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PERSONALIZED DRUG DELIVERY VIA 3D PRINTING: RECENT INNOVATIONS IN FORMULATION DESIGN, RELEASE KINETICS AND CLINICAL TRANSLATION

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ABSTRACT

Personalized medicine aims to tailor therapy to individual patient needs, and three-dimensional (3D) printing has emerged as a promising platform for customized drug delivery systems. This technology enables precise control over dose, geometry, drug combinations, and release profiles, overcoming limitations of conventional formulations. Recent innovations in formulation design include the development of printable polymers, hydrogels, and nanocomposites that enhance drug stability and printability. Advanced techniques such as fused deposition modelling (FDM), stereolithography (SLA), and selective laser sintering (SLS) allow fabrication of complex dosage forms with tuneable release kinetics.3D printing also facilitates the design of immediate, sustained, and multi-phasic drug release through structural modifications and material selection, supporting precision therapeutics. Integration with computational tools and patient-specific data further strengthens its role in individualized treatment. However, challenges such as regulatory approval, scalability, material safety, and limited clinical validation hinder widespread implementation. This review summarizes recent advances in formulation design, controlled drug release, and progress toward clinical translation of 3D-printed drug delivery systems, highlighting their potential in advancing patient-centric healthcare.

Keywords: 3D Printing, Drug Delivery Systems, Personalized Medicine, Additive Manufacturing, Controlled Release, Formulation Design, Release Kinetics

1. INTRODUCTION

1.1 Drug Delivery System and Personalized Medicine

Personalized medicine represents a paradigm shift in healthcare, focusing on tailoring drug therapy to individual patient characteristics such as age, genetics, disease state, and therapeutic response. However, conventional pharmaceutical manufacturing largely relies on standardized dosage forms, which often fail to address patient-specific needs. In this context, three-dimensional (3D) printing, also known as additive manufacturing, has emerged as a promising technology for developing customized drug delivery systems.3D printing enables precise control over drug dose, geometry, and spatial distribution of active ingredients, allowing the fabrication of complex and patient-specific dosage forms. Recent advances in formulation design, including the use of printable polymers, hydrogels, and nanomaterials, have significantly improved drug stability, printability, and performance. Moreover, various 3D printing techniques such as fused deposition modelling (FDM), stereolithography (SLA), and selective laser sintering (SLS) facilitate the production of dosage forms with tailored release kinetics, including immediate, sustained, and multi-phasic drug release profiles. Despite its potential, the clinical translation of 3D-printed drug delivery systems faces challenges related to regulatory approval, scalability, and quality assurance. This paper highlights recent innovations in formulation design, advancements in controlling drug release kinetics, and the current status of clinical translation, emphasizing the role of 3D printing in advancing personalized therapeutics. Personalized Medicine marks an important change from the conventional "one-size-fits-all" method in medical care by providing treatments that are designed for each patient based upon their own individual characteristics, such as genetics, disease type, age, weight, and the way their body processes drugs **[1]**. While there are many different types of drug delivery systems available, the traditional systems are limited in their ability to accommodate the differences in how patients process medications, their availability of medications to treat them, and the types of medications needed by each patient **[2]**. Often the inability to be flexible in drug delivery systems can lead to unsuccessful treatment, over or under-dosing for a patient, and (in the case of pediatric and geriatric patients) poor patient compliance due to the need to use non-standard dosages **[3, 4]**.

1.2 Role 3D Printing in Pharmaceuticals

3D printing also called additive manufacturing-- is a revolutionary technology that gives the capability to make complex three-dimensional objects through

a process of building layer upon layer of material based upon computer-aided design (CAD) files **[5, 6]**. 3D printing has been available since the 1980s, when stereolithography was developed, and has transitioned from being a prototyping tool in industrial settings to a disruptive technology in the fields of biomedical and pharmaceutical sciences **[7]**. The approval of Spritam® (levetiracetam) in 2015 as the first commercially available 3D printed drug **[8]** by the United States Food and Drug Administration (FDA) represented a significant milestone in pharmaceutical 3D printing **[9]**.

2. 3D Printing Technologies

2.1 Fused Deposition Modeling (FDM)

Due to its lower cost, ease of use, and large variety of materials that can be used in FDM, fused filament fabrication (FFF) is one of the most widely studied technologies in terms of its potential for use in the manufacture of pharmaceuticals. The FFF process utilizes a thermoplastic polymer filament that has been melted and then deposited in layers on top of each other according to the coordinates of the object to be manufactured **[10, 11]**. To create the drug-loaded filaments using FFF, an active pharmaceutical ingredient (API) is incorporated into a thermoplastic polymer matrix via hot melt extrusion (HME) before fabricating the filament **[12]**. This method of combining HME and FFF has been shown to be an efficient way to create solid dispersions that may improve the solubility and bioavailability of poorly soluble APIs **[13]**. The mechanical properties and drug release profile of FFF printed dosage forms are influenced by many factors; polymer type, API loading, infill density, print temperature, and layer thickness are just a few examples **[14]**. Studies have shown that by controlling the internal geometry of the dosage form, including creating channels, or changing the way the filaments are filled, researchers are able to precisely control the drug release rate from immediately following printing to extended-release profiles **[15]**. Although there are numerous benefits associated with FDM (fused deposition modeling), this method can be problematic for thermolabile drugs as it requires exposure to high temperatures during the melting and extrusion processes of polymers. Common melt processing temperatures for polymers typically range from approximately 150 degrees Celsius to 250 degrees Celsius, depending on the specific polymer system **[16]**.

2.2 Stereolithography

Stereolithography (SLA) uses the process of photopolymerization to selectively cure a liquid photosensitive resin into solid geometric forms with high resolution and surface quality by employing focused ultraviolet (UV) or visible light **[17]**. To produce a 3D object, a laser beam scans the

cross-sectional geometry of the 3D part on the surface of a bath of photopolymer resin before curing the previously cured material that was scanned during the previous layer **[18]**. Digital Light Processing (DLP) is a related technology to SLA that cures the entire layer of the 3D printed part simultaneously with a digital projector instead of scanning each point in sequence with the laser. As a result of this, print times are drastically reduced and the resolution of the printed part is maintained **[19]**. The benefits of stereolithography include exceptional dimensional accuracy, an excellent surface finish, and the capability of drug incorporation at ambient temperatures (i.e., temperature required to maintain the physical form of the drug) which will be particularly beneficial for thermolabile materials. Recent studies have shown positive results for integrating many APIs into photopolymer systems with the potential application of controlled-release formulations and complex multi-drug systems **[19]**. Despite the promise of stereolithography for several pharmaceutical applications, the availability of both photopolymers and photoinitiators with acceptance for use in pharmaceuticals is quite limited. Concerns about the potential cytotoxicity of residual unreacted monomer and photoinitiator require careful assessment of the materials used and appropriate use of post-processing procedures to assure the biocompatibility of the materials **[20]**.

2.3 Selective Laser Sintering (SLS)

Selective laser sintering utilizes a powerful laser for selective sintering of materials in powder form, mainly polymers, metals, or ceramics, into solid shapes based on computer design. In the process, the laser sweeps across the bed of powders to raise the temperatures of desired areas to cause sintering or melting, after which fresh layers of powders are then added using a roller system. One major strength of SLS technology is the lack of need for support structures because the non-sintered powder acts as the support for overhangs **[21, 22]**. In the pharmaceutical industry, selective laser sintering offers an alternative approach that allows solvent-free manufacturing with superior resolution and higher efficiency compared to extrusion-based techniques. There is evidence on the successful manufacture of orally administered dosage forms with porosity control capabilities through laser sintering of pharmaceutical grade polymers **[23]**. One of the main limitations related to SLS in the pharmaceutical industry is the high temperature generated in the process of laser sintering, which may result in thermal degradation of temperature sensitive APIs However, this can be avoided through the careful selection of the speed of the laser

scan, its power density, and type of polymer used **[24]**.

2.4 Inkjet-Based 3D Printing

This type of technology includes systems capable of dispensing liquids into droplets and depositing them on a surface, resulting in 3D printing due to the sequential layering process The two main categories include drop-on-demand inkjet printing that forms droplets as required and continuous inkjet printing that forms a continuous stream of droplets guided towards the substrate **[25]**. The inkjet technology that stands out in its application to the field of pharmaceutics is binder jetting technology when a liquid binder is applied selectively onto a powder bed consisting of drugs and excipients. Porous material that can easily break apart is created using this process **[26]**. The primary benefits of using inkjet technologies include the capability to perform at both room temperature and in moderately warm environments, the use of a diverse range of materials, and the construction of very porous structures which allow for quick release of drugs from a product Multi-nozzle devices also allow multiple materials to be deposited at once, helping to build multi-drug combinations in a complex fashion, while allowing for spatial control over how the drug is distributed **[27]**. The limitations placed upon printable materials for inkjet printing are viscosity and particle size. Nozzles also have the potential to become clogged, and either drying or sintering of product post-processing is needed to provide adequate mechanical strength **[28]**.

Materials Used to Formulate Medications Via Three-Dimensional Printing [29, 30]

Category of material	Examples	3D Printing Technique	Role in Formulation	Limitations
Thermoplastic Polymers	PLA, PVA, ABS, HPMC	FDM (Fused Deposition Modelling)	Matrix former, drug carrier	High temperature may degrade drugs
Hydrophilic Polymers	PEG, PVP, HPMC	FDM,SSE	Controlled release, binder	Moisture sensitivity
Photopolymers	Methacrylate-based resins	SLS, Binder Jetting	Structural support	Limited biocompatibility
Powder based materials	Lactose, Mannitol, Calcium Phosphate	SSE (Semi- solid extrusion)	Filter, carrier, fast disintegration	Poor Mechanical strength
Hydrogels	Alginate, Gelatin, Chitosan	Hybrid techniques	Controlled release	Low structural stability
Nanomaterials / composites	Lipid Nanoparticles	FDM, SSE	Targeted delivery	Complex formulation process
Lipids / Waxes	Stearic acid	FDM, SSE	Controlled release	Limited Drug loading

2.5 Personalized Tablets and Polypills

The manufacture of individualised oral solids (tablets) is one of the most researched areas where 3D printing has been applied in pharmaceutical development. As most traditional tablet forms are produced in fixed, standard dosages, patients requiring a non-standard dosage have to rely on splitting tablets, liquid formulations, or compounding (which will all have a degree

of variability), resulting in the patient being at a disadvantage, as well as experiencing an inconvenience **[31- 40]**. With 3D printing, patients can receive an accurate dosage through modification of the tablet's geometry, or the amount of drug added to the tablet's internal structure **[41]**. Tablets can be manufactured in varying amounts by using a range of drugs or by altering the geometry of the tablets; for example, the complete range from micrograms to several hundred milligrams can be produced via 3D printing for paediatric and adult patients. Polypills, defined as one-dose pills comprised of several different active pharmaceutical ingredients (APIs), represent an especially promising target for 3D printing technology. People with chronic illnesses like heart diseases, diabetes, and HIV/AIDS need multiple medicines with differing release mechanisms. Combining all of them in a single polypill will greatly improve adherence and treatment efficacy **[42]**. Various research groups have shown the possibility of producing 3D-printed polypills consisting of at least five different APIs with separate release profiles in one pill by separating the components spatially in the dosage form design, 3D printing allows for combinations of APIs that cannot be done using traditional methods because some drugs could not be combined due to incompatibility **[43]**. Besides customizing drug and dose amounts, 3D printing also makes it possible to customize other features of the tablets for certain patient groups. Fast-dissolving pills for those who have trouble swallowing, small pills for children, and scored pills for flexible dosages have all been shown to be feasible **[44]**.

2.6 Implants, Microneedles, and Transdermal Systems

3D printing techniques have significantly contributed to the design and manufacture of patient-tailored implantable drug delivery systems due to their ability to create complex structures **[45]**. These types of implants may include contraceptives, localized chemotherapy delivery devices, and antibiotic-releasing orthopedic implants. Patient-tailored implant design based on the results of imaging provides for better fitting, higher comfort level, and improved efficacy. 3D printed implants featuring well-defined porous and internal structure may enable drug release over periods from several weeks to several years **[46]**. Experimental studies show that delivery of chemotherapeutic drugs from such 3D printed implants placed in proximity of a surgically removed tumor ensures high concentration of drugs in a localized area. **Microneedle array** technique is an innovative technique for transdermal drug delivery. The method involves the use of arrays of microneedles that create channels through the stratum corneum and allow the delivery of

macromolecules and other molecules that cannot penetrate healthy skin into the body **[47]**. Three-dimensional (3D) printing allows for quick prototyping and tailoring of microneedle design, material, and drug content. There are empirical studies showing that microneedles manufactured via 3D printing technology can be made of biodegradable polymers and carry vaccines, proteins, and small molecule drugs. The versatility of microneedle designs and manufacturing processes, compared to traditional microneedle manufacturing approaches such as micromolding or silicon etching, is one of the benefits of 3D printing technology **[48]**.

Transdermal patches

Various 3D printing technologies have been used to manufacture customized transdermal patches containing different drugs, release kinetics, and patch design. It becomes possible to build complex, multi-layered patches that contain different drugs with a well-regulated distribution throughout the layers [49].

3. Dose Customization and Patient Compliance

One of the advantages of 3D printing technology in the pharmaceutical field is the ability to accurately customize doses, which overcomes the discrepancy between commercially available drugs' pre-set dose strengths and their individualized needs for patients **[50]**. In particular, patients who belong to pediatric or geriatric categories are likely to receive doses that are very different from adult drug product **[51]**. In pediatric dosing by weight or body surface area, one often finds that they do not match the dose strengths in existing tablet products, forcing practitioners to use liquids, compounded medicines, or fractionated tablets, all of which lack precision and compliance. Creating drugs in forms that are more acceptable to patients, including chewable tablets, orally disintegrated drugs, and mini-tablets, increases acceptability among people with dysphagia problems **[52]**. Some studies show that 3D printed tablets with customized shapes, tastes, and textures could be beneficial in increasing pediatric medicine acceptability. In polypill formulation, combining several drug products in a single unit addresses the proven link between pill load and non-compliance. Research proves that poly-pill users have lower adherence rates than single-pill users, and every extra daily dose decreases adherence possibilities **[53]**.

4. Challenges in Regulation and Manufacturing Processes

Despite the potential benefits associated with 3D printing pharmaceuticals, challenges relating to regulation pose significant obstacles to development, due to the nature of the innovation and deviation from traditional manufacturing methods. The regulatory guidelines set out for the

mass manufacturing of medications assume batch processing with built-in quality controls, which cannot be applied in this innovative case **[54]**. Technical guidance documents have been published by the U.S. Food and Drug Administration regarding additive manufacturing of medical devices. Still, a full regulatory framework for 3D printing pharmaceuticals is still yet to be established. Key issues include process validation for all possible variants of products, quality control for personalized medications, and consistency in operation of the printing machinery **[55]**. There are material constraints on the variety of drugs and formulations that can be produced using existing 3D printing technology. Pharmaceutical-grade printing materials suitable for human consumption are limited, particularly for those involving photopolymerization methods, as there may still be issues regarding toxicity from the monomers **[56]**. Scalability is one of the main challenges when trying to commercialize laboratory demonstrations of 3D printing **[57]**. There could be variations between different machines, including those within the same series, which might affect drug formulations **[58]**.

5. Artificial Intelligence and 4D Printing

Integration between artificial intelligence (AI) and machine learning approaches in combination with 3D printing represents a groundbreaking leap in pharmaceutical technology advancement **[59]**. Formulation design using AI makes possible optimization of multifactorial design spaces such as material choice, printing factors, and geometry, which would have been impossible to explore using conventional experimentation. Machine learning models trained on empirical data can predict properties including printability, mechanics, and release profile based on formulations and printing processes **[60]**. **The concept of 4D printing** is an advancement of 3D printing because 4D printing involves the addition of materials that can transform their physical properties over time due to external triggers **[61]**. This temporal aspect of 4D printing has been used in drug delivery systems to design devices whose properties such as shape, porosity, or rate of drug delivery can be altered after the device is delivered inside the body. Some examples of 4D printing in drug delivery include self-folding designs, stimuli-responsive implants, and shape-memory implants **[62]**.

6. Commercialization and Personalized Medicine

Commercialization of pharmaceutical 3D printing technology occurs via several channels, which include point-of-care printing, compounding pharmacy printing, and customized manufacturing units **[63]**. Point-of-care printing involves the production of medicines within a hospital or pharmacy just before dispensation and is the

most personalized approach; however, there exist numerous difficulties that need to be overcome. Several firms have started commercializing platforms for 3D printing of pharmaceuticals, ranging from the provision of medicines for use in clinical trials to commercial manufacturing **[64]**. One such company is FabRx's M3DIMAKER printer, which represents a dedicated platform for pharmaceutical printing with regulatory compliance. The intersection of 3D printing technology with other emerging precision medicine fields, such as pharmacogenomics, therapeutic drug monitoring, and digital health solutions, is predicted to pave the way for true personalized pharmacotherapy **[65]**. Future solutions will be able to factor in genetic data, biomarker information, and patient feedback to refine drug therapies that are 3D-printed on demand. Bioprinting refers to an advanced stage of 3D printing technology in which live biological elements, in addition to pharmaceutical drugs, can be printed for therapeutic purposes; these include drug screening organs and cellular scaffolding **[66]**. While bioprinting of therapeutic tissue remains more theoretical than practical at this point, great strides have been made in pre-clinical research involving skin, bone, cartilage, and vascular tissue regeneration.

7. CONCLUSION

The advent of 3D printing can be considered as a revolutionary innovation with substantial implications for the future of drug manufacturing and personalized medicine. The ability to produce drug delivery devices allowing for fine-tuning the dose, shape, content, and delivery properties offers a way to overcome inherent limitations of the conventional manufacturing technologies which provide one-size-fits-all products. At the moment, the applications of 3D printing technology in the field of pharmacy include personalized dosage systems, polypills with multiple drugs, implants, microneedles, and transdermal patches. Every particular type of application utilizes distinctive features of 3D printing technology to obtain results which cannot be achieved using any other technique. Numerous obstacles remain before 3D printed medicines become commonplace in the clinic. Regulations will need to evolve to address the shift from batch manufacturing to personalized medicine. More pharmaceutically compatible materials will need to be added to the list to support the production of a greater variety of medications with diverse release profiles. It will be necessary to prove that manufacturing processes are both reproducible and scalable for business purposes. Recent advances in areas like artificial intelligence, 4D printing, and bioprinting point to an era where drug

delivery is personalized yet capable of adapting to the unique needs of the patient. The combination of 3D printing with digital health solutions and precision medicine could make the goal of personalized medicine—a medication tailored to each patient's needs—finally achievable.

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