



Emerging Applications of Three-Dimensional Printing in Personalized Medicine: A Review

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Abstract

The increasing importance of personalized medicine and personalized dosage has led to the diffusion of Three-Dimensional (3D) printing to the pharmaceutical domain, where different 3D printing methods have been applied to formulate various pharmaceutical forms and devices used in Drug Delivery Systems (DDS). 3D printing technology encompasses a wide range of manufacturing techniques, all based on the digitally controlled deposition of materials to produce complex free-form geometries. This review presents up-to-date information on current advances in 3D printing technology in DDS, technological gaps, and regulatory considerations. It also includes the examination of different characterization studies, analysis of the different geometric forms of the obtained pharmaceutical products and the relationship between structure, properties, performance and process. Drug development is continuously advancing through innovations in the design of novel drug delivery systems aimed at improving therapeutic efficacy. 3D printing technology has emerged as a promising approach for the fabrication of customized and personalized medicines, enabling maximum therapeutic benefit and driving a paradigm shift in the healthcare industry.

Keywords: 3D Printing, Personalized Medicine, Drug Delivery Systems, Oral Tablets, Fused Deposition Modeling, Pharmaceutical Polymers

Introduction

The Food and Drug Administration (FDA) approved the first 3D printing product in 2015, creating significant momentum among biopharmaceutical manufacturers to adopt 3D printing as a next-generation tool for developing pharmaceutical products and biomedical devices. Because of such rapid progress, the FDA issued Technical Considerations for Layered Manufacturing of Medical Devices in December 2017, providing 'potential regulatory insights, current agency thinking, and essential Chemistry, Manufacturing, and Control (CMC) requirements for approval of 3D printed pharmaceutical products and medical devices [1]. Conventional

pharmaceutical production is generally based on large-scale manufacturing and standard dose strengths. Although this approach is efficient for routine drug production, it does not always meet the needs of patients who require individualized doses, combined therapies, or specific release profiles. The increasing interest in the use of different 3D printing techniques can clearly be seen in a wide range of 3D printed products, from rapidly disintegrating tablets to extended-release tablets and from nano-suspensions to polypills. Along with continuous innovations in technologies for designing dosage forms with advanced therapeutic capabilities, there has been a paradigm shift towards the design of personalized

DDS with the advent of additive manufacturing in the last few years [2,3]. The first 3D printed tablet Spritam (levetiracetam); manufactured by Aprelia Pharmaceuticals, and a single 1000 mg dose of large doses of FDA-approved in 2015 in the form of combining, to simplify compliance helps improve the treatment of epileptic patients [4]. This event encouraged wider interest in applying 3D printing to pharmaceutical products and biomedical devices [5,6]. These developments show that 3D printing is not only a laboratory technique but also a technology with real regulatory and industrial relevance [1,7]. Drug delivery has evolved from simple immediate-release forms toward targeted and controlled-release systems [8,9], in this context, 3D printing is a valuable technique because it can produce dosage forms that are difficult to obtain using traditional compression, coating, granulation, or capsule-filling processes [10,11]. By combining computer-aided design with layer-by-layer manufacturing, the technology provides a foundation for personalized drug delivery systems that are more adaptable to patient needs [12,13].

Drug delivery refers to the approaches, systems, technologies,

and formulations used to transport pharmaceutical compounds within the body in a controlled manner to achieve the desired therapeutic effect safely and effectively. Over the years, drug delivery concepts have evolved significantly, progressing from immediate-release oral dosage forms to sophisticated targeted-release DDS. The need to control drug release profiles has become a critical factor in improving therapeutic efficacy, enhancing patient safety, and increasing patient compliance. Consequently, traditional manufacturing methods used for immediate-release systems, such as direct tableting and capsule filling, have gradually evolved into advanced controlled-release manufacturing technologies incorporating granulation, extrusion, coating, and other multistep processes.

In this review we collected and analyzed literature devoted to 3D printing approaches used in DDS production and applications. Figure 1 illustrates common 3D printing applications in personalized medicine and pharmaceutical drug delivery systems (Figure 1).

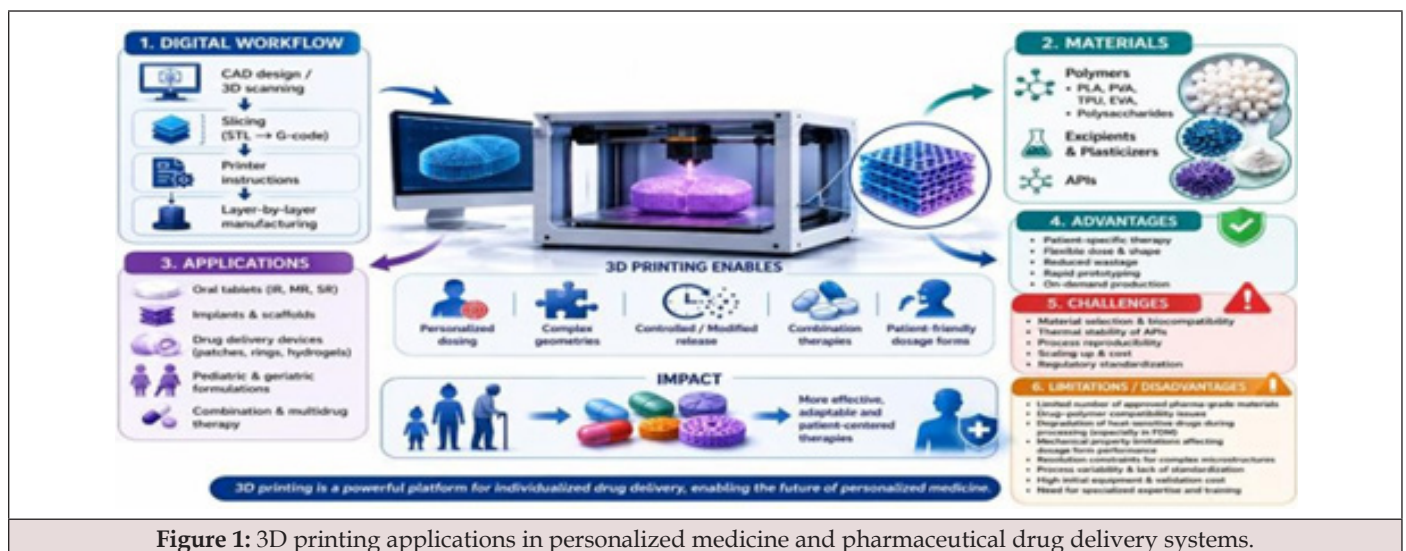


Figure 1: 3D printing applications in personalized medicine and pharmaceutical drug delivery systems.

Engineering Behind 3D Printing and Materials Used

In the early stages of additive manufacturing during the 1970s and 1980s, fabrication was primarily carried out using basic techniques such as casting, molding, forming, joining, and co-machining to produce Two-Dimensional (2D) objects [14]. Since then, researchers have developed a wide range of advanced Three-Dimensional (3D) printing methods. The integration of specialized computer software with flexible visual customization capabilities has revolutionized 3D printing. Over the past few decades, numerous techniques have been developed for designing and customizing 3D geometries, converting digital images into

mathematical models, and translating these models into objects of desired size and shape through equipment control systems [15]. 3D printing fundamentally relies on a layer-by-layer manufacturing process, which mimics natural layered production approaches. This technology operates through advanced computer simulations and is commonly associated with the "three Ds": Design, Development, and Distribution, which together facilitate successful personalized drug therapy [8,16]. These stages involve the preparation of digital models using computer simulations or Computer-Aided Design (CAD) software. The software generates output files that are interpreted by the printer to fabricate 3D objects or therapeutic products, which can then be delivered directly to the end users or patients.

Although a wide variety of materials are used in 3D printing, they are generally classified into metals, ceramics, and polymers. Among metallic materials, stainless steel is one of the most commonly used, while gold, silver, and titanium are also frequently employed. Titanium, in particular, has gained significant importance in biomedical applications due to its favourable biocompatibility and mechanical properties [16,17]. Polymers play a crucial role in the fabrication of components, especially in Fused Deposition Modelling (FDM) technology. Commonly used polymers include nylon, Polylactic Acid (PLA), Polystyrene (PS), Acrylonitrile Butadiene Styrene (ABS), Polyethylene Terephthalate Glycol-Modified (PETG), Thermoplastic Polyurethane/Thermoplastic Elastomer (TPU/TPE), Polypropylene (PP), Polyether Ether Ketone (PEEK), Polyether Ketone Ketone (PEKK), and Polyetherimide (PEI) [18]. In biomedical applications, 3D printing technology enables the rapid production of customized tissue-engineering scaffolds, supports the precise placement of cells within tissue constructs, and even allows the direct printing of tissues and organs. Currently, 3D printing is becoming an increasingly important tool in pharmaceutical and clinical applications by enabling rapid drug production and personalized clinical solutions. Patient-specific 3D-printed anatomical structures are gradually emerging as supportive platforms for drug DDS and personalized drug dosing [16].

Advanced 3D Printing Techniques

3D printing techniques can be categorized into photopolymerization, extrusion-based systems, powder-based systems, and lamination. These categories are not interchangeable; each method has a different working principle, material requirement, resolution, cost, and pharmaceutical suitability [19].

Photopolymerization

Photopolymerization, including Stereolithography (SLA) and Digital Light Processing (DLP), uses ultraviolet light, high-energy light, or laser radiation to harden photo-reactive polymers. A computer-controlled light source selectively cures the liquid resin layer-by-layer, producing a solid object [20]. This method provides high surface quality, good resolution, and relatively fast production [14].

In pharmaceutical applications, photopolymerization has been used to produce drug-containing microneedles, hydrogels, micro-reservoirs, salicylic acid anti-acne patches, and modified-release systems containing drug combinations [20]. DLP differs from SLA mainly in the light source and curing approach; because it can cure an entire projected layer at once, it can be faster [14]. However, there are important limitations. The number of pharmaceutically acceptable photopolymerizable materials is limited, and some resins may create toxicological concerns. Exposure time, wavelength, and light power must therefore be carefully controlled [14].

Extrusion

Extrusion-based printing is presented as one of the most

important approaches for pharmaceutical 3D printing. Fused Deposition Modelling (FDM) produces solid dosage forms by heating a polymer filament and depositing it layer-by-layer through a nozzle. This technique is widely used because it is relatively inexpensive, simple, solvent-free, and suitable for producing customized geometries [21]. It can be applied to implants, release tablets, multilayer tablets, floating systems, and rapidly dissolving dosage forms [22]. Unlike FDM, Pressure-Assisted Micro syringe (PAM) printing does not require melting of the material. Instead, a viscous semi-liquid material is released from a syringe under controlled pressure, followed by drying or solidification. This makes PAM useful for materials that cannot tolerate high temperatures [12]. The weakness of extrusion systems is that mechanical strength, surface quality, layer adhesion, and thermal stability must be optimized carefully [12,13].

Powder-Based Systems

Powder-based systems include inkjet printing, binder deposition, selective laser melting, selective laser sintering, and electron beam melting. In these approaches, powders are fused or bound together to form a 3D structure. Binder deposition is especially relevant to pharmaceuticals because a liquid binder or drug-containing solution can be sprayed onto powder layers to form tablets. This mechanism resembles wet granulation and can be used to produce porous dosage forms [4]. Selective Laser Sintering (SLS) uses laser energy to fuse powder particles without a separate binder. The surrounding powder supports the structure during printing, which allows the fabrication of complex geometries. The particle size and shape, powder spreading, and laser parameters are critical because they influence resolution, porosity, mechanical strength, and printability. Powder-based methods can produce porous and rapidly disintegrating systems, but high temperature and material compatibility remain limitations for some biopolymers and active pharmaceutical ingredients [4,23].

Lamination

Lamination is described as a process in which thin layers of paper, plastic, or metal are joined and cut into the desired shape. Laminated object manufacturing and ultrasound additive manufacturing are examples of this group; it is a relatively low-cost and material-efficient method. It is also notable that excess material can be recycled. Although lamination is not as dominant in pharmaceutical studies as FDM, SLA, DLP, or SLS, it remains part of the broader additive manufacturing field [23].

Applications of 3D Printing Technologies in Pharmaceutical Drug Delivery

Solid Free-Form Fabrication (SFF) methods are processes that allow ceramic bodies to be formed directly from Computer-Aided Design (CAD) files, without the use of any forming tools such as molds or die [24]. 3D printing offers ease of use, affordable cost and fast production compared to other SFF techniques [13]. In the field of health, 3D printing is used in medical devices, implants, and

pharmaceutical dosage applications [25]. Additive manufacturing allows the preparation of dosage forms with complex structures, adjustable drug loading, and controlled release profiles [2,12,13]. The example of Spritam demonstrates the feasibility of a high-dose, rapidly disintegrating tablet produced using 3D printing. This is important because large drug doses are normally difficult to formulate as tablets that disintegrate quickly and remain acceptable for patients [7]. It is also emphasized that printed geometry can influence drug release. Further, with the development of 3D printers, the production of pharmaceutical products was paved the way. Tablets with different shapes, including cube, pyramid, cylinder, sphere, and torus designs, show different dissolution profiles depending on surface area and surface area-to-volume ratio [26,27]. Therefore, geometry is not only an aesthetic feature but also a formulation variable. By changing shape, porosity, infill, and internal compartments, drug release can be modified without changing the drug itself [26,28]. Mostly production is based on low-cost, consumer-friendly FDM systems using poly (lactic acid) [29], poly (vinyl alcohol) [30] and ethylene vinyl acetate, polysaccharides, and polyurethanes as base polymers [31]. Currently commercially available filaments are not suitable for use for pharmaceutical applications. Apart from that, most conventional polymer excipients used in pharmaceuticals do not have the appropriate thermal and mechanical properties that can be used to make them into filaments required for FDM 3D printing. At this point, Hot Melt Extrusion (HME) comes into play. HME is the transformation of raw materials into a product of homogeneous shape and density with a screw rotating through a mold at high temperature and pressure [22]. As an example of a pharmaceutical study using HME, 'Preparation and research of a new controlled-release glipizide oral device by three-dimensional printing' carried out by Li, et al., (2017) can be given [32].

3D Printed Oral Drug Forms

Oral dosage forms are one of the most advanced areas of pharmaceutical 3D printing due to their usability and suitability for personalized dose adjustment. Tablets with specific strength, shape, and release characteristics can be produced with 3D printing according to patient needs [12]. This is particularly useful when fixed-dose commercial products do not provide a suitable dose [3,12]. There are various examples to be discussed. Prednisolone-loaded PVA filaments have been used to print tablets with different doses and a strong dose-response correlation [33]. Haloperidol tablets have been prepared using polymer screening to identify suitable systems for rapid release. Metformin and glimepiride have been combined in a bilayer tablet to provide different release profiles in a single dosage form [34,35]. Isoniazid, enalapril maleate, hydrochlorothiazide, metronidazole, progesterone, rifampicin, and other drugs have also been presented with different formulation strategies [28,36,37,38,39]. The main goal of 3D printing technology in this field is to create personalized drug forms in order to make dose adjustment. In other words, it allows a personalized medicine

approach in place of therapeutic treatment for each individual using a single type of drug, as well as oral medication delivery devices.

As a first precedent, Spritam (levetiracetam), the first 3D printed tablet manufactured by the aforementioned Aprelia Pharmaceuticals and approved by the FDA in 2015, was produced with the patented Zip Dose ® technology based on the BJ technique. Zip Dose ® Technology is the first drug formulation platform to integrate 3D Printing (3DP) into the pharmaceutical industry [7].

3D Printed Drug Delivery Devices

Pharmaceutical developments progress through the stages of drug discovery, drug development and drug delivery. Drug delivery covers from oral dosages to drug-releasing micro implants. It provides solutions for controlled release, minimally invasive delivery, high precision targeting, biomimetic models and personalized medicine with targeted micro-scale devices in DDS. If this can be achieved in drug applications requiring high targeting, toxicity is reduced and a higher dose is provided to a certain area. In this section, we mention other non-oral DDS obtained by using 3D printing. Microneedles are highlighted as minimally invasive alternatives to hypodermic needles. They can improve patient compliance, reduce pain and tissue damage, and support transdermal drug delivery [40]. Microneedles reduce pain and tissue damage, reduce the need for qualified personnel for application, and most importantly, prevent microbial entry [41]. 3D printing can eliminate the limitations in microneedle production. The uniformity of the geometric properties of microneedles such as heights, widths, aspect ratios and tip thicknesses increases their efficiency. SLA, DLP, MPP methods and photopolymer spraying are of great interest for the production of microneedles due to the higher resolution they offer and the wide choice of materials [41]. SLA 3D printing was used in the production of cross-shaped polymeric microneedles with a height of 1,000 µm. Then, coating of chemotherapy drug (cisplatin) formulations on needles was applied by inkjet printing for the treatment of skin cancer [42]. Personalized mouthguards, which can be 3D printed based on the case of tooth structure obtained from personalized intraoral scans, can deliver a compound pre-loaded into the oral cavity. Such devices show how 3D printing can connect patient-specific anatomy with localized therapy [43]. Specific targeting is very important for hard-to-reach and limited sections in drug delivery applications, and this is difficult with traditional methods. Micro-swimming devices come to the fore at this point. These miniature mobile systems are designed to load, transport, and release therapeutic agents at specific sites [44]. Magnetic, thermal, chemical, electrostatic, or mechanical stimuli can be used to guide and/or activate them. Although still developmental, micro swimmers show the potential of 3D printing for highly targeted therapy [44,45].

Micro implants and scaffolds are another important group. Implants have been used in medicine for many years. Additive manufacturing is used in this field. Design is very important for

pharmaceutical implants as well as for other types of implants. Implantable systems are available for long-term release and tissue-related applications, including bone repair scaffolds and growth factor delivery. Additive manufacturing can control pore size, porosity, architecture, and drug loading, which is valuable for regenerative medicine and localized therapy [6,41,46]. The benefits of 3D printing technology include high flexibility to customize different geometric shapes and sizes, low production cost, and negligible unit-to-unit variability, among others. Therefore, 3D printing is valuable for the design and manufacture of various DDS for therapeutic applications and for the development of artificial tissues and organs for biomedical applications. Thanks to the versatile applications of 3D printing, there has been a significant increase in interest in the use of this technology for industrial production, along with research innovations to design more flexible and robust methods for 3D printing applications [47,48,49].

Challenges, Advantages and Disadvantages of 3D Printing Technology in Pharmaceutical Applications

It is important to emphasize that 3D printing has become an important approach in pharmaceutical applications, mainly because it enables the production of patient-centred dosage forms [3,10,47,50]. The most notable benefit of this technology is personalisation. In contrast to traditional manufacturing approaches, the dose, shape, size, internal structure and release characteristics of a dosage form can be tailored to the specific needs of a patient by using 3D printing [3,26,50]. This is especially useful for the formulation of multidrug products, porous dosage forms, compartmentalized dosage forms and customized release profiles [26,51-53].

Clinically, patients may find it easier to take the medicine, have less pill burden, swallow the medicine more easily, and/or have treatment regimens tailored to their age, weight, disease state and therapeutic needs [10,47,50,51].

An additional benefit of 3D printing is that it can be used for rapid prototyping and small-batch manufacturing [1,3,47]. The dosage form is derived from a digital design, so it can be customized and produced within a relatively short period of time without the need for expensive molds or large-scale tooling changes [1,3,47]. The technology is appealing to the pharmaceutical industry, hospital pharmacies and point-of-care manufacturing, where custom or low-volume manufacturing might be needed [10,47,50,54]. Besides, 3D printing can also contribute to material saving and offer greater flexibility in production than conventional manufacturing methods [1,3,47].

However, there are still some drawbacks that limit the potential of 3D printing in the pharmaceutical industry. A major challenge is the limited availability of printable pharmaceutical materials [50,55]. Many commonly used excipients lack adequate thermal, mechanical and rheological characteristics for printing, particularly

in extrusion-based systems [55,56]. Thermosensitive drugs or excipients can also degrade under exposure to high processing temperatures during heat-based processes such as HME and/or FDM [55,56]. Although high resolution and good surface quality can be obtained using photopolymerization-based processes, the potential toxicity of resins, photo initiators or unreacted monomers is an important factor in terms of pharmaceutical acceptability [57,58].

Furthermore, powder flowability, particle size distribution, binder properties, layer formation and post-treatment must be carefully controlled in powder-based systems to ensure uniform and mechanically stable products [52,59]. Quality control is another critical issue. In pharmaceutical products, dose accuracy, content uniformity, mechanical strength, dissolution behaviour, stability, reproducibility and sterility, if required, must be consistently proven [1,54,60]. The quality characteristics of 3D-printed products are significantly affected by printing parameters, including printing speed, layer thickness, infill pattern, nozzle temperature, humidity, material properties and equipment performance [1,55,56]. Thus, understanding the relationship between material, process, structure and product performance is essential before 3D-printed medicines become common in clinical practice [1,54,60].

Regulatory needs also pose a major challenge [1,54,60]. Unlike traditional mass production, patient-specific production is more complex because each product may be unique in dose, geometry, size and/or release profile [3,26,50]. Therefore, digital design control, printer qualification, process validation, traceability and real-time quality monitoring are crucial for safe and reproducible manufacturing [1,54,60].

Conclusions

In conclusion, 3D printing is a computer-aided, layer-by-layer manufacturing technology with strong potential for customized drug delivery systems [2,13,15]. Its ability to create simple or complex dosage forms, including oral controlled-release systems, implants, microchips, multiphase release systems, and patient-specific devices, makes it highly relevant to the future of pharmaceutical sciences [5,6,7]. The approval of the first 3D printed drug product accelerated research into new dosage forms and demonstrated that additive manufacturing can reach pharmaceutical use [6,10]. Each printing technique has its own strengths and weaknesses, so the choice of method must depend on the drug, material, dose, release requirement, and intended clinical application [3,5,8,13]. Overall, 3D printing offers formulation flexibility that is difficult to achieve using traditional manufacturing methods [2,8,12]. With further progress in printable materials, characterization studies, process control, and regulatory frameworks, the technology may support the preparation of personalized medicines in pharmacies, clinics, hospitals, or other point-of-care settings [1,17]. The future value of 3D printing in pharmaceuticals therefore lies not only in producing unusual shapes, but in connecting digital design with individualized

therapy [17].

Conflict of Interest

None.

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