Chapter 51

Prototypes of Personalisation and Customisation for Next-generation Medicines

Subham Banerjee

Department of Pharmaceutics, National Institute of Pharmaceutical Education and Research (NIPER), Guwahati, Assam, India

Abstract

The growing demand for personalised medicine has highlighted the limitations of conventional drug delivery systems, which often fail to address individual variability in genetics, lifestyle, and therapeutic responses. Advances in personalised therapy have necessitated flexible manufacturing platforms capable of producing patient-specific dosage forms. Pharmaceutical additive manufacturing (PAM), particularly 3D/4D printing technologies, has emerged as a disruptive tool that enables the on-demand fabrication of individualised drug delivery systems. Techniques such as fused deposition modelling (FDM), stereolithography (SLA), selective laser sintering (SLS), semi-solid extrusion (SSE), and direct powder extrusion (DPE) facilitate customisable geometry, dosage, drug release kinetics, multidrug layering, and stimuli-responsive behaviour. This chapter discusses the recent progress in PAM for personalised medicine, outlining its potential to revolutionise therapeutic precision and patient adherence through digitally controlled pharmaceutical fabrication.

Keywords: *Pharmaceutical additive manufacturing, 3D/4D printing, Personalised medicine, Drug delivery systems, Patient-specific dosage forms*

Introduction

Conventional drug development has successfully investigated specific pharmacological agents for the development of high-quality medications. However, targeting several mechanisms simultaneously may be more effective than single-drug regimens. Different transmission routes can be modulated in a synergistic or additive manner using a combination of drug treatments[1]. The landscape of modern healthcare is undergoing profound transformation with the advent of personalised medicine, a therapeutic approach that seeks to tailor medical treatment to the unique genetic, physiological, and lifestyle characteristics of each individual. Pharmaceutical additive manufacturing (PAM) and rapid prototyping have advanced significantly in the pharmaceutical sector because of the demand for versatile, individualised, and customisable products. Pharmaceutical products with intricate geometries and structures, which are challenging to fabricate using traditional production techniques, can be developed using 3D printing. 3D printing is an AM technique that uses computer-aided design (CAD)

[1]Serena Boccella et al., "Combination Drug Therapy for the Management of Chronic Neuropathic Pain", *Biomolecules,* 13, no. 12: 1802 (2023).

to fabricate customised objects layer by layer. 3D printing enables the production of personalised medications in small quantities with tailored dosages, release profiles, and multi-drug combinations, addressing individual variations in physiology, genetics, lifestyle, and the needs of vulnerable populations such as paediatric, geriatric, and chronically ill patients[2]. Recently, there has been an increase in the number of scientific publications and patents detailing the pharmaceutical uses of 3D printing, which indicates the growing interest in this method within the pharmaceutical sector owing to its benefits. The FDA authorised the first 3D-printed drug product in August 2015, which benefited 3D printing as a method of pharmaceutical manufacturing[3].

As the pharmaceutical industry moves towards digitally enabled patient-centric care, PAM technologies present an unprecedented opportunity to bridge the gap between standard production and personalised therapy. This chapter discusses the importance of personalised drug delivery, the core technological advancements supporting it, and the potential impact of pharmaceutical 3D/4D printing on revolutionising healthcare.

Lab of Additive Manufacturing in Pharmaceuticals (LAMP)

The Lab of Additive Manufacturing in Pharmaceuticals (LAMP) is a specialised research facility focused on the design, development, and advancement of pharmaceutical 3D and 4D printing technologies. The primary objective of our LAMP is to develop personalised and customised medicines using cutting-edge additive manufacturing tools such as fused deposition modelling (FDM), stereolithography (SLA), semi-solid extrusion/direct powder extrusion (SSE/DPE), and selective laser sintering (SLS).

Our lab pioneers the fabrication of next-generation medicines, including nano-filled capsules, sintered printlets, microneedles, patches, bilayered pills, QR-coded films, ghost tablets, sorbents, and responsive 4D constructs. These innovations aim to meet the growing demand for precision drug delivery, especially in areas such as chronic diseases, paediatric care, and implantable systems. By merging pharmaceutical science, materials engineering, and additive manufacturing, LAMP is positioned at the forefront of transformative healthcare technologies—enabling a shift from conventional mass production to highly individualised therapy.

3D Printing Techniques

The tremendous versatility of 3D printing technology makes it an excellent choice for creating drug delivery systems (DDSs) with dimensions and designs that are difficult to achieve using traditional techniques. Our research exclusively focuses on various platform technologies for the development of personalised DDSs.

Key technologies in PAM include:

[2]Subham Banerjee, ed., *Additive Manufacturing in Pharmaceuticals*, (Springer, 2023).

[3]Jiaxiang Zhang et al., "Pharmaceutical Additive Manufacturing: A Novel Tool for Complex and Personalized Drug Delivery Systems," *AAPS PharmSciTech,* 19, no. 8 (2018): 3388-3402.

- **Fused deposition modelling (FDM)** drugs and polymers are first extruded using a hot-melt extruder (HME) to prepare filaments, which are then coiled on a spool to prepare them for printing. The printer deposits the developed 3D object onto the printing platform by pulling the filament from the spool and allowing it to extrude through the pre-heated nozzle. It utilises thermoplastic polymers to fabricate oral dosage forms with precise control over geometry and internal structure.
- **Stereolithography (SLA)** when exposed to UV or visible light, the photoreactive liquid resin initiates a photopolymerisation reaction. This process is initiated by the production of free radicals in the photoinitiator and the formation of a covalently crosslinked network. SLA offers high precision and resolution, making it suitable for use in intricate dosage forms and implantable devices.
- **Selective Laser Sintering (SLS)** works primarily by projecting a laser beam onto the surface of a powder bed containing the polymer and drug. This caused the powder to instantly sinter by increasing the temperature of the powder bed. New layers of powder are repeatedly spread over the sintered ones using a roller until the 3D object is fully formed. This allows the creation of porous solid dosage forms, ideal for controlled and sustained drug release.
- **Semi-solid Extrusion (SSE) and Direct Powder Extrusion (DPE)** involve the extrusion of pastes or gels under pressure, which is ideal for incorporating heat-sensitive drugs. DPE facilitates direct extrusion of powder blends without prior filament formation. Proper ink characteristics and appropriate printing parameters, such as pressure, speed, and nozzle size, are necessary for effective printing as they enable accurate dosing and layering of numerous medications. This method reduces the number of processing steps and is suitable for high drug load formulations (Figure **1**).

3D Printed Dosage Forms

The literature provides a number of demonstrations of 3D printed dosage forms that were developed in our lab, and use of various polymers and processes. Examples of 3D printed formulations are covered in this section.

Tablets

Using 3D printing to manufacture tablets allows the development of tablets with various geometric and medication release patterns. In our study, tablets were printed using a SmartEx QD 100 polymer with isoniazid through an SLS 3D printer, which showed immediate gastric release within 15 minutes[4].

[4]Tukaram Karanwad et al., "Additive manufacturing of SmartEx QD 100 designed oral three-dimensional printlets containing isoniazid for immediate gastric release by selective laser sintering", *Molecular Pharmaceutics,* 21, no.10 (2024): 5272-5284.

Figure 1: Thrust research areas of LAMP.

Implants

Drugs can be successfully delivered to the site of action for a prolonged period via implants. In our lab, prolonged delivery of tenofovir was achieved using a subcutaneous hydrogel-based porous implant. The implant was fabricated using an SSE 3D printer with a methyl cellulose-reinforced BSA hydrogel. The hydrogel exhibited shear thinning and self-healing behaviours, and the implant showed thermal stability, cytocompatibility, and sustained release behavior over 28 days[5].

[5]Marepally Karthik Venkat Sai Sharan et al., "3D printed subcutaneous implant for prolonged delivery of tenofovir with desired release capability, biocompatibility, and viability," *Journal of Molecular Structure,* 1319 (2025): 139559.

Microneedles

Microneedles can puncture the skin and deliver drugs directly into the dermis, making them highly effective for transdermal drug delivery. In our study, the transdermal delivery of ceftriaxone was achieved using hollow microneedles. Bio-inspired labrum tip microneedles were fabricated using an SLA 3D printer with biomed amber resin. The microneedles exhibited efficient penetrability through porcine skin within 18 hr and excellent bioavailability.[6]

Capsules

In our lab, sustained release of levofloxacin was achieved using a gastro-retentive floating-hollow capsular device. The capsule was developed using a SLS 3D printer employing Kolliphor P188 and Kollidon SR. The capsular device exhibited prolonged delivery to the gastric region[7].

Films and hydrogels

Our lab fabricated dental 3D-printed oral films using CompactCel® polymers loaded with diclofenac sodium via SSE 3D printing for toothache management. The films demonstrated an initial burst release followed by sustained drug release over 150 min[8]. Similarly, Aspirin-loaded, QR-encoded enteric films were fabricated using Kollicoat® MAE 100P and PLA via FFF 3D printing for targeted intestinal delivery. The films showed enhanced release at alkaline pH, suitable for enteric delivery, while the QR code enabled patient access to detailed drug information[9]. Similarly, oral films were prepared using a self-healing mineralised hydrogel with diclofenac sodium using an SSE bioprinter. The films showed an increased pore size, faster release, and considerable bioavailability to the targeted area[10].

Conclusion and Future Perspectives

3D and 4D printing are transforming pharmaceutical science by enabling patient-specific drug fabrication with precise dosing, shape, and release profiles, thereby enhancing treatment efficacy and safety. Advancements in 4D printing are driving the development of smart medicines that respond dynamically to physiological conditions, offering significant potential for personalised, paediatric, and geriatric care, as well as targeted and controlled drug delivery. 3D printing has introduced new

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[6]Shubham Kawre et al., "Bioinspired labrum-shaped stereolithography (SLA) assisted 3D printed hollow microneedles (HMNs) for effectual delivery of ceftriaxone sodium," *European Polymer Journal,* 204 (2024): 112702.

[7]Ganesh Pandav et al., "3D printed gastroretentive floating-hollow capsular device (GRF-HCD) for levofloxacin oral delivery using selective laser sintering (SLS) platform technology," *Journal of Biomaterials Science, Polymer Edition* (2025): 1-18.

[8]Rohit Bhawale et al., "Three-dimensional (3D) printing of oral dental films (ODFs) using blended Compactcel®polymers through semi-solid extrusion (SSE) bioprinter", *Bioprinting,* 33 (2023): e00287.

[9]Thotapalli Lahari et al., "Quick response-encoded chip engraved onto multifunctional aspirin loaded enteric films by fused filament fabrication-3D printing." *Journal of Applied Polymer Science,* 141, no. 8 (2024): e55048.

[10]Nachiketa Palit et al., "3D Printable Self-Healing Mineralized Hydrogels Loaded With Diclofenac Sodium: In Vitro and In Vivo Assessment," *Biotechnology and Bioengineering*, 122, no. 6 (2025): 1530-1540.

manufacturing paradigms, enabling local and decentralised production. Future advancement requires strong regulatory frameworks and close collaboration among researchers, healthcare professionals, and regulatory bodies to fully harness its potential.

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