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Original Article

3D Printing Of Oral Solid Dosage Forms: A New Era In Drug Delivery

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ABSTRACT

The advent of three-dimensional (3D) printing technology has presented radical opportunities in the field of pharmaceutical production. Conventional approaches to manufacturing oral solid dosage products, e.g., tablets and capsules, are based on a one-size-fits-all paradigm not taking into consideration patient differences in terms of age, weight, metabolism, or disease condition. The approach of three-dimensional printing is fundamentally different: it enables every dosage form to be highly customized, including the amount of active pharmaceutical ingredient (API) it carries and the shape, size, and rate of how it releases the drug into the body. This review explores the key 3D printing technologies that are under investigation in the pharmaceutical science field, their mechanism of action, the form of oral dosage delivery that can be achieved, their clinical relevance, and the regulatory and manufacturing challenges that should be overcome before their mass adoption is a reality. It was a turning point when the United States Food and Drug Administration (FDA) approved Spritam, the first 3D-printed drug in the world, in 2015. Based on this, scientists and pharmaceutical enterprises are pushing the boundaries of additive manufacturing in medicine to enable the creation of drugs that are completely personalized, on-demand, and on-site, which would be fully utilized in the point of care.

Keywords: 3D printing in pharmaceutics, additive manufacturing, oral solid dosage forms, personalized medicine, fused deposition modeling, binder jetting, polypill, modified-release formulations, point-of-care manufacturing, AI-driven drug design, precision dosing, regulatory challenges.

INTRODUCTION

Modern medicine has achieved great progress in the discovering new drugs. Nevertheless, the manner in which those drugs are produced and administered to patients has not changed much over decades. Tablets and capsules are mostly made in large batches with a constant dose, which presupposes that all the patients with a specific condition require the same dosage of a specific medication. As a matter of fact, the correct dose differs widely among individuals based on such factors as body weight, kidney or liver activity, genetic composition, and age. Particularly children are frequently given adult tablets, which have to be broken or crushed, a practice that is inaccurate and in some cases dangerous **[1]**.

Three-dimensional (3D) printing, also referred to as additive manufacturing, is a technology based on the production of objects by adding layers one after another, starting with a digital design file. Started as an industrial prototype tool, it is now used in healthcare, making prosthetics, surgical implants, dental crowns, and, most recently, medications. In the pharmaceutical industry, 3D printing is a gift of a different kind: the opportunity to customize all the features of a drug product to a single patient. The dosage, the shape, the texture, the color, and even the

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speed or the slowness with which the drug is released can be changed without altering the production line **[2]**.

This review paper focuses on oral solid dosage forms (OSDFs) specifically tablets and related products consumed by mouth and how 3D printing is redefining the design and production of such products. Oral dosage forms are the most widely used and preferable form of drug administration across the world because it is very convenient, easily administered, and accepted by patients. The synergistic approach to the convergence of digital design, materials science, and pharmaceutical technology in this domain has tremendous potential in enhancing patient outcomes.

Overview of 3D Printing Technologies Used in Pharmaceutics

Several distinct 3D printing techniques have been studied for the production of oral dosage forms. Each works differently and is better suited to certain types of drugs, excipients, and dosage form designs. **Table 1** provides a summary of the five most widely explored technologies.

Technology	Mechanism	Advantages	Limitations
Fused Deposition Modeling (FDM)	Extrusion of thermoplastic filaments	Low cost, widely available, drug-loaded filaments	High temperatures may degrade heat-sensitive drugs
Stereolithography (SLA)	UV light cures liquid resin layer by layer	High precision, smooth surface finish	Limited biocompatible resins available
Inkjet/Binder Jetting	Liquid binder deposited onto powder bed	Fast, suitable for porous structures	Weak mechanical strength, residual solvents
Selective Laser Sintering (SLS)	Laser fuses powder particles	No need for support structures	Expensive equipment, limited pharma powders
Direct Powder Extrusion (DPE)	Powder blend directly extruded without pre-processing	Simpler workflow, less thermal stress	Still under development for pharma use

Table 1: Overview of Major 3D Printing Technologies in Pharmaceutical Oral Solid Dosage Form Manufacturing

1. Fused Deposition Modeling (FDM)

The most popular and cheapest 3D printing is FDM. It is based on the principle of melting a polymer filament, which often loaded with a drug, and depositing it in fine layers using a heated nozzle. The substance is cooled and solidified quickly, forming the solid dosage form. Tablets with complex internal geometries, which dictate how drugs are released, have been made by FDM where simple compression cannot. Nevertheless, the temperatures involved (usually 150-250°C) may cause degradation of heat-sensitive drugs, restricting their application to certain active ingredients. Researchers have been able to solve this problem by designing drug-loaded filaments with hot-melt extrusion (HME) as a prior step, which aids in the equal distribution of the API in the polymer matrix prior to printing **[3,4]**.

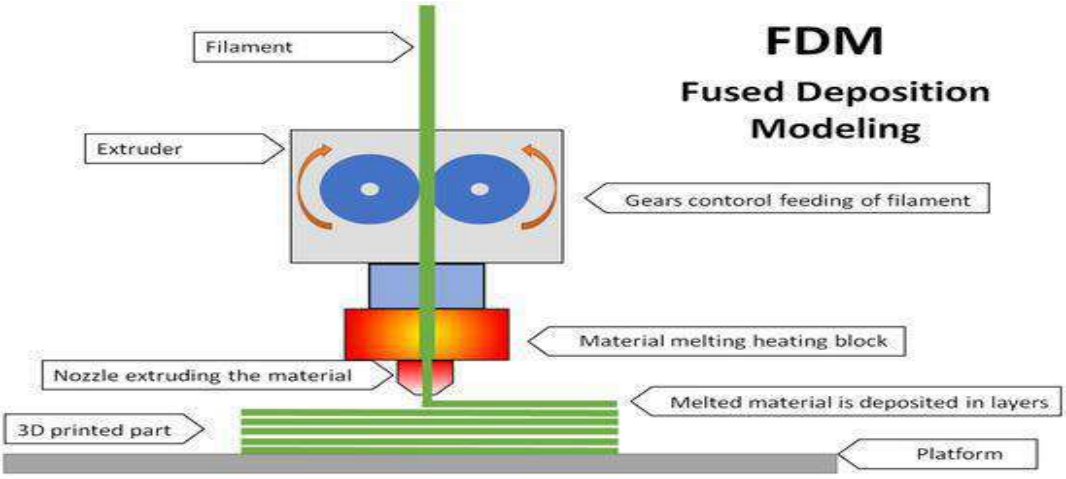

Figure 1:3D printing process using the FDM technique.

Source: https://www.mdpi.com/2076-3417/13/13/7393

2. Stereolithography (SLA)

SLA utilizes an ultraviolet (UV) light source to cure a liquid photopolymer resin, building the dosage form at a very high level of accuracy and producing smooth surface finishes. The technology is especially appealing for manufacturing extremely small or intricately shaped tablets. The primary drawback of pharmaceutical use is that not much biocompatible pharmaceutical-grade resin is available and approved to be consumed by the human being. Current studies aims to develop novel photopolymers that can satisfy structural and safety standards during ingestion **[5,6]**.

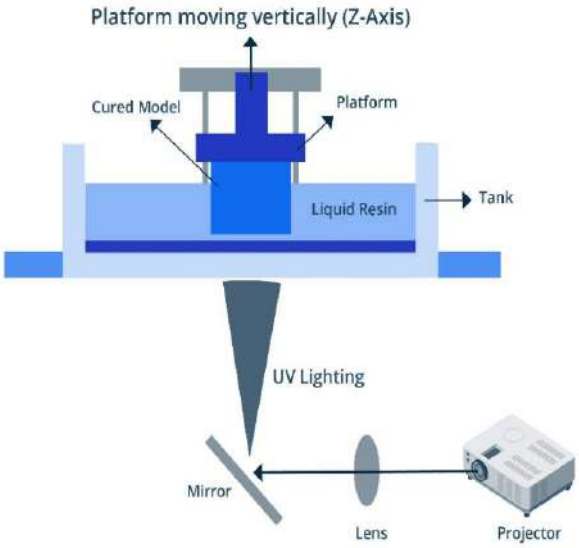

Figure 2: SLA 3D printing process

Source: https://xometry.pro/en-tr/articles/3d-printing-sla-overview/

3. Binder Jetting / Inkjet Printing.

To bond the particles together, binder jetting applies a liquid binder to a powder bed. The Aprecia Pharmaceuticals-produced FDA-approved levetiracetam tablet, Spritam, was produced using a proprietary binder jetting process called ZipDose technology. The process produces very porous pills that dissolve extremely fast when they come into contact with minimal water, hence their suitability in patients with swallowing problems. The challenge lies in achieving consistent mechanical strength and eliminating residual solvent from the binder **[7,8]**.

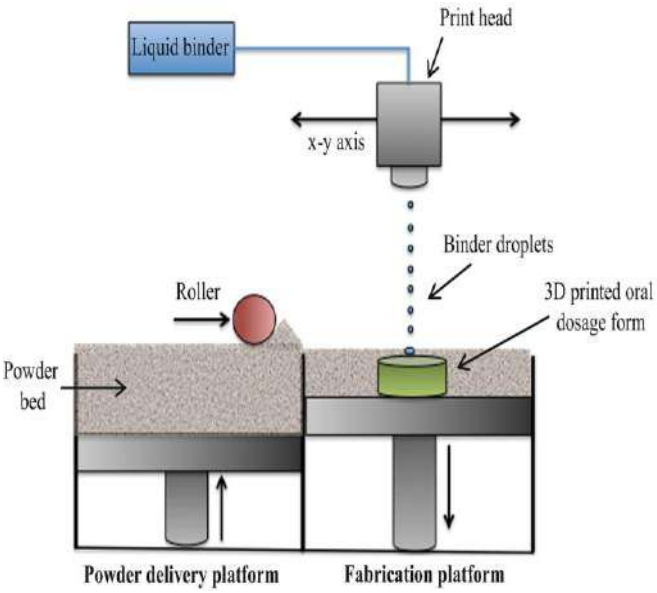

Figure 3: Binder Jet Printing process

Source: https://link.springer.com/chapter/10.1007/978-3-319-90755-0_3

4. Selective Laser Sintering (SLS)

SLS involves fusing the pharmaceutical-grade powder particles with the help of a laser without a liquid binder or support structure. The method has the ability to work with a greater range of excipient powders and generates controlled porosity tablets. Since no molds or tooling are required, SLS is highly flexible in dosage form design. The equipment is, however, very expensive compared to the FDM printers, and the range of pharmaceutical-grade powders validated for SLS is still limited [9,10].

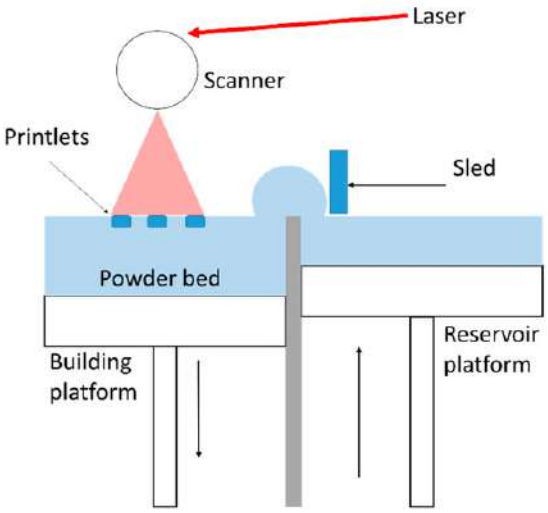

Figure 4: SLS printer printing process

Source: https://www.mdpi.com/1999-4923/13/8/1212

5. Direct Powder Extrusion (DPE)

A newer approach, DPE bypasses the need to first convert powder into a filament. The powder blend of drugs and excipients is directly fed into the printer and extruded at a controlled temperature. This streamlines the process, which may lessen the impact of thermal degradation and make personalized or smaller-batch manufacturing feasible. DPE is a relatively in early-stage pharmaceutical development but has significant potential **[11,12]**.

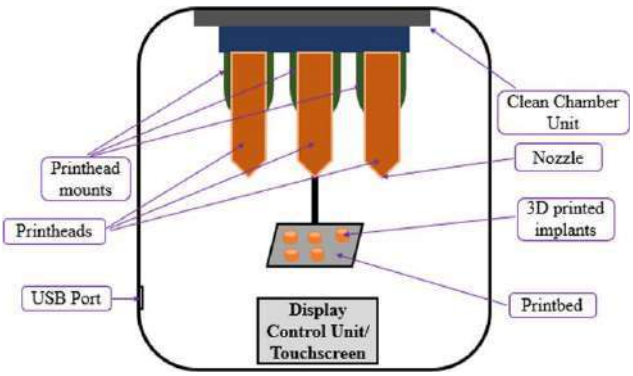

Figure 5: Direct Powder Extrusion (DPE) printing process

Source: https://www.mdpi.com/1999-4923/13/8/1212

TYPES OF ORAL SOLID DOSAGE FORMS PRODUCED BY 3D PRINTING

The oral dosage forms that can be produced using 3D printing are very diverse and can be customized. The following are the most clinically/commercially relevant examples currently studied in the field.

1. Personalized Tablets

The simplest example is the use of a tablet whose dose is modified to fit a specific patient. An example is that rather than taking a normal 10 mg pill, a pharmacist might print a 7.5 mg pill that exactly corresponds to the child's weight. Research has established that FDM and SLS can produce tablets that are within the pharmacopeial acceptance criteria and have a dose accuracy within ±5%. This degree of accuracy allows small adjustments of small dosages to be possible without re-formulation of a completely new batch **[13]**.

2. Polypills

A polypill is one medication that has several various drugs in the same product. In the case of patients who are dealing with such conditions as cardiovascular disease, hypertension, and diabetes at the same time, it is inconveniencing and challenging to take four or five different pills every day. A multi-compartment tablet (also known as a polypill) can be created using 3D printing with each drug being physically isolated in a separate layer or compartment. By doing this, every drug is able to release at its rate without undesired chemical reactions, and it also makes the

regimen easier to follow on the part of the patient and enhances compliance with medication **[14]**.

3. Modified-Release Dosage Forms

Controlling exactly when and how fast a drug is released is one of the most important aspects of pharmaceutical design. The development of tablet geometries, including hollow cores, matrix layers, or gradient compositions, which give rise to extended, delayed, or pulsatile drug release profiles, is possible with 3D printing. To protect acid-sensitive drugs, an example is a tablet with a protective outer shell and a drug-filled core that only leaks its contents when it gets to the intestine and not the stomach **[5,15]**.

4. Orodispersible Tablets and Films.

ODTs or orodispersible tablets (ODTs) dissolve or disintegrate in the mouth in seconds and do not need any water. This is very helpful to patients who find it hard to swallow, such as the elderly and young children. ODT structures with high porosity with controlled disintegration times and pleasant flavors can be built with 3D printing, particularly inkjet and SLA technology, and enhance patient compliance **[16,17]**.

CLINICAL APPLICATIONS AND PATIENT-CENTERED BENEFITS

Application Area	Drug/Formulation Type	Release Profile	Key Benefit
Personalized dosing	Pediatric and geriatric formulations	Immediate or modified	Exact dose per patient body weight/age
Polypills	Multiple APIs in one tablet	Sequential or simultaneous	Improved adherence, simplified regimens
Extended release	Chronically ill patients (e.g., hypertension)	Sustained/controlled	Once-daily dosing, better compliance
Orodispersible tablets	Dysphagia patients, children	Rapid disintegration	No water needed; dissolves on the tongue
Chewable/gummy forms	Pediatric vitamins, vaccines adjuvants	Immediate	Patient-friendly, pleasant taste, custom shape

Table 2: Clinical Applications of 3D-Printed Oral Dosage Forms

The potential of the 3D-printed OSDFs are widespread in terms of the patient population. Dose-precise, palatable, and mini-sized formulations are beneficial to the pediatric patients. It is possible to provide elderly patients with multiple chronic conditions with a personalized polypill, which could replace multiple medications. On-demand, small-scale printing may be used to serve patients with rare conditions who need orphan drugs, which are usually not available in commercial dosages. Bedside 3D printers could be used even in hospital pharmacy environments to create personalized medication for patients in intensive care **[18]**.

Another interesting application is the use of cancer chemotherapy. The chemotherapeutic agents frequently demand extremely individualized doses depending on the body surface area, organ functioning, and reaction to treatment. Oncology pharmacists could have the opportunity to make patient-specific oral chemotherapy pills with specific doses using 3D printing without the dangers of manual compounding **[19]**.

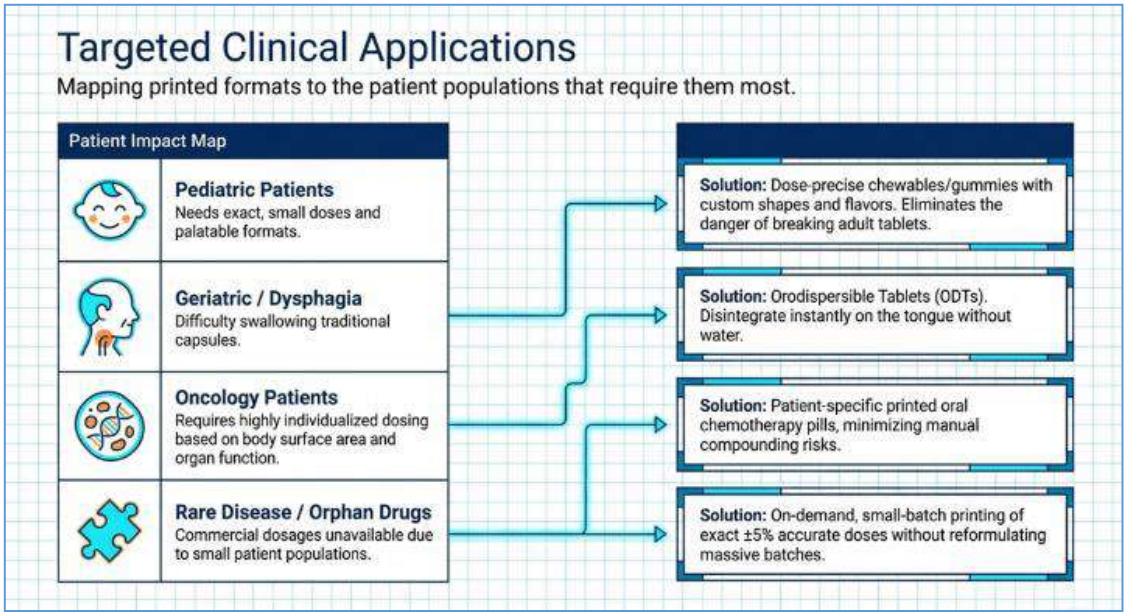

Figure 6: Patient-Centered Applications of 3D-Printed Oral Dosage Forms

PHARMACEUTICAL MATERIALS AND EXCIPIENTS USED IN 3D PRINTING

The success of 3D-printed oral dosage forms depends heavily on the materials used. Pharmaceutical-grade polymers are used as the structural matrix and, in other instances, the drug-release-controlling component. Polymers that are frequently used are hydroxypropyl methylcellulose (HPMC), polyvinyl alcohol (PVA), polyethylene oxide (PEO), and different grades of Eudragit. Such materials should be able to meet the conditions of biocompatibility, non-toxicity, acceptable melt or dissolution characteristics, and also compatibility with the selected API **[20]**.

Polyethylene glycol (PEG) and triethyl citrate plasticizers are frequently used to enhance the flexibility of filaments in FDM printing. Depending on the target formulation, solubility-enhancing agents, disintegrants, and taste-masking agents can also be added. One of the issues in the development of materials is that all ingredients should retain their chemical and physical integrity throughout the printing process, especially when elevated temperatures are required **[21]**.

Emerging work is concerned with the use of natural polymers like cellulose derivatives, starch, and gelatin as sustainable and biodegradable printing matrices. These sources are in line with the increasing popularity of green pharmaceutical production and minimization of the environmental impact of the pharmaceutical sector.

REGULATORY CONSIDERATIONS AND CHALLENGES

Regulatory Aspect	Current Status	Challenge/Opportunity
FDA Guidance	Spritam (levetiracetam) approved 2015	First 3D-printed drug approval; sets precedent
Quality control (QC)	Per-unit testing still lacking	Need real-time monitoring during printing
GMP compliance	Adapting existing GMP frameworks	Printer validation and process reproducibility

Point-of-care printing	Experimental/clinical trial stage	Pharmacist oversight, traceability needed
Intellectual Property	Evolving legal frameworks	Digital file sharing raises IP concerns

Table 3: Regulatory Landscape for 3D-Printed Oral Dosage Forms

The regulatory pathway of 3D-printed drugs remains to be established. The FDA approval of Spritam in 2015 was a first in that the approval was as a regular new drug application (NDA)—so that the 3D printing process itself was not specifically regulated but was detailed in the manufacturing part of the submission. Since that time, the FDA has released technical considerations and guidance documents accepting the peculiarities of additive manufacturing to medical products, yet broad pharmaceutical-specific regulations are being developed.

The questions to be considered as key regulatory are the following: How should 3D-printed products be tested as uniform when each unit is potentially unique? What are the ways of adapting Good Manufacturing Practices (GMP) to digital, on-demand manufacturing? What is the best approach to intellectual property in the case of drug designs, which are computer files that are transferable and duplicable? The collaboration among regulatory bodies, academic researchers, pharmaceutical companies, and patient advocacy is needed to answer these questions.

There is the idea of point-of-care (POC) manufacturing—printing drugs in a hospital, pharmacy, or even at home—which puts even more regulatory complexity in place **[22]**. Every printing location would practically be a production location, and it would need oversight and validation. The use of real-time process analytical technology (PAT) tools has the potential to be critical to ensure the accuracy of doses and quality of dosage forms is achieved during printing instead of post-manufacture **[23]**.

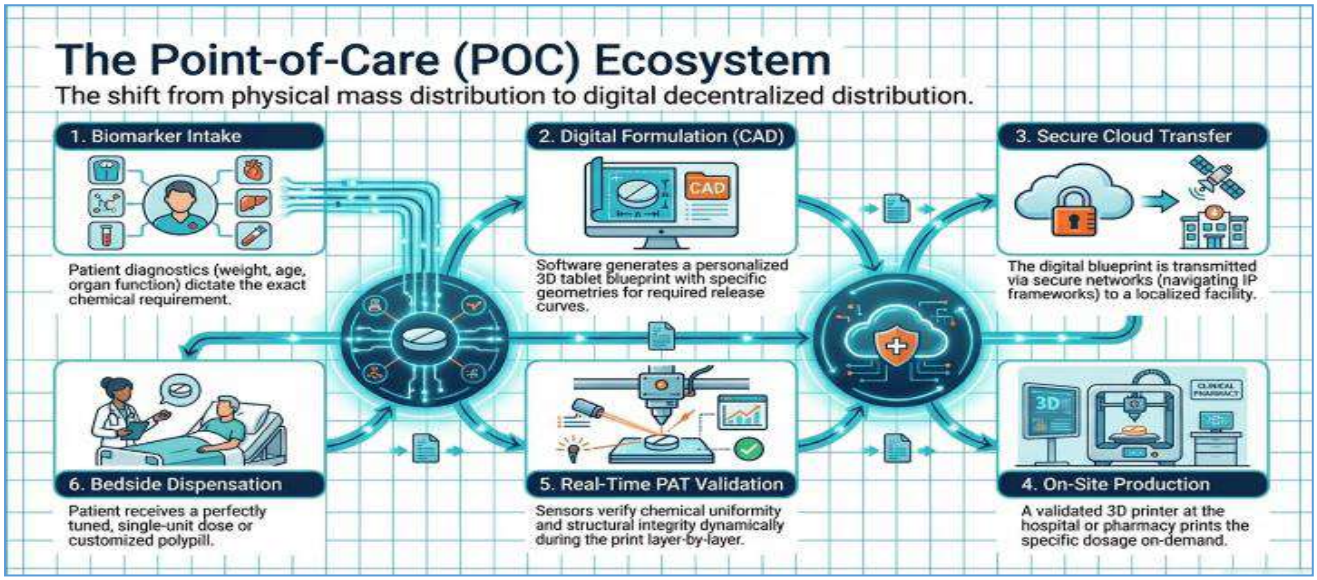

Figure 7: Schematic representation of the point-of-care (POC) ecosystem for 3D-printed oral solid dosage forms

LIMITATIONS OF THE CURRENT AND FUTURE.

Although there have been impressive advances, there are still a number of limitations between the research and clinical reality. Speed of printing is also a weakness: 3D printing a batch of 100 personalized tablets is still much slower than the traditional tablet compression. The need to scale up without sacrificing personalization is a paradox in scaling up that has to be addressed by smarter automation and non-stop printing systems.

The variety of drugs that may be incorporated successfully into 3D-printed dosage forms is also restricted. There are numerous potent drugs with small concentrations (micrograms), and to have uniform distribution at this low concentration in a printed matrix must have very tight control of formulation and process. Drugs that are highly soluble can leach unevenly during binder jetting, and drugs that do not dissolve well might have to be subjected to special amorphous dispersion methods prior to printing.

Another factor is cost. Although 3D printing consumes less waste and removes the need to produce in large batches and use small populations of patients in small-population drugs, the initial cost of equipment, technical skills, and the cost of developing materials may be high. With the maturity of the technology and increasing validation of pharmaceutical-grade materials, the costs will drop.

The future studies are anticipated to be in artificial intelligence (AI)-guided formulation design, where machine learning algorithms suggest printing parameters, excipient combinations, and geometry according to the desired pharmacokinetic results **[24]**. Combination hybrid printing methods that integrate two or more technologies of 3D printing to form complex multi-layered dosage forms are also in active research. Another frontier to consider is bioprinting of drug-loaded hydrogels of highly soluble or biological drugs.

CONCLUSION

Three-dimensional printing is a true paradigm shift in the manufacture and delivery of drugs. It removes the fundamental constraints of traditional manufacturing by allowing the creation of oral solid dosage forms with customizable doses, geometry, and release profiles that are digitally controlled and can be manufactured. The clinical implications, especially the pediatric dosing, polypharmacy, rare disease, and customized oncology, are enormous.

Although there are still major issues regarding the aspects of regulatory frameworks, speed of printing, availability of materials, and cost, the trajectory is clear and promising. The approval of Spritam was not an end point but a beginning. With ongoing collaboration between pharmaceutical scientists, engineers, clinicians, and regulators, 3D printing will become a common and indispensable pharmaceutical tool—a new era of medicine in which every patient can be provided with a medication that is specifically designed for them.

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