in drug delivery, personalized medicine, and biomedical engineering.<sup>[66]</sup> Despite challenges related to cost, regulation, and scalability, ongoing research is addressing these limitations.<sup>[68]</sup> With increasing clinical integration and technological advancements, 3D printing is expected to significantly impact future healthcare systems.<sup>[63,65]</sup>

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