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Review Article

Recent Progress in 3D Printing of Pharmaceuticals: Personalized Medicine and On-Demand Dosage Forms

Abubakar Mohamedali Omer Idress[1], Amgad Gamal Abdulrahman Abbas[1], R. Shirisha[2], K. Venkata Janardhanreddy[2], M. Rizwana[2], Nawaz Mahammed[2,*]

[1]Department of Industrial Pharmacy, Raghavendra Institute of Pharmaceutical Education and Research, Anantapur, Chiyyedu, Andhra Pradesh, INDIA.
[2]Department of Pharmaceutics, Raghavendra Institute of Pharmaceutical Education and Research, Anantapur, Chiyyedu, Andhra Pradesh, INDIA.

ABSTRACT

Additive manufacturing (also referred to as 3D printing, 3DP) has become a disruptive technology in the pharmaceutics industry, providing an opportunity to produce individualized and custom dosage forms on demand. In contrast to traditional manufacturing where batch production is used, 3DP has the ability to control drug dose, geometry, and release profiles accurately thereby managing interpatient variability and enhancing therapeutic outcomes. To show the clinical viability of 3D printed medicines, the FDA approval of Spritam® (levetiracetam) in 2015 was a milestone. Other types of 3DP technology, including inkjet printing, Fused Deposition Modelling (FDM), Selective Laser Sintering (SLS), stereolithography (SLA), and Semi-Solid Extrusion (SSE), have been effectively used to print custom formulation as polypills, orally disintegrating tablets, and implants. Such innovations can improve patient compliance, maximize pediatric, geriatric, and chronic disease therapy and point-of-care production in the hospital, pharmacy, and resource-limited environments. Regulatory, reproducibility, and scalability issues notwithstanding, in the recent past, the field of translational 3DP in pharmaceutics has been pointed out as a promising field of research. It is likely that artificial intelligence, digital health, and telepharmacy will continue to support its contribution to precision medicine. This review provides an overview of recent advances, policy implications, and case studies with a focus on how 3DP can transform the drug delivery model and define the future of personalized healthcare.

Keywords: 3D printing, Fused deposition modelling, On-demand dosage forms, Personalized medicine, Regulatory challenges, Selective laser sintering.

Correspondence:
Dr. Nawaz Mahammed
Associate Professor, Department of Pharmaceutics, Raghavendra Institute of Pharmaceutical Education and Research, K.R. Palli Cross, Anantapur, Chiyyedu-515721, Andhra Pradesh, INDIA.
Email: mohammednawaz151@gmail.com

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INTRODUCTION

Additional manufacturing, which is also called 3D printing (3D printing) has become a disruptive technology in pharmaceutical sciences. It allows creating drug products with doses, shapes and release profiles that were previously customizable, creating a narrowing of the gap between large scale manufacturing and individual needs of patients, which is currently in increasing demand (Wang *et al*., 2023). 3D printing gives unmatched design capabilities in creating patient-specific treatment and on-demand production because it allows materials to be stacked into intricate dosage form designs (Borthakur *et al*., 2025). This portion presents the background of 3DP in the healthcare sector, its applicability to personalized medicine, and its benefits over traditional manufacturing in addition to the overview of the review scope (Serrano *et al*., 2023).

Background of 3D Printing (3DP) in Healthcare and Pharmaceuticals

The invention of 3D printing dates back to 1980s as a prototype in the engineering world and has since diversified into many other sectors such as the medical industry. The initial 3D-printed drug in pharmaceuticals was approved as Spritam® (levetiracetam) in 2015, with the FDA paving the way to 3D printing of pharmaceuticals (Saleh-Bey-Kinj *et al*., 2025). The method allows accurate positioning of Active Pharmaceutical Ingredients (APIs) and excipients in controlled patterns resulting in dosage forms with controlled release dynamics and physical characteristics. In the medical field, 3DP has been applied to surgical models, prosthetic, tissue scaffold, and medical equipment. The rise in 3DP popularity in pharmaceutics can be attributed to the fact that this system may help change the current paradigm of drug production that is centralized and one-size-fits-all to a new approach where therapies are personalized and produced on-demand (Shaikh, 2024).

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Need for Personalized Medicine and Patient-Centric Dosage Forms

Traditional drug development is based on a blockbuster approach whereby standard doses of drugs are developed and offered to large groups of patients. But due to interpatient variability in age, genetics, metabolism and comorbidities, it would be untrue to expect that a standardized dose will be optimal in most patients (Greene, 2024). Pediatrics, geriatrics, and chronically ill patients may need special dosage, non-oral dose (e.g., chewables, orodispersibles) or combination therapy (Mortazavi *et al.*, 2025). Personalized medicine aims to achieve this goal through maximizing therapeutic effect and minimizing toxicity by designing customizable dosage forms with exact quantities, sizes, shapes, and release profiles of drugs (Pandey & Gupta, 2024). 3D printing can be a potent tool to this end since it allows customization of dosage forms to include the right quantities of drugs, sizes, and shapes, as well as release characteristics. As an illustration, polypills may be printed with a combination of several drugs, which are given to patients with polydrug problems, decreasing the number of pills and increasing the adherence rate. Likewise, child friendly flavored formulations or geriatric friendly tablets that dissolve fast can be made on orders (Vaz & Kumar, 2021).

Advantages of 3DP over Conventional Pharmaceutical Manufacturing

There are a number of benefits of 3D printing as compared to the conventional pharmaceutical manufacturing methods such as compression and coating, it has dose flexibility whereby the strengths of the drugs can be customized without having different production lines, it enables intricate geometries and release profiles - such as multilayered tablets with immediate and delayed release compartments can be printed in one print, 3DP allows on-demand production, generating less storage space and ensuring medicines are made on-site at the care point, which is particularly important in remote or emergency environments. Also, 3DP is compatible with polypill manufacture, in which several drugs are combined in one dosage, which streamlines the treatment of patients with chronic illnesses. It minimizes the wastage of material, minimizes time to produce and prototyping new formulations is very fast compared to conventional methods. Notably, 3DP has prospects of decentralization, which may lead to the distribution of production not only on large production plants but also on hospital pharmacies or even homes of patients under controlled conditions. All these benefits make 3DP a disruptive technology in pharmaceutics that can serve the unmet requirement in personalized and precision medicine (Desu *et al.*, 2021; Tyagi *et al.*, 2024).

FUNDAMENTALS OF 3D PRINTING IN PHARMACEUTICS

Principles of Additive Manufacturing

Additive manufacturing works through the concept of adding layers of a 3D object based on a digital representation of the object as a Computer-Aided Design (CAD) file. In pharmaceuticals, the digital design determines, in addition to geometry of dose form, the spatial distribution of Active Pharmaceutical Ingredients (APIs), as well as excipients. The material is either deposited, melted or polymerized in layers, depending on what technology is applied, i.e. Fused Deposition Modelling (FDM), inkjet printing, Selective Laser Sintering (SLS), or Stereolithography (SLA) (Erinle *et al.*, 2023). This process provides unrivaled flexibility in the manufacture of dosage form with tailorable drug doses, complicated geometries and controlled-release profiles. As an example, one print run can be used to produce multilayer tablets that have immediate and sustained release segments. Moreover, 3DP allows the use of various APIs in one dosage, allowing the development of polypharmacy patients in polypills. Additive manufacturing therefore offers a platform of precise dosing, personalized therapy, and quick prototyping and therefore is very relevant in the production of pharmaceuticals on-demand, personalized (Bernatoniene *et al.*, 2025; Zhou *et al.*, 2024).

Old methods of pharmaceutical manufacturing (like compression, coating and extrusion) and 3D printing approaches. The traditional methods are very scalable with familiarity with the regulations, but they are not flexible in terms of dose personalization and complexity of designing. On the other hand, patient-specific dosing, new geometries and rapid prototyping are available with 3D printing, but large-scale production and regulatory standardization is still a problem (Pethappachetty *et al.*, 2025). The comparison brings out the complementary nature of 3D printing as a new technology of personalized and on-demand delivery of drugs in the market as shown in Table 1.

FDA, EMA Perspectives

3D printing in pharmaceutics is gaining acceptance as a potential opportunity by regulatory bodies but there are no formalized guidelines. The U.S. FDA defines 3D printing as a subset of additive manufacturing, which implies joining materials to create objects on 3D model data, in layers. In 2015, the approval of 3D-printed drug Spritam® (levetiracetam) by FDA has become a first step toward the approval of such drugs (Poudel *et al.*, 2024). The pharmaceutical 3D-prints cannot be classified with a single simple system because these medicines can be classified into a drug, device or a combination product, depending on their formulation and the purpose they serve. The most important regulatory issues are the validation of printing processes, material safety and consistency of batches. Regulators, academia and industry continue to debate on how to come up with standardized

frameworks that can enhance innovation but do not jeopardize the safety of patients (Tähtinen, 2023).

3D PRINTING TECHNOLOGIES FOR PHARMACEUTICALS

3D printing encompasses a variety of additive manufacturing techniques, each with distinct mechanisms, material requirements, and applications in drug delivery. The choice of technology influences the drug loading, dosage precision, release characteristics, and scalability of pharmaceutical products (Muhindo *et al.*, 2023). While some techniques, like inkjet printing, excel in micro-dosing and personalization, others like Fused Deposition Modeling (FDM) and Selective Laser Sintering (SLS) enable the fabrication of robust solid dosage forms with controlled release. Stereolithography (SLA) and Semi-Solid Extrusion (SSE) further expand the possibilities by offering complex structures and compatibility with heat-sensitive drugs. Understanding these technologies is essential to evaluate their translational potential in personalized medicine and on-demand dosage manufacturing (Pavan Kalyan & Kumar, 2022).

Inkjet Printing

Mechanism, Advantages, Limitations

Ink jet printing is a non-contact method in which droplets of ink containing drug are deposited onto a substrate. It has two main modes of operation, which include continuous inkjet and drop-on-demand. Such benefits are; control of dosage to an exact degree, use in low-dose/high-potency drugs, and the capacity of printing multifaceted patterns. In addition to this, it enables high-speed prototyping and tailoring of pediatric and geriatric medicines. Nevertheless, some of these are shortcomings such as the constraints on ink viscosity, possible loss of drugs when solvents are used, and restrictions on scalability of formulations to high dose. The technology is also susceptible to nozzle clogging and needs to be optimized on the properties of the ink very keenly to guarantee reproducibility (Daly *et al.*, 2015; Du *et al.*, 2022).

Uses in Printing Accurate Doses

Inkjet printing has been especially useful in producing individualized doses that are very precise when the number of droplets is altered and the location is altered. It has been used to print micro-tablets, films which are orodispersible and transdermal patches with an accurate amount of drug content. As an example, pediatric formulations and antihypertensive medications have been printed with appropriate dose changes to patient requirements. This has rendered inkjet printing a potential instrument of precision dosing in hospitals (Pawar *et al.*, 2025).

Fused Deposition Modeling (FDM)

Use of Thermoplastic Polymers, Extrusion-Based Printing

Fused Deposition Modeling (FDM) is one of the most popular 3DP technologies that has many applications in the field of pharmaceutics. It is a manufacturing process that includes the heating up of thermoplastic polymers (e.g. PLA, PVA, HPMC) loaded with drug molecules and the extrusion of the solution into a layer-wise mode to form a solid dosage form. Before the printing process, hot melt extrusion is employed extensively in the preparation of the drug-polymer filaments. Advantages include economy of scale, high mechanical properties of the printed product, and the opportunity to be able to achieve complex release profiles. However, the high processing temperatures used degradable heat sensitive APIs and the polymer compatibility limits the drug loading (Dubey *et al.*, 2025).

Selective Laser Sintering (SLS)

Powder-Based Method, High Drug Loading Capacity

SLS uses a high-power laser to selectively fuse powdered mixtures of drug and excipients to build up, layer by layer, into solid structures. Unlike FDM, it does not use filaments and therefore it has more flexibility in terms of the material you can use. One of the key benefits is the high drug loading, since powders can be prepared with high API loadings. Also, SLS eliminates the need to use solvents. However, the high energy input has the potential to degrade the drug, and the powder flowability/particle size distribution has to be very well controlled (Karanwad *et al.*, 2023).

Applications in Solid Dosage Forms

SLS has been successfully used in the formulation of Orally Disintegrating Tablet (ODT), high porosity and rapid dissolving system and sustained release systems. The ability to produce complex geometries and to control the porosity renders them useful in the design of advanced oral dosage forms. In addition, SLS can be used in the fabrication of implants and localised delivery systems for cancer or bone infections (Gueche *et al.*, 2021).

Stereolithography (SLA)

Photopolymerization Method

SLA involves the use of a UV or a visible light source to cure photosensitive resins selectively in a layer-by-layer process. In the pharmaceutical sector, the drug molecules are added to photocurable polymers which solidify on being exposed to light. SLA enables complex shapes and microstructures to be fabricated in high-resolution which is beneficial in innovation dosage forms (Çerlek *et al.*, 2024). The scarcity of photodegradable drugs and safety and biocompatibility of photopolymers is however a major challenge (Deshmane *et al.*, 2021).

Potential in Fabricating Complex Structures

SLA allows making extremely complex structures, including micro-Implants, personalized drug-eluting implants and geometrical complex pills with distinctive release kinetics. It has potentials in personalized drug delivery systems, particularly where low dosage potent APIs and implantable devices are concerned. The biocompatible photopolymers will be further developed in the future to give it clinical applicability (Günay & Meral, 2025).

Semi-Solid Extrusion (SSE) and Emerging Techniques

In SSE, dosage forms are constructed by extrusion of drug-containing semi-solid preparations (e.g. gels, pastes, or suspensions) through a syringe-type nozzle. It also uses lower temperatures as compared to FDM, which means that it can be used with thermolabile drugs and biologics like peptides and proteins. SSE gives great flexibility in the inclusion of an extensive number of APIs and excipients. It has been used in the production of orodispersible films, chewable tablets and topical preparations (Monaco, 2023). Nevertheless, it may be complicated to ensure consistency during extrusion and even to attain good mechanical properties. New technologies, including continuous inkjet and hybrid 3DP processes, are being explored to address shortcomings of each of the separate printing technologies. Multifunctional dosage forms with customized therapeutic properties might be possible because the various approaches (e.g., FDM with inkjet) can be combined (Zub *et al.*, 2022).

MATERIALS USED IN PHARMACEUTICAL 3D PRINTING

The optimization of dosage form to personalized medicine and on-demand through alignment of material properties and capabilities of the particular 3DP method allows researchers to optimize dosage forms as shown in Table 2.

APPLICATIONS OF 3D PRINTING IN PHARMACEUTICALS

The uses of 3D printing (3DP) in pharmaceutics go much further than simply creating convenient dosing; it is a paradigm shift to personalized medicine, types of dosages on-demand and multifunctional systems (Borthakur *et al.*, 2025). Conventional drug development is oriented on the mass production of fixed-dose preparations which do not usually accommodate interpatient variability as well as the different therapeutic requirements (Desai *et al.*, 2013). As compared, 3DP facilitates fine-tuning of dose, release kinetics and physical design of dosage forms, thus aligning to contemporary objectives of precision medicine. Combining patient-centered care with engineering innovation, 3DP offers inimitable chances to promote adherence, enhance therapeutic response and increase access to pharmaceuticals among various healthcare environments as shown in Table 3.

Personalized Medicine

Personalized medicine will focus on the customization of drug therapy based on patient needs, such as genetics, age, disease condition, and preferences, a feat that 3DP is able to accomplish due to its customized dosages and patient-centered designs.

Table 1: Comparison of 3D Printing with Traditional Pharmaceutical Manufacturing Methods.

Aspect	Traditional Methods (Compression, Coating, Extrusion)	3D Printing (Additive Manufacturing)
Principle	Bulk processing, batch manufacturing, subtractive/stepwise processes.	Layer-by-layer fabrication from digital design.
Dose Flexibility	Limited - new batch required for dose variation.	High - individualized doses possible without retooling.
Complexity of Dosage Forms	Simple tablets, capsules, coatings; complex designs require multiple steps.	Highly complex geometries achievable in a single process (e.g., polypills, multi-release tablets).
Drug Release Profiles	Mainly immediate or sustained release, using coatings or matrices.	Precise control over release kinetics; multilayer and compartmentalized systems feasible.
Scalability	Well established, suitable for large-scale mass production.	Currently limited to small- or medium-scale; scalability is a challenge.
Material Waste	Moderate, due to overages in batch manufacturing.	Low, as printing is more material-efficient.
Speed of Development	Longer prototyping times, slower optimization.	Rapid prototyping and design modifications possible.
Regulatory Familiarity	Mature, with established GMP guidelines.	Emerging, with evolving FDA/EMA regulatory frameworks.

Table 2: Common Materials Used in Pharmaceutical 3D Printing.

Category	Examples	Key Properties	Suitable 3DP Techniques	Applications	References
Polymers	PVA, PLA, PCL, HPMC, Eudragit®	Structural backbone, biocompatible, modulate drug release	FDM (PVA, PLA, PCL), SSE (HPMC), SLA (photocurable polymers)	Filaments for tablets, implants, oral films, controlled release	(Surini *et al.*, 2022)
Binders	Povidone (PVP), Starch, PEG	Provide cohesion, mechanical strength	Inkjet, SSE, FDM	Tablet hardness, oral films, structural integrity	(Monaco, 2023)
Disintegrants	Crospovidone, Sodium starch glycolate	Facilitate rapid breakup of dosage forms	SSE, Inkjet	Orodispersible tablets, fast-dissolving systems	(Pippa *et al.*, 2023)
Taste-Masking Agents	Sweeteners (sorbitol, sucralose), Flavors, Eudragit® coatings	Improve palatability, patient compliance	Inkjet, SSE	Pediatric/geriatric formulations	(Bernatoniene *et al.*, 2025)
Plasticizers	Glycerol, Sorbitol, Triethyl citrate	Enhance flexibility, reduce brittleness	SSE, FDM	Flexible oral films, chewable tablets	(Pereira *et al.*, 2020)
APIs (Low-dose)	ACE Inhibitor's	High potency, small dose requirement	Inkjet, SLA	Personalized micro-tablets, orodispersible films	(Serrano *et al.*, 2023)
APIs (High-dose)	Metformin, Levetiracetam	Require high drug loading, good thermal stability	FDM, SLS	Solid dosage forms, extended-release tablets	(Paipa-Jabre-Cantu *et al.*, 2025)
APIs (Thermolabile)	Proteins, Peptides, Vaccines	Sensitive to heat, require mild processing	SSE, Inkjet	Biologics, heat-sensitive drugs	(Abdul Rasool & Shahiwala, 2019)

Tailored Dosages for Pediatrics, Geriatrics, and Special Populations

The conventional drug formulations can be very difficult due to mismatched dose formulations in the pediatric and geriatric population, difficulties in swallowing the pills, and the formulation of these drugs, which include the lack of control over the size and geometry of the pills and load drug content and require no specific production batches. 3DP allows flexible dosing with adjustment of the pill size and geometry and drug loading without requiring a complete investment into new production batches. In the case of pediatrics, orodispersible formulations can be printed to comply with small-sized, flavored orodispersible formulations. Geriatrics Modified-release tablets that have lower dosing frequency could be created in order to improve compliance in polypharmacy settings. Uniqueness in dosage can additionally be used on patients who have rare ailments or genetic variations, which cannot be found in mainstream markets (Hanning *et al.*, 2016). Therefore, 3DP offers a direct route to patient-specific treatment, and reduces the possibility of underdose or overdose.

Patient-Centric Drug Design (Taste, Shape, Color, Swallowability)

In addition to dosage accuracy, patient acceptability is a significant factor to adherence, 3DP makes medicines easy to use by providing the opportunity to customize taste, shape, color, and texture. As a case in point, the orodispersible tablets with fruit flavors can be made chewable to children and the aesthetically pleasing tablets with color codes can be made to assist the elderly patients with polypharmacy. Tablet geometry can be altered to be easier to swallow, e.g., oral strips, which are made thin and have a film-like consistency. This is also a flexible design that gives the ability to customize drug product to cultural or psychological preferences, which enhances patient adherence. The emphasis on functionality and design contributes to a holistic patient-centric drug design, which is advanced by 3DP (Drumond, 2020).

On-Demand Dosage Forms

On-demand manufacturing has been shown to be flexible in clinical and emergency response, making medicines available at the point of need and response. 3DP can be used in the production of point-of-care and medicine delivery in remote or emergency situations.

Point-of-Care Production in Hospitals and Pharmacies

Using 3D printing, the manufacturing of drugs can be decentralized, with the hospitals or community pharmacies producing medicines in real-time depending on the needs of the patients. This does away with the reliance on mass production that is centralized and it also minimizes wastage of drugs out of expiration. An example is the case of cancer patients who get dosage changes in hospitals and get customized therapy immediately at the pharmacy. Raw materials (polymers, excipients, APIs) can be kept in pharmacies, and a formula can be manufactured there, which would guarantee fast availability and increased personalization. Such method also enables clinical trials to enjoy the advantage of flexible increases and decreases in dosage as opposed to costly batch production (Andreadis *et al.*, 2022).

Emergency or Remote Area Applications

3DP is especially useful in the emergency background or resource scarce environment, including disaster areas, military operations, or space exploration. Because drugs could be produced using stored digital blueprints and raw materials, the technology will guarantee availability of drugs even in the case of disruption of supply chains. An example would be the printing of customized antibiotics or analgesics in the disaster relief centers. NASA has already done research on the 3DP in the development of medicines in the long range of space travel, which highlights the use of the technique in remote healthcare. 3DP increases resilience to healthcare crisis because it allows on demand, local production (Subramanya & Kermanshachi, 2021).

Complex and Multifunctional Dosage Forms

With 3DP, it is possible to produce dosage forms that incorporate several functions or therapeutic activities in a single product-which is very hard to do in the context of conventional manufacturing. These are polypills, controlled release base, and novel delivery systems.

Polypills for Multi-Drug Therapy

Polypills combine various Active Pharmaceutical Substances (APIs) into one tablet, making treatment of such chronic patients as hypertension, diabetes, or HIV easier. 3DP enables building of compartmentalized structures wherein every drug retains its stability and release kinetics. As an example, a layer can offer instantaneous dishypertensive treatment whereas another can offer prolonged disdiabetic drug treatment. This will minimize pill load, increase compliance and promote therapeutic outcomes among people who need polypharmacy (Baumgartner *et al.*, 2020).

Controlled Release and Pulsatile Systems

The 3DP allows to control drug release kinetics with precise control based on infill density, geometry, and polymer composition. Tablets of bimodal release profile (e.g. immediate release and sustained release) or pulsa-lutary release (drug released at regular intervals) can be produced with a single print. This is specifically useful in chronotherapy, in which drug

Table 3: Applications of 3D Printing in Pharmaceuticals.

Application Area	Specific Focus	Examples	Key Benefits
Personalized Medicine	Tailored dosages for pediatrics, geriatrics, and special populations.	Pediatric micro-tablets, geriatric-friendly modified-release tablets.	Precise dose adjustment, improved safety, reduced adverse effects.
	Patient-centric drug design (taste, shape, color, swallowability).	Flavored orodispersible films, color-coded tablets for polypharmacy.	Enhanced patient compliance, psychological acceptability.
On-Demand Dosage Forms	Point-of-care production in hospitals and pharmacies.	Customized cancer therapies in hospital pharmacies.	Real-time availability, reduced wastage, flexible dosing.
	Emergency or remote area applications.	Medicines printed in disaster zones, military missions, or space travel.	Ensured drug supply in crisis/ remote conditions, digital blueprint-based production.
Complex & Multifunctional Dosage Forms	Polypills for multi-drug therapy.	Multi-layered tablets combining antihypertensive + antidiabetic drugs.	Reduced pill burden, improved adherence.
	Controlled release and pulsatile systems.	Chronotherapy tablets with bimodal release.	Optimized therapeutic outcomes, synchronized with circadian rhythm.
	Orally disintegrating tablets (ODTs) and implants.	Rapidly dissolving porous tablets, patient-specific implants.	Improved swallowability, localized sustained delivery.

Table 4: Commercially Available or Clinically Tested 3D-Printed Formulations.

Product / Study	Indication & Setting	Technology / Dosage Form	Key Highlights	Status
Spritam® (levetiracetam) — Aprecia	Epilepsy (adjunct therapy)	Powder-liquid 3DP (ZipDose®); highly porous ODT	First FDA-approved 3D-printed drug; rapid disintegration with a sip of water; four strengths (250-1000 mg). (Aprecia, Nature, TIME)	FDA approved (2015); on market in the U.S. (Aprecia)
Triastek T19/T20/ T21	RA; cardiovascular/clotting disorders; GI targeting	Melt-extrusion deposition (MED®) 3DP; oral solid dose	Multiple FDA IND clearances; progressing through PK/clinical studies; platform targets site-specific release in GI tract. (triastek.com, European Pharmaceutical Review, PMC)	IND-cleared; in clinical development. (triastek.com)
Hospital/point-of-care personalized meds (paediatrics)	Rare metabolic disorders; personalized dosing	Inkjet/SSE/FDM "printlets"	Prospective paediatric clinical study showed feasibility and dosing accuracy for individualized therapies. (ScienceDirect)	Clinically tested (trial/ observational study). (ScienceDirect)
M3DIMAKER™ (FabRx) implementations	Pharmacy/manufacturing small batches	Multi-tech (FDM/ SSE/inkjet) pharma-dedicated printer	GMP-oriented workflows for personalized/ on-demand production; deployed in clinical/ compounding settings. (fabrx.co.uk, ONdrugDelivery)	Commercial printer; used in pilot clinical contexts. (ONdrugDelivery)

delivery is synchronized with circadian rhythms (e.g., in asthma or arthritis). In comparison to traditional manufacturing which requires several stages of coating, 3DP attains such profiles through a single integrated manufacturing process, which increases patient outcomes and reproducibility (Nashed, 2023).

Orally Disintegrating Tablets (ODTs) and Implants

ODTs manufactured with 3DP technology can be made very porous, allowing prompt disintegration of the drug to patients who have swallowing problems. These dosage forms are very appropriate in pediatrics, geriatrics, and psychiatric patients. In addition to oral preparations, 3DP can be used to create personalized implants, provide local and prolonged delivery of drugs to cancer, bone infections, or contraceptives. Clinical utility can be further increased by the capability to create patient specific implant geometries (Wojtyłko *et al.*, 2024).

REGULATORY AND MANUFACTURING CHALLENGES

FDA's Approval of the First 3D-Printed Drug (Spritam®)

The first FDA-approved 3D-printed drug was the spitam® by aprecia pharmaceuticals, created with ZipDose® technology, a very porous tablet that dissolves quickly under the influence of a liquid (West & Bradbury, 2019). It has been approved and proves that 3DP can be taken as safe, effective, and of high quality as required by the regulations. This achievement confirmed the possibility of additive manufacturing in the production of unique dosage forms that were once challenging to produce through traditional production. Nevertheless, another issue pointed out by Spritam® was the regulatory issues- specifically in the areas of batch-to-batch reproducibility, process validation, and quality control. Since that, FDA has been holding discussions with stakeholders

to contextualize the regulation of 3D-printed pharmaceuticals, but there is no comprehensive regulation. A typical example is the Spritam® case: although it demonstrated viability on a regulatory level, it highlighted the importance of having effective structures to deal with issues of scalability, monitoring of the processes, and compliance with GMP (Reddy *et al.*, 2020).

Issues in Reproducibility, Scalability, and Cost

Reproducibility is still one of the biggest issues of pharmaceutical 3D printing. As The dosage forms are created by adding layers, small changes in the calibration of the printer, feedstock material or environmental factors can cause irregularities in drug content, mechanical strength or release profile. Another issue is the ability to scale up having done the production at personalized or small batch to the level of manufacturing at an industrial scale. Although 3DP can achieve high levels of customization, it is slower by nature than more conventional methods of mass production such as tablet compression which would shape its economic feasibility with blockbuster drugs. Also, 3D printers, special polymers and inks may be prohibitive, particularly where resources are limited. On-demand production can help to minimize storage and waste expenses, but the initial expenses of equipment and training are huge. Therefore, the challenges of reproducibility, scalability, and cost will be overcome through technological enhancements in the speed of printers, automation and cost of materials and regulatory flexibility to give industries an incentive to adopt them (Dowling *et al.*, 2020).

Quality Control and Validation of 3D-Printed Products

The Quality Control (QC) in the traditional manufacturing processes is based on the well-established GMP protocols, in-process controls, and validating batches. In 3DP, nevertheless, the quality is determined by digital designs and printing parameters, which are prone to errors and variation. Important quality features are uniformity of drug content, mechanical

Table 5: Research Highlights from the Last 5 Years.

Year	Technology / Dosage	API / Use-case	Key Finding	Source
2025	SLS tablets	Prednisone (dose titration)	Produced accurate, customized doses across a clinical range; demonstrated precision for titration therapy. (ScienceDirect)	(ScienceDirect)
2025	SLS tablets	Atomoxetine	Showed flexible small-scale manufacturing with robust content uniformity and dissolution control. (PMC)	(PMC)
2024	SLS bilayer tablets	Rosuvastatin + Aspirin (polypill)	Successful bilayer co-printing enabling combination therapy in one unit. (ScienceDirect)	(ScienceDirect)
2024	SLA (photopolymerization) review	Platform/Materials	Surveyed advances in biocompatible photopolymers and high-resolution drug devices. (ACS Publications)	(ACS Publications)
2024	General 3DP review	Multiple	Comprehensive update on oral/other dosage forms and translational trends. (ScienceDirect)	(ScienceDirect)
2024	Decentralized/on-demand case study	Efavirenz; carvedilol	Demonstrated feasibility of dispersed, point-of-care 3D-printed tablets (dispersible/laser-sintered). (Pharma Excipients)	(Pharma Excipients)
2025	Clinical framework	Trial design	Proposed practical pathway and regulatory guardrails for clinical trials with 3D-printed meds. (PMC)	(PMC)

Table 6: Case Studies of Personalized & On-Demand Printing.

Case	Patient/Setting	Tech	What Was Personalized	Outcome / Relevance
Pediatric personalized "printlets"	Children with rare metabolic disorders (hospital pharmacy)	Inkjet/SSE/FDM	Exact dose per child; flavor/shape adjustments	Demonstrated accurate dosing and feasibility for routine care; supports point-of-care use. (ScienceDirect)
ZipDose® ODT for swallowability	Patients with dysphagia/need rapid disintegration	Powder-liquid 3DP (Aprecia)	Porosity and disintegration tailored; unit-dose strengths	Improved ease of administration and adherence; first marketed 3DP drug. (Aprecia)
SLS dose-titration regimen	Adults needing steroid titration	SLS tablets	Tablet strength and geometry	High accuracy in custom doses → supports algorithm-driven titration/personalized therapy. (ScienceDirect)
Bilayer SLS polypill	Cardiovascular prevention	SLS bilayer	Fixed-dose combo (ASA + rosuvastatin)	Single-unit combination with controlled layers; adherence-oriented design. (ScienceDirect)
On-demand decentralized ARVs	Resource-limited settings / clinics	SSE/SLS	Local manufacture; dispersible formats	Feasibility for resilient supply and patient-friendly forms. (Pharma Excipients)
Triastek GI-targeted OSDs	Systemic diseases needing site-specific release	MED® 3DP	Release region/time in GI tract	IND-stage human studies; blueprint for scalable, regulated pipelines. (triastek.com)

stability, disintegration time, dissolution profile and sterility (in case of implants). As compared to mass-produced tablets, each 3D-printed object can be slightly different, which will require new methods of validation. In-line spectroscopy, thermal imaging, and machine vision are some of the real-time monitoring technologies being investigated to maintain uniform quality during the printing process. Print files, material inputs and process conditions should also be kept in digital form so they can be traced. Validation systems should ensure that the design to product process is known to produce effective and safe medicines. Therefore, the regulatory acceptance would require strong QC strategies that would integrate traditional pharmacopeial testing with new digital and process monitoring tools (Wu & Chen, 2018).

Intellectual Property and Legal Aspects

The concept of the intellectual property in the 3D printing is not limited to the traditional patent of drugs, but goes further to encompass the digital files of designs, printer configurations and proprietary printing technologies. There is a concern regarding liability, who should be liable in case of harm by a 3D-printed drug, whether it is the API supplier, the printer manufacturer, or the pharmacist, or the software designer? Moreover, decentralization of point-of-care printing makes it difficult to implement GMP and regulatory controls because hospitals or pharmacies might take up some of the functions of manufacturers. Legal systems should thus be modified to make a balance between innovation, access, and patient safety, so that there is proper licensing, traceability, and accountability. The pharmaceutical industry should also protect against the presence of fake or illicitly-sold digital blueprints that may result in products of poor quality. The response to IP and legal issues will be essential to show that the implementation of 3DP contributes to the innovation without the risk to the health of the population (Osborn, 2016).

FUTURE PERSPECTIVES

Integration with Digital Health and AI for Automated Personalized Dosing

Digital health platforms and Artificial Intelligence (AI) would be expected to transform the 3D-printed pharmaceuticals by providing personalized dosing based on data and automation. AI algorithms could receive patient-specific information, including genomics, pharmacogenomics, electronic health records, and real-time data provided by wearable gadgets. Such algorithms would then develop a dosage form that would be optimal to the therapeutic requirements of the patient, which could then be fed directly to a 3D printer to be fabricated. As an illustration, AI can identify the optimal combination of drugs and polymer, structure, and the release pattern, where the efficacy will be maximum and the side effects will be minimal. Also, AI-driven

predictive models would have an opportunity to optimize the process, increasing its reproducibility and decreasing the number of trial and error during formulation design. This digital health + AI + 3D continuum may turn the therapy process into a completely personalized one, particularly in chronic disease, oncology, and pediatrics. Nonetheless, its widespread adoption will need powerful data security platforms, regulatory approval of AI-powered processes, and health system-pharmaceutical printer interoperability (Bernatoniene *et al.*, 2025).

At-Home 3D Printing of Medicines: Potential and Risks

At-home medicine printing is one of the most dystopian uses to 3DP whereby patients or caregivers print or mill their own drugs out of licensed, digital blueprints and raw materials. The possible advantages are that this offers unparalleled convenience, on-demand access to custom doses and the minimization of reliance on pharmacy supply chains. Patients with chronic diseases would have the ability to modify doses within the medical supervision without receiving refills, and patients with rare diseases would have the ability to access commercially unavailable formulations. But this method has great dangers: due to the absence of professional control, dosing errors, misuse, or the creation of low-quality or counterfeit drugs are possible. Other concerns include maintenance of printers, quality of materials used and compliance to safety measures. Further, the legal and ethical aspects of the at-home drug manufacturing are not clear. At-home printing is technically possible, but in the near future will probably be restricted to highly managed and controlled settings (e.g., home care programs based in hospitals) instead of uncontrolled personal use (Malviya & Sharma, 2024).

Role in Precision Medicine and Telepharmacy

Precision medicine focuses on personalizing therapy according to genetic, physiological, and lifestyle information. 3DP fits the paradigm perfectly, as it allows customizing dosage, tuning drug-release, and formulation based on the specifics of the patient. Examples of such include a cancer patient that is variant in pharmacogenomic might get individualized chemotherapy dose whereas a kid might get flavored, low dose orodispersible tablets. The 3DP role will be optimised further when used alongside telepharmacy whereby digital prescriptions will be sent to a local or centralised 3D printer to print on demand. This will result in a dynamic system in which patients in remote or underserved neighborhoods will be able to get precision medications as soon as it is necessary. Telepharmacy implementation would additionally enable real time monitoring and adjustments of doses which would limit the risks of adverse drug reactions. Nevertheless, this vision needs robust IT infrastructure, harmonisation of regulation, as well as well-defined roles of quality control. Precision medicine, telehealth, and 3DP can be used together to make personalized care democratic around the world (Serrano *et al.*, 2023).

Opportunities in Developing Countries and Resource-Limited Settings

There are longstanding obstacles to the availability of affordable and quality medicines in developing countries, including weak supply chains, high prices, and the lack of local manufacturing. 3DP has the potential to introduce new solutions through providing small-scale production of vital medicines, locally, without depending on imports. With 3D printers installed in pharmacies or local hospitals, much-needed drugs could be printed on order to reduce wastage and enhance supply of drugs to rural or isolated societies. Moreover, 3DP can be used to prepare pediatric formulations, which are frequently not accessible in the low-income areas, thus mitigating the unmet healthcare requirements. This digital and portable ability of 3DP also facilitates quick implementation in humanitarian disasters, natural disasters or refugee camps. Nevertheless, the effectiveness of 3DP in the resource-scarce environments will require the availability of low-cost technologies in printers, access to low-cost raw materials, reliable power supply, and skilled labor. Government strategic partnerships with NGOs and international health agencies can make this innovation be scaled to enhance health systems in the developing world (Kamble *et al.*, 2023).

RECENT ADVANCES AND CASE STUDIES

Pharmaceutical 3D printing has been advanced very quickly over the last ten years, and has made significant gains in commercially available items, translational studies, and tailor-made on-demand uses. The most significant breakthrough was a 2015 approval of Spritam® (levetiracetam), the first FDA-approved 3D-printed drug that demonstrated the capability of 3DP to make highly porous tablets so that they disintegrated quickly as seen in Table 4. Since that time, others such as Triastek have been the first to release 3DP systems based on extrusion, and already a number of formulations have achieved FDA IND clearance to undergo clinical testing. Also, hospitals pharmacies and specialized compounding facilities have installed FabRx M3DIMAKERtm printer to formulate individualized preparations to pediatric and geriatric patients. The case studies reflect the possibility of commercial and clinical integration of 3DP technologies (Saleh-Bey-Kinj *et al.*, 2025).

Recent research has enlarged the application of 3DP in pharmaceutics substantially as shown in Table 5. Selective Laser Sintering (SLS) studies have shown high accuracy in dose titration of steroids and the production of bilayer polypills with aspirin and rosuvastatin as a cardiovascular preventive drug. Other developments in Stereolithography (SLA) have been directed towards biocompatible photopolymers to high-resolution structure, and Semi-Solid Extrusion (SSE) has been successfully implemented in decentralized, on-need production of antiretrovirals within resource-limited environments. Notably, regulatory and clinical trial systems are also undergoing to enable

the integration of 3DP-based medicines into normal practice (Keikhosravi *et al*., 2020).

Case studies also highlight the flexibility and patient-centred capabilities of 3DP depicted as shown in in Table 6. Pediatrics Personalized printlets have been created in uncommon metabolic disorders, which include the correct dosage and increased child palatability. On-demand SLS-printed prednisone tablets provided precise titration therapy in adults, whereas bilayer cardiovascular polypills provided better adherence opportunities. Also, printing methods can be implemented on a decentralized basis which implies the possibility of on-demand production of medicines in hospitals, pharmacies, and even in the field where there are necessary and flexible drug supply chains. All these developments point to the fact that 3D printing is leaving the stage of proof-of-concept research and entering clinical and commercial reality, becoming a technology foundation of personalised and on-demand medicine (Carou-Senra *et al*., 2023).

CONCLUSION

3D printing is revolutionizing pharmaceutics by enabling flexible, patient-centered drug production with customizable doses, combinations, and release profiles. Techniques like FDM, SLS, SLA, and inkjet printing support polypills, implants, and controlled-release tablets. The approval of Spritam® proved regulatory feasibility, while future applications promise on-demand, decentralized drug manufacturing. However, challenges like reproducibility, scalability, material limitations, and regulatory alignment persist. Integrating AI, digital health, and telepharmacy will further advance 3D-printed medicines, especially in precision and resource-limited healthcare. Overall, 3D printing holds immense potential to transform drug delivery and personalized treatment in modern pharmaceutics.

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ABBREVIATIONS

3D: Three-dimensional; **3DP:** Three-dimensional printing; **AI:** Artificial intelligence; **API:** Active pharmaceutical ingredient; **CAD:** Computer-aided design; **EMA:** European Medicines Agency; **FDA:** Food and Drug Administration; **FDM:** Fused deposition modeling; **GMP:** Good Manufacturing Practice; **IND:** Investigational New Drug; **MED®:** Melt extrusion deposition; **ODT:** Orally disintegrating tablet; **OSD:** Oral solid dosage; **PCL:** Polycaprolactone; **PLA:** Polylactic acid; **PVA:** Polyvinyl alcohol; **PVP:** Polyvinylpyrrolidone; **QC:** Quality control; **RA:** Rheumatoid arthritis; **SLA:** Stereolithography; **SLS:** Selective laser sintering; **SSE:** Semi-solid extrusion; **UV:** Ultraviolet; **ZIPDOSE®:** Proprietary powder-liquid 3D printing technology (Aprecia); **HPMC:** Hydroxypropyl methylcellulose; **PEG:** Polyethylene glycol; **ASA:** Acetylsalicylic acid.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTION

Abubakar Mohamedali Omer Idress conducted the literature review, gathered and organized data, and contributed to drafting the sections on 3D printing technologies and materials used in pharmaceutics. Amgad Gamal Abdulrahman Abbas contributed to writing and revising the manuscript, focusing on applications, regulatory challenges, and future perspectives, and assisted in the preparation of figures, tables, and references. Dr. Nawaz Mahammed conceptualized and supervised the overall work, provided critical insights into pharmaceutical relevance, and finalized the manuscript for submission. All authors read and approved the final version of the manuscript.

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