

Revolutionizing Drug Formulation: The Role of 3D Printing in Personalized Medicine

Sayyed Atik¹, Madaje Amir², Etesam Shaikh³, Sayyad Azharali⁴, Saudagar Sameer⁵, Ansari Mohd Saquib⁶

¹*Department of Pharmaceutics, Abasaheb Kakde College of B. Pharmacy, Savitribai Phule Pune University, Bodhegaon, MH*

²*Birla Institute of Technology & Science Pilani, Hyderabad Campus, Hyderabad, Telangana*

³*Department of Pharmaceutical Chemistry, Shri Sharda Bhavan Education Society's Nanded Pharmacy College, Nanded, MH*

⁴*Department of Quality Assurance, School of pharmacy, SRTM University Nanded, MH*

⁵*Department of Pharmacology, School of pharmacy, SRTM University Nanded, MH*

⁶*Department of Pharmaceutical Chemistry, School of pharmacy, SRTM University Nanded, MH*

Abstract- 3D printing (additive manufacturing) is revolutionizing pharmaceutical sciences by enabling the creation of customized drug formulations tailored to individual patient needs. Unlike traditional methods, it allows flexible dosage forms, complex geometries, and multi-drug combinations, improving patient compliance, especially in pediatric and geriatric populations. Techniques like FDM, SLA, and SLS offer unique benefits in drug delivery, while material selection and thermal stability remain crucial for product quality. Despite challenges in regulation and large-scale production, advancements in AI, smart materials, and decentralized models are paving the way for broader adoption. This review highlights the key technological, material, and regulatory aspects driving 3D printing's role in personalized medicine.

Keywords- 3D Printing, Additive Manufacturing, Personalized Medicine, Drug Formulation, Fused Deposition Modeling (FDM), Stereolithography (SLA), Selective Laser Sintering (SLS), Custom Dosage Forms, Polypill, Drug Release Profiles, Regulatory Challenges, Material Science, Thermal Stability of APIs

1. INTRODUCTION

The pharmaceutical industry is experiencing a transformative phase with the integration of advanced manufacturing technologies such as 3D printing, also known as additive manufacturing. This technology, once primarily associated with prototyping and engineering, has made significant inroads into the realm of drug formulation and delivery. The capacity of 3D printing to fabricate complex, customized

structures with high precision offers an unprecedented opportunity to tailor medications to individual patient needs, thereby advancing the goal of personalized medicine. Personalized medicine defined as medical care designed to optimize efficiency or therapeutic benefit for individual patients, especially by using genetic or molecular profiling is a growing trend in healthcare. Traditional pharmaceutical manufacturing methods often fall short in supporting this model due to their limitations in customization, scalability, and cost-effectiveness for small-batch production. 3D printing, with its ability to create bespoke dosage forms with varied drug release profiles, shapes, and compositions, is poised to bridge this gap. The FDA's approval of Spritam®, the first 3D-printed drug, in 2015 marked a pivotal milestone that validated the technology's potential in mainstream pharmaceutical applications (Aprecia Pharmaceuticals, 2015). This review explores the application of 3D printing in drug formulation with a special focus on personalized medicine. It delves into the various printing technologies employed, discusses material and design considerations, evaluates the regulatory and scale-up challenges, and envisions the future trajectory of this innovative approach.

2. OVERVIEW OF 3D PRINTING IN PHARMACEUTICALS

3D printing, or additive manufacturing, is a process by which three-dimensional objects are constructed layer-by-layer from a digital file. The versatility of this

technology has led to its adoption in a wide array of industries, including aerospace, automotive, and healthcare. Within the pharmaceutical sector, 3D printing is being explored for its potential to revolutionize drug manufacturing, particularly in creating customized and complex drug delivery systems. In pharmaceuticals, 3D printing offers several distinct advantages over traditional methods such as compression or extrusion. It allows for precise control over drug loading, geometry, and internal microstructures, enabling the development of formulations with tailored drug release profiles. This level of customization is particularly beneficial for producing medications that meet the specific needs of individual patients, such as pediatric or geriatric populations, or those with rare diseases. Moreover, 3D printing can reduce the need for large-scale production and warehousing by facilitating on-demand manufacturing. This capability is especially valuable in clinical settings or for medications with short shelf lives. It also opens the door to decentralized production models, such as hospital-based printing units, which can produce personalized medicines at the point of care (Norman et al., 2017). Several types of 3D printing technologies are being investigated in pharmaceutical applications, including Fused Deposition Modeling (FDM), Stereolithography (SLA), and Selective Laser Sintering (SLS), each with its own advantages and limitations. These techniques differ primarily in the type of materials used and the mechanisms by which layers are built. The pharmaceutical applications of 3D printing are not limited to oral solid dosage forms. The technology is also being explored for fabricating transdermal patches, implants, microneedles, and even tissue scaffolds for regenerative medicine. The scope of 3D printing's potential in healthcare continues to expand with advancements in materials science and printing resolution. However, despite its promise, the adoption of 3D printing in mainstream pharmaceutical manufacturing remains limited due to regulatory uncertainties, lack of standardization, and challenges in scaling up production. Addressing these hurdles will be essential to fully realize the benefits of this innovative technology.

3. PERSONALIZED MEDICINE THROUGH 3D-PRINTED TABLETS

The advent of 3D printing, also known as additive manufacturing, represents a paradigm shift in pharmaceutical science, especially in the field of personalized medicine. Unlike traditional drug manufacturing processes that rely on mass production of standardized dosage forms, 3D printing offers a versatile and customizable platform for fabricating patient-specific drug products tailored to individual needs. This capability aligns seamlessly with the principles of personalized medicine, which seeks to optimize therapeutic outcomes by considering genetic, physiological, and lifestyle differences among patients (Norman et al., 2017).

3.1 Tailored Dosage Forms

Traditional pharmaceutical manufacturing typically involves the production of a limited range of fixed-dose formulations intended to serve the general population. This approach often fails to accommodate interindividual variability in drug metabolism, organ function, disease progression, and polypharmacy. In contrast, 3D printing allows for precise control over both the quantity and spatial distribution of active pharmaceutical ingredients (APIs) within a dosage form (Skowrya et al., 2015). It enables the creation of complex tablet architectures such as polypills, multi-layered systems, and modified-release formulations that can deliver multiple drugs at customized dosages and release rates. For instance, tablets can be engineered to release one drug immediately upon ingestion and another in a sustained manner over several hours simply by modifying the internal geometry or layering of the printed object (Awad et al., 2021). This level of control facilitates the development of dosage forms specifically designed to match the pharmacokinetic and pharmacodynamic requirements of individual patients, thereby enhancing efficacy and minimizing adverse effects.

3.2 Improved Patient Compliance

Beyond pharmacological customization, 3D-printed tablets offer unique opportunities to improve patient compliance, particularly in populations with special needs such as pediatrics, geriatrics, and individuals with dysphagia. The technology enables the production of dosage forms in a wide array of shapes, colors, sizes, and even flavors, which can increase the appeal and acceptability of medications (Goyanes et al., 2015). For example, chewable or rapidly

dissolving mini-tablets with pleasant flavors can be designed specifically for children, making the medication process less intimidating and more engaging. Furthermore, 3D printing can simplify polypharmacy by consolidating multiple medications into a single "polypill," thus reducing pill burden and dosing frequency factors that are known to improve adherence, especially in chronic diseases such as hypertension, diabetes, and HIV/AIDS (Jamróz et al., 2018).

3.3 Case Studies and Commercial Products

A prominent commercial milestone in this field is Spritam® (levetiracetam), developed by Aprelia Pharmaceuticals and approved by the FDA in 2015. This product is the first 3D-printed drug to reach the market and utilizes ZipDose® technology, which allows for the creation of high-dose tablets that disintegrate rapidly in the mouth with minimal liquid. This innovation addresses the needs of patients with swallowing difficulties and marks a significant step toward mainstream application of 3D printing in pharmaceuticals (Aprelia Pharmaceuticals, 2015). Academic research has also validated the potential of 3D printing in personalizing drug delivery. For example, Goyanes et al. (2015) demonstrated that paracetamol tablets printed in various shapes—such as rings and pyramids exhibited distinct drug release profiles due to differences in surface area-to-volume ratios. These findings underscore the role of tablet geometry in controlling drug kinetics and affirm the feasibility of design-based customization. Despite the promise, widespread clinical adoption is still hindered by regulatory uncertainties, scale-up challenges, and the need for robust quality control frameworks. However, ongoing advances in printing technologies, material sciences, and digital health integration are expected to accelerate the translation of 3D-printed pharmaceuticals into routine practice (Norman et al., 2017; Trenfield et al., 2018).

4. 3D PRINTING TECHNOLOGIES IN DRUG FORMULATION

Several types of 3D printing technologies have been adapted for pharmaceutical applications. Each technique offers distinct advantages and limitations depending on the nature of the drug, the desired dosage form, and the complexity of the formulation.

4.1 Fused Deposition Modeling (FDM)

FDM is one of the most widely used techniques in pharmaceutical 3D printing. In this process, a thermoplastic polymer filament is heated to a semi-liquid state and extruded through a nozzle to form a layer-by-layer structure. The drug is either embedded within the filament before printing or coated afterward. This method offers high resolution and is particularly suitable for creating solid oral dosage forms with modified release characteristics. Skowyra et al. (2015) demonstrated the use of FDM to fabricate prednisolone tablets with extended-release properties by adjusting the internal structure and polymer composition. However, a key limitation of FDM is the requirement for high processing temperatures, which can degrade thermally sensitive drugs. Additionally, the availability of pharmaceutically acceptable filaments remains limited, although progress is being made in developing drug-loaded printable materials (Goyanes et al., 2015).

4.2 Stereolithography (SLA)

SLA employs a laser or light source to polymerize photosensitive resin in a layer-by-layer fashion. This technique allows for extremely high resolution and is ideal for creating intricate geometries and microstructures. In pharmaceutical applications, SLA has been explored for fabricating oral films and transdermal patches. Hollander et al. (2018) reported the successful fabrication of oral dosage forms using SLA that showed uniform drug distribution and customizable release profiles. Despite its precision, SLA's main limitation is the scarcity of biocompatible and photopolymerizable resins suitable for human consumption. Additionally, post-processing steps such as washing and curing add to production complexity and time.

4.3 Selective Laser Sintering (SLS)

SLS uses a high-powered laser to sinter powder particles together without the need for binders. This method is particularly suitable for heat-stable drugs and allows for the incorporation of high drug loads. Goyanes et al. (2017) successfully utilized SLS to create tablets with porous structures, which influenced both mechanical properties and drug release behavior. The flexibility in tuning tablet porosity makes SLS a promising approach for controlled-release formulations. However, like other thermal techniques,

SLS may not be suitable for all APIs. The need for inert processing conditions and the limited number of pharmaceutically approved powders are significant barriers to its broader adoption. In conclusion, the choice of 3D printing technology for pharmaceutical applications depends on several factors, including the physical and chemical properties of the drug, the required dosage form, and the desired release profile. Continued innovation in printer design, material science, and post-processing methods is expected to expand the utility of each technique in the near future.

5. MATERIAL CONSIDERATIONS FOR 3D-PRINTED DRUG PRODUCTS

Material selection plays a pivotal role in the successful formulation of 3D-printed drug products. The choice of polymers, excipients, and active pharmaceutical ingredients (APIs) determines not only the printability and mechanical strength of the final dosage form but also its drug release behavior and stability.

5.1 Polymers and Excipients

Polymers act as the primary matrix-forming agents in most 3D printing techniques. The selection of appropriate polymers is critical to ensure that the formulation meets mechanical, thermal, and biopharmaceutical requirements. In Fused Deposition Modeling (FDM), thermoplastic polymers such as polyvinyl alcohol (PVA), polylactic acid (PLA), and ethyl cellulose are commonly used due to their good thermal processability and mechanical properties (Goyanes et al., 2015). Hydrophilic polymers like hydroxypropyl methylcellulose (HPMC) can be employed to create immediate or controlled-release profiles depending on the drug and application. Stereolithography (SLA) and Digital Light Processing (DLP) rely on photopolymerizable resins, which are typically based on acrylates or methacrylates. However, the number of GRAS (Generally Recognized As Safe) photopolymers approved for pharmaceutical use remains limited (Hollander et al., 2018). Excipient selection must consider printability, biocompatibility, and the desired pharmacokinetics. Plasticizers (e.g., polyethylene glycol, triethyl citrate), disintegrants (e.g., croscopovidone), and fillers (e.g., lactose, mannitol) can be included to improve processability and control drug release.

5.2 Drug Stability and Compatibility

The integration of APIs into 3D printing processes poses unique challenges related to thermal and chemical stability. Many 3D printing techniques, particularly FDM and SLS, involve high temperatures that may degrade heat-sensitive drugs. Pre-formulation studies are crucial to assess the thermal behavior and chemical compatibility of APIs with selected excipients and polymers. Techniques such as thermogravimetric analysis (TGA) and differential scanning calorimetry (DSC) are often employed to evaluate thermal stability. The interaction between APIs and polymers can influence drug release and bioavailability. For instance, hydrophilic polymers may promote rapid drug dissolution, whereas hydrophobic matrices can sustain drug release. Therefore, formulation scientists must consider the physicochemical properties of both the drug and the excipients to tailor the desired pharmacokinetic profile. Moreover, the drug's solubility and molecular weight influence its distribution within the printed matrix and its eventual release. Incorporating poorly water-soluble drugs may require the use of solubilizers or nanosizing techniques prior to printing (Awad et al., 2021). In summary, a deep understanding of material science is essential to design safe, effective, and reliable 3D-printed pharmaceuticals. Continued research into novel biocompatible polymers and smart materials (e.g., stimuli-responsive polymers) will further expand the capabilities of 3D printing in drug delivery.

6. REGULATORY LANDSCAPE AND CHALLENGES

Despite its transformative potential, 3D printing in drug formulation faces significant regulatory hurdles. The adoption of this technology demands the evolution of current regulatory frameworks to address the unique aspects of 3D-printed pharmaceuticals.

6.1 FDA Guidelines and Approval Pathways

The U.S. Food and Drug Administration (FDA) made a significant milestone in 2015 by approving Spritam® (levetiracetam), the first 3D-printed drug developed by Aprelia Pharmaceuticals using ZipDose® technology. This approval highlighted the FDA's openness to innovation but also underscored the need for specialized evaluation criteria for 3D-printed drugs (FDA, 2015). While current regulations do not

specifically target 3D-printed drugs, the FDA has issued general guidance on emerging manufacturing technologies. The Center for Drug Evaluation and Research (CDER) encourages early communication with developers to navigate regulatory pathways more efficiently (FDA, 2017). Regulatory agencies globally are exploring strategies to adapt their frameworks. The European Medicines Agency (EMA) and other national regulators are conducting research and consultations to evaluate the implications of 3D printing in clinical and industrial settings.

6.2 Quality Control and GMP Requirements

Ensuring consistent product quality in 3D printing is complex due to the technology's layer-by-layer fabrication and material variability. Current Good Manufacturing Practices (cGMP) must be tailored to address these factors. Critical quality attributes (CQAs) such as content uniformity, mechanical strength, and dissolution profile require stringent control and validation. Traditional analytical methods may need to be supplemented with in-line process analytical technology (PAT) tools to monitor printing accuracy and consistency in real time (Norman et al., 2017). Batch release testing and validation protocols must be redesigned to accommodate small-batch, customized production that is typical in personalized medicine. This shift from mass manufacturing to batch-of-one poses novel challenges in documentation and traceability.

6.3 Intellectual Property and Ethical Concerns

3D printing raises new questions regarding intellectual property (IP) protection. Since digital design files can be easily shared or modified, securing IP rights over drug formulations and device designs becomes more complex (Lima et al., 2019). Ethical concerns also emerge in personalized medicine. Equitable access, data security, and the potential for unauthorized use or counterfeit production are all critical issues that regulators must address proactively. Moreover, there is a pressing need to ensure that 3D-printed medications are not only effective but also affordable and accessible. Policies must be developed to prevent socio-economic disparities in access to personalized treatments. In summary, the regulatory framework must evolve in tandem with technological advancements to ensure that 3D-printed

pharmaceuticals meet safety, efficacy, and quality standards while supporting innovation.

7. SCALE-UP AND MANUFACTURING CHALLENGES

Scaling up 3D printing technologies from laboratory settings to commercial pharmaceutical manufacturing presents several formidable challenges. While the precision and customization offered by 3D printing are unparalleled, replicating these benefits at an industrial scale requires careful planning, robust validation, and integration with existing manufacturing systems.

7.1 Process Optimization

For successful scale-up, optimization of 3D printing parameters is essential. Factors such as nozzle diameter, printing speed, extrusion temperature, and layer height significantly influence product quality and consistency (Zhao et al., 2020). In multi-drug formulations or complex dosage forms, maintaining uniformity across large production volumes becomes increasingly difficult. Advanced computational modeling, machine learning, and in-process monitoring technologies are being explored to predict and control product characteristics during the manufacturing process. Additionally, reproducibility is critical in pharmaceutical manufacturing. Unlike traditional methods, 3D printing introduces variability at multiple stages—material feeding, melting, deposition, and post-processing. Therefore, establishing validated standard operating procedures (SOPs) for different formulations and equipment is crucial.

7.2 Cost and Time Efficiency

Despite its advantages, 3D printing currently lags behind conventional pharmaceutical manufacturing in terms of cost-effectiveness and throughput. The unit cost of production remains high due to the slow printing speed and the need for specialized equipment and materials. Batch production of hundreds or thousands of tablets using 3D printers is time-intensive. While parallel printing strategies (e.g., multi-nozzle systems, printer arrays) are under development, their implementation adds layers of complexity in synchronization and quality assurance (Awad et al., 2019). Material waste, energy consumption, and equipment maintenance further increase the operational costs. Economies of scale are

not yet fully realized in 3D pharmaceutical printing, although modular production systems and decentralized manufacturing models may offer new opportunities for efficiency.

7.3 Integration into Current Pharmaceutical Supply Chains

Integrating 3D printing into existing pharmaceutical infrastructure requires significant adjustments. Traditional supply chains are designed around bulk production and centralized manufacturing. In contrast, 3D printing supports decentralized, on-demand manufacturing that could revolutionize drug distribution models. This paradigm shift involves rethinking storage, transportation, and inventory management. Digital formulation files could be transmitted to local pharmacies or hospitals, where personalized drugs are printed close to the point of care (Norman et al., 2017). However, this model necessitates robust cybersecurity, standardized data formats, and regulated access to ensure safety and prevent counterfeit production. Moreover, training personnel to operate 3D printers and manage digital workflows is essential. In conclusion, the transition from bench-scale to large-scale production of 3D-printed pharmaceuticals is feasible but complex. Overcoming these challenges requires interdisciplinary collaboration among formulation scientists, engineers, regulatory experts, and supply chain professionals.

8. FUTURE PERSPECTIVES AND OPPORTUNITIES

The future of 3D printing in drug formulation is bright, driven by the increasing demand for personalized medicine, technological advancements, and a growing understanding of materials science and regulatory requirements. While current limitations exist, ongoing innovations promise to overcome these hurdles and redefine pharmaceutical manufacturing.

8.1 Advancements in Printing Technologies

Emerging 3D printing techniques such as continuous liquid interface production (CLIP), multi-material printing, and hybrid manufacturing platforms are expected to enhance speed, resolution, and material diversity (Chai et al., 2017). Integration with artificial intelligence (AI) and machine learning will enable predictive modeling and adaptive printing processes.

This will allow real-time adjustments during fabrication, leading to greater precision and consistency in drug production. Microfluidics and bioprinting are also gaining attention for producing complex, multi-compartmental dosage forms and organ-on-a-chip systems, opening new avenues for personalized drug screening and delivery.

8.2 Personalized and On-Demand Medicine

As healthcare shifts towards patient-centered models, 3D printing offers unmatched potential in delivering customized therapies. Pharmacogenomics, wearable devices, and mobile health platforms can be integrated with 3D printing workflows to produce patient-specific medications in real time (Sadia et al., 2016). Pharmacies and hospitals equipped with desktop 3D printers may become mini-manufacturing hubs, capable of producing medication tailored to an individual's age, weight, genetic profile, and disease state. Such decentralization could drastically reduce drug wastage, minimize supply chain delays, and improve therapeutic outcomes by ensuring optimal dosing and adherence.

8.3 Sustainability and Eco-Friendly Manufacturing

3D printing promotes a more sustainable pharmaceutical industry by reducing raw material usage, lowering carbon footprints, and enabling localized production. Recyclable materials and energy-efficient printers further enhance its environmental appeal (Khaled et al., 2014). Future research may focus on developing biodegradable polymers and solvent-free printing processes to align with green chemistry principles.

8.4 Challenges and Research Directions

Despite promising opportunities, several challenges remain. Limited material choices, regulatory uncertainty, high initial costs, and technical complexity continue to restrict widespread adoption. Collaborative research between academia, industry, and regulatory bodies is essential to expand the material library, establish safety standards, and develop user-friendly systems. Training programs and knowledge-sharing platforms will play a pivotal role in building the next generation of pharmaceutical professionals skilled in 3D printing. In conclusion, 3D printing holds transformative potential in pharmaceuticals. With sustained investment,

regulatory support, and scientific innovation, it is poised to become a cornerstone of modern drug delivery systems.

9. CONCLUSION

3D printing has emerged as a groundbreaking technology in drug formulation, particularly in the context of personalized medicine. Its ability to create complex, customizable dosage forms tailored to individual patient needs represents a significant shift from the traditional one-size-fits-all approach. The adoption of 3D printing enables the production of medicines with precise dosages, controlled release profiles, and enhanced patient compliance. Technologies such as FDM, SLA, and SLS have demonstrated promising results in preclinical and clinical settings, while innovative materials and drug-excipient combinations continue to expand the frontiers of pharmaceutical manufacturing. However, several challenges must be addressed to realize its full potential. Regulatory frameworks are still evolving to accommodate this disruptive technology, with the FDA's approval of Spritam® marking an important milestone. Scale-up complexities, cost barriers, and integration into existing supply chains also pose considerable obstacles. Despite these challenges, ongoing research and collaboration among stakeholders industry, academia, and regulatory agencies are paving the way for more robust, efficient, and patient-centered drug delivery solutions. With sustained investment and policy support, 3D printing could become an integral component of the pharmaceutical landscape, revolutionizing how medicines are designed, manufactured, and administered. The future lies in harnessing the full capabilities of 3D printing to transform personalized medicine from a vision to a widespread reality. This requires a multidisciplinary approach and a willingness to embrace technological evolution for better healthcare outcomes.

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