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Review Article

3D Printing (Additive Manufacturing) in Pharmaceutical Drug Delivery: Technologies, Materials, Applications, and Future Perspectives

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ABSTRACT

Three-dimensional (3D) printing, or additive manufacturing, has emerged as a transformative technology in pharmaceutical drug delivery, enabling the layer-by-layer fabrication of dosage forms with patient-specific dose, geometry, and release profile that conventional tableting cannot achieve. Since the 2015 FDA approval of Spritam (levetiracetam), manufactured using Aprelia Pharmaceuticals' binder-jetting-based ZipDose technology, pharmaceutical 3D printing has progressed from a novel manufacturing curiosity to an actively researched platform spanning fused deposition modeling (FDM), stereolithography/digital light processing (SLA/DLP), selective laser sintering (SLS), binder jetting, and semi-solid extrusion (SSE). This review consolidates the principles, classification, materials, formulation strategies, and process parameters underlying each major 3D printing technology used in pharmaceutics, and examines their applications in personalized dosing, polypill development, pediatric and geriatric formulations, orphan drug manufacturing, and modified-release dosage form design. The evaluation framework specific to printed dosage forms, persistent manufacturing and regulatory challenges, and the emerging integration of Quality by Design (QbD) and artificial intelligence/machine learning into print-parameter optimization are also discussed. Finally, the review considers future directions—point-of-care and decentralized manufacturing, 4D (stimuli-responsive) printing, and sustainable additive manufacturing—as the technology moves toward routine clinical translation.

INTRODUCTION

1.1 Definition and Concept

Three-dimensional (3D) printing, also known as additive manufacturing (AM), is a digital manufacturing process in which a three-dimensional object is built layer by layer directly from a computer-aided design (CAD) file, in

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contrast to subtractive or formative conventional manufacturing methods.^{1,2}

In pharmaceuticals, this layer-by-layer construction allows a dosage form's internal architecture, drug distribution, and release-controlling geometry to be engineered with a degree of precision and complexity unattainable by compression-based tableting.^{2,3}

1.2 Evolution from Conventional to Additive Manufacturing in Drug Delivery

Conventional solid oral dosage form manufacturing—direct compression, wet/dry granulation, and multilayer compression—is optimized for large-scale, fixed-dose, fixed-geometry production.³

The pharmaceutical translation of 3D printing began with powder-liquid binder-jetting technology developed at the Massachusetts Institute of Technology in the late 1980s, which Aprelia Pharmaceuticals later commercialized as ZipDose Technology, culminating in the 2015 FDA approval of Spritam (levetiracetam)—the first 3D-printed drug product to reach market.^{4,5,6}

Since then, pharmaceutical research has expanded to include FDM, SLA/DLP, SLS, and semi-solid extrusion platforms, each offering different trade-offs in resolution, materials compatibility, and drug-loading capacity.^{1,7,8}

1.3 Need for Personalized/Precision Dosing

Patient populations (pediatric, geriatric, renally/hepatically impaired) often require doses that fall between commercially available tablet strengths, historically addressed by tablet splitting or compounding—both associated with dosing inaccuracy.^{3,9}

Polypharmacy in chronic disease management creates a need for multi-drug, multi-release-rate dosage forms (polypills) that conventional bilayer/multilayer compression can only partially address.^{9,10,11}

Orphan and low-volume drug manufacturing is economically difficult with conventional large-batch tableting infrastructure, whereas 3D printing supports small-batch, on-demand production.^{2,3}

1.4 Scope and Objectives of the Review

This review consolidates the principles, classification, materials, formulation strategies, applications, evaluation methodology, and regulatory context of pharmaceutical 3D printing, with particular attention to the Spritam case study, the emerging QbD framework for printed dosage forms, and the integration of artificial intelligence into print-parameter optimization.

2. PRINCIPLES OF PHARMACEUTICAL 3D PRINTING

2.1 General Workflow

Pharmaceutical 3D printing follows a common digital workflow regardless of the specific technology used: a dosage form is first designed in CAD software, specifying external geometry, internal infill pattern/density, and (for multi-material printers) the spatial distribution of each drug-loaded material; the CAD model is then converted into a machine-readable format and 'sliced' into sequential cross-sectional layers; the printer then fabricates the object by depositing, curing, sintering, or binding material layer by layer according to the sliced file.^{1,2}

2.2 Concept of Personalized Dose, Shape, and Release Engineering



Because each printed object originates from a digital file, the dose can be adjusted simply by altering the object's volume or infill density, without requiring new tooling, compression punches, or a new formulation batch—a fundamental departure from conventional tablet manufacturing where each new dose strength typically requires a new blend and compression run.^{2,3,9}

Internal geometry (infill percentage, channel structures, shell thickness) can additionally be used to program drug release kinetics directly into the object's architecture, independent of excipient selection alone.^{1,3}

2.3 Advantages Over Conventional Tableting

- Dose flexibility and titration without reformulation.^{2,3,9}
- Complex, multi-drug, multi-layer, or multi-release-rate geometries (e.g., core-shell, compartmentalized polypills) achievable in a single fabrication run.^{10,11}
- On-demand, small-batch, or point-of-care manufacturing potential, reducing dependency on centralized large-scale production for low-volume or personalized products.^{1,3}
- Novel disintegration/porosity behavior, exemplified by Spritam's rapidly disintegrating, high-drug-load porous matrix.^{4,5}

3. CLASSIFICATION OF 3D PRINTING TECHNOLOGIES

3.1 Fused Deposition Modeling (FDM)

FDM operates by material extrusion: a thermoplastic polymer filament is heated to a

semi-molten state and extruded through a heated nozzle, depositing material layer by layer onto a build platform.^{7,8}

In pharmaceutical applications, drug-loaded filaments are typically prepared by hot-melt extrusion (HME) prior to printing. FDM offers a print resolution of approximately 40 μm and is widely used owing to its relatively low cost and operational simplicity, though it requires thermally stable drugs given the elevated processing temperatures.^{7,8}

3.2 Stereolithography (SLA) / Digital Light Processing (DLP)

SLA/DLP systems use a UV or visible light source to selectively photopolymerize (cure) a liquid resin layer by layer, building the object from a vat of photocurable material.^{7,8}

SLA offers the highest resolution among the major pharmaceutical AM techniques, down to approximately 10 μm , but requires the drug to be compatible with a photopolymerizable resin system and to withstand UV exposure.^{7,8}

3.3 Selective Laser Sintering (SLS)

SLS uses a laser (commonly a blue diode laser in pharmaceutical systems) to selectively sinter particles within a powder bed, fusing them layer by layer into a solid structure without the need for a binder liquid.^{7,8}

SLS-printed oral solid dosage forms have shown particular value for modulating internal porosity, which directly influences disintegration and dissolution behavior, and has been explored for improving compliance in fragile patient populations.^{7,8}

3.4 Binder Jetting (Powder-Bed and Inkjet Printing)



Binder jetting deposits a liquid binder onto a powder bed to selectively bind powder particles layer by layer, building a porous solid structure.^{4,5}

This is the technology underlying Aprecia's ZipDose platform and Spritam, and is notable for its ability to incorporate very high drug loads (up to 1,000 mg per unit dose) while producing a porous matrix that disintegrates rapidly with minimal liquid.^{4,5}

3.5 Semi-Solid Extrusion (SSE) / Pressure-Assisted Microsyringe (PAM)

SSE extrudes a semi-solid paste or gel formulation (rather than a molten filament or liquid resin) through a nozzle under applied pressure, building

the object layer by layer at or near room/body temperature, making it well suited to thermolabile drugs that cannot withstand FDM's processing temperatures or SLA's photoinitiator/UV exposure.^{2,3}

3.6 Material/Inkjet Jetting

Inkjet-based systems deposit small, precisely controlled droplets of drug-containing liquid or ink onto a substrate or powder bed, offering fine dose control at very small unit volumes, and are increasingly explored for personalized, low-dose applications.^{2,3}

3.7 Comparative Overview

TABLE 1. COMPARATIVE OVERVIEW OF MAJOR PHARMACEUTICAL 3D PRINTING TECHNOLOGIES.^{7,8}

Technology	Mechanism	Resolution	Materials	Key Advantage	Key Limitation
FDM	Material extrusion	≈ 40 μm	Thermoplastic filaments (drug-loaded via HME)	Low cost, simple operation, wide polymer choice	Requires thermally stable drugs; high processing temperature
SLA / DLP	UV/ light photo-polymerization	≈ 10 μm (highest)	Photocurable resins	Highest resolution; smooth surface finish	Requires photocurable resin; UV-sensitive drug compatibility concerns
SLS	Laser sintering of powder bed	≈ 20 μm	Sinterable polymer/drug powders	No solvent/binder needed; tunable porosity	Laser heating limits pharmaceutical powder options
Binder Jetting	Liquid binder onto powder bed	Moderate	Powder blends + aqueous binder	Very high drug loading (up to 1000 mg); rapid disintegration (Spritam)	Mechanically fragile structures
Semi-Solid Extrusion (SSE)	Extrusion of paste/gel	Moderate	Gels, pastes, semi-solid drug-polymer mixtures	Room-temperature processing; suits thermolabile drugs	Lower mechanical strength; slower processing

4. MATERIALS AND EXCIPIENTS FOR 3D-PRINTED DOSAGE FORMS

4.1 Materials by Technology

FDM (thermoplastic filaments): polyvinyl alcohol (PVA), hydroxypropyl cellulose (HPC), Eudragit grades (e.g., EPO, RL/RS), polycaprolactone (PCL).^{7,8}



SLA/DLP (photopolymer resins): PEG-diacrylate and other photocurable monomers/oligomers formulated with a photoinitiator.^{7,8}

SLS (sinterable powders): polymer powders such as polyamide-type materials and thermoplastic polyurethane (TPU), alongside pharmaceutical-grade sinterable excipient powders.^{7,8}

Binder jetting (powder + binder): powder blends of drug and hydrophilic excipients bound by an

aqueous binder solution, as used in ZipDose Technology.^{4,5}

SSE (gels/pastes): hydrogel- or paste-based drug-polymer semi-solids, often hydrophilic polymer matrices suited to room-temperature extrusion.^{2,3}

4.2 Table of Commonly Used Materials and Functional Roles

TABLE 2. MATERIALS AND EXCIPIENTS COMMONLY USED ACROSS PHARMACEUTICAL 3D PRINTING TECHNOLOGIES.^{4,5,7,8}

Material Category	Representative Examples	Functional Role
Thermoplastic polymer (FDM)	PVA, HPC, Eudragit EPO/RL/RS, PCL	Forms the printable filament matrix; controls mechanical strength and release
Photopolymer/resin (SLA)	PEG-diacrylate, photocurable acrylate oligomers	UV-curable matrix; determines print resolution and surface finish
Photoinitiator (SLA)	Common UV-activated initiators	Triggers photopolymerization/curing on light exposure
Sinterable powder (SLS)	Polyamide-type powders, TPU	Powder-bed substrate fused by laser sintering
Binder liquid (binder jetting)	Aqueous binder solution	Selectively binds powder-bed particles to form the porous matrix
Plasticizer	PEG, triethyl citrate	Lowers processing temperature/improves filament flexibility for FDM
Release modifier	Eudragit (pH-dependent grades), HPMC	Adjusts drug release rate/site across technologies

5. FORMULATION STRATEGIES

5.1 Drug-Loaded Filament Preparation (FDM)

Drug-loaded filaments for FDM are commonly prepared by hot-melt extrusion, in which drug and thermoplastic polymer are blended under heat and shear to form a homogeneous, printable filament of consistent diameter, directly linking pharmaceutical HME expertise to FDM-based printing.^{7,8}

5.2 Photopolymer-Drug Ink Formulation (SLA)

The drug must be dispersed or dissolved within a photocurable resin system while preserving both

printability (viscosity, cure depth) and drug stability under UV/visible light exposure.^{7,8}

5.3 Powder-Drug Blend Preparation (SLS / Binder Jetting)

Drug and excipient powders are blended to achieve uniform distribution and appropriate particle size/flow for either laser sintering (SLS) or selective binder deposition (binder jetting), as exemplified by the ZipDose powder-liquid platform.^{4,5,7,8}

5.4 Paste/Gel Formulation (SSE)

Drug is incorporated into a semi-solid hydrogel or paste vehicle with rheological properties (yield



stress, viscosity recovery) tuned for extrusion through a fine nozzle while retaining shape post-deposition.^{2,3}

5.5 Solubility and Stability Considerations

Across all techniques, formulation scientists must reconcile drug solubility/stability with the physical and thermal/photochemical demands of the chosen printing process—thermal stability for FDM, photostability for SLA, sintering-temperature stability for SLS, and aqueous stability for binder jetting and SSE.^{7,8}

6. DESIGN AND PROCESS PARAMETERS

6.1 CAD Design and Dosage Form Architecture

Infill density, internal channel/lattice structures, geometry (surface-area-to-volume ratio), and shell thickness are primary design levers used to program drug release behavior directly into the printed object.^{1,2,3}

6.2 Critical Process Parameters by Technology

TABLE 3. REPRESENTATIVE CRITICAL PROCESS PARAMETERS BY 3D PRINTING TECHNOLOGY.^{7,8}

Technology	Key Critical Process Parameters
FDM	Nozzle temperature, print speed, layer height, infill density
SLA/DLP	Light intensity/exposure time, layer thickness, resin viscosity
SLS	Laser power, scan speed, powder-bed temperature, layer thickness
Binder Jetting	Binder saturation level, powder-bed density, drying time
SSE	Extrusion pressure, nozzle diameter, deposition speed

6.3 Software and Slicing Considerations

Slicing software converts the CAD model into machine instructions and governs layer resolution, print orientation, and support-structure generation,

all of which influence final dosage-form mechanical integrity and drug-release behavior.^{1,2}

7. APPLICATIONS IN DRUG DELIVERY

7.1 Personalized/Precision Dosing

3D printing allows dose and, where relevant, shape/geometry to be adjusted per patient without new tooling, directly supporting precision-dosing needs in narrow-therapeutic-index drugs and individualized titration regimens.^{2,3,9}

7.2 Polypills and Multi-Drug, Multi-Layer Dosage Forms

Multi-material and multi-nozzle printers have been used to fabricate polypills incorporating several APIs with independently controlled, compartmentalized release profiles within a single printed unit—a natural extension of bilayer tablet principles into a higher-complexity, digitally customizable format.^{10,11}

AI-assisted design approaches have specifically been applied to multi-layer, multi-drug capsule/tablet architectures to predict and control release profiles for personalized medicine.¹¹

7.3 Pediatric and Geriatric-Friendly Formulations

Printed dosage forms can be engineered with reduced size, altered disintegration behavior, or flavored/shaped presentations, and Spritam itself was specifically designed to address swallowing difficulty through its rapidly disintegrating porous ZipDose matrix—a challenge reported by 40–50% of U.S. adults for conventional tablets and capsules.^{4,5,6}

7.4 Orphan and Low-Volume Drug Manufacturing



The absence of dedicated compression tooling requirements makes 3D printing economically attractive for small-batch or orphan-drug production runs relative to conventional large-scale tableting infrastructure.^{2,3}

7.5 Modified-Release Systems via Printed Geometry

Immediate, sustained, pulsatile, and delayed-release behavior can be engineered directly through printed geometry (e.g., shell thickness, core-shell architecture, infill density) in addition to, or instead of, conventional excipient-based release control, as demonstrated in container-tablet designs for multi-drug self-nanoemulsifying delivery systems.¹

7.6 Implants and Drug-Eluting Devices

Beyond oral dosage forms, additive manufacturing has been applied to patient-specific implants and drug-eluting medical devices, leveraging the same digital-design-to-fabrication workflow used for oral solids.^{1,2}

8. REGULATORY MILESTONE AND CASE STUDY: SPRITAM®

In August 2015, the U.S. FDA approved Spritam (levetiracetam), developed by Aprelia Pharmaceuticals, as the first 3D-printed prescription drug product to reach the market, indicated as adjunctive therapy for partial-onset seizures, myoclonic seizures, and primary generalized tonic-clonic seizures in adults and children with epilepsy.^{4,5,6}

Spritam is manufactured using Aprelia's proprietary ZipDose Technology, a binder-jetting-based platform originally developed at the Massachusetts Institute of Technology, which combines formulation science with 3D printing to produce a highly porous tablet matrix capable of

incorporating a high drug load—up to 1,000 mg in a single dose—while disintegrating rapidly in the mouth with just a sip of liquid.^{4,5,6}

This directly addressed a recognized clinical need: difficulty swallowing conventional tablets and capsules, reported by an estimated 40–50% of U.S. adults.⁶

8.1 Lessons from the Spritam Approval Pathway

- Demonstrated that a 3D-printed solid oral dosage form could meet the same quality, safety, and efficacy standards as conventionally manufactured products under existing FDA regulatory pathways, without requiring an entirely new regulatory category.^{4,5}
- Established binder jetting as a commercially viable, GMP-scalable pharmaceutical 3D printing technology, manufactured in a regulated commercial-scale facility.⁶
- Signaled that high drug-load, rapidly disintegrating architectures—difficult to achieve with conventional compression—represent a clear differentiated value proposition for pharmaceutical 3D printing, rather than novelty alone.^{4,5,6}

9. EVALUATION PARAMETERS FOR 3D-PRINTED DOSAGE FORMS

- Dimensional accuracy and weight uniformity—verifying that the printed object matches the CAD-specified dimensions and target dose.^{1,2}
- Mechanical strength/hardness—particularly important for porous binder-jetted or SLS structures, which can be more fragile than compressed tablets.^{4,5}



- Drug content and content uniformity—critical where multiple drugs are deposited in spatially distinct regions of a multi-material print.^{10,11}
- Disintegration and dissolution testing—assessing both overall release rate and, where geometry-programmed release is used, correlation with the designed infill/shell architecture.^{1,3}
- Microstructural characterization—scanning electron microscopy (SEM) and X-ray micro-computed tomography (micro-CT) to visualize internal porosity, layer adhesion, and printed architecture.^{7,8}
- Drug–polymer compatibility—FTIR, DSC, and XRD studies to confirm absence of degradation or unwanted interaction introduced by thermal (FDM/SLS), photochemical (SLA), or aqueous (binder jetting) processing.^{7,8}
- Stability studies—accelerated and long-term testing appropriate to the specific printed matrix's moisture sensitivity and porosity.^{7,8}

10. CHALLENGES IN PHARMACEUTICAL 3D PRINTING

- Scale-up and throughput limitations: most pharmaceutical 3D printers are optimized for small-batch or unit-dose production, and translating this to commercial-volume throughput remains a significant engineering challenge relative to high-speed rotary tablet presses.^{1,2,3}
- GMP compliance and quality control of printed batches: ensuring batch-to-batch and even unit-to-unit consistency in a technology designed around customization requires new

quality control paradigms distinct from traditional batch-uniformity testing.^{1,2}

- Printer/hardware variability and reproducibility: differences between printer models, nozzle wear, and calibration drift can affect dose accuracy and release behavior over time.^{7,8}
- Limited excipient/polymer library qualified for pharmaceutical printing: comparatively few polymers and excipients have established pharmaceutical-grade printability data relative to the large excipient library available for conventional tableting.^{7,8}
- Regulatory framework gaps: existing batch-release and validation paradigms were designed for homogeneous, large-batch conventional manufacturing and require adaptation for a technology capable of producing individualized, single-unit doses.^{1,2}
- Cost considerations: equipment, qualified materials, and per-unit production costs can exceed conventional tableting for standard (non-personalized) dose strengths, limiting near-term applicability to cases where personalization or complex architecture provides clear clinical value.^{1,2,3}

11. QUALITY BY DESIGN (QbD) IN 3D-PRINTED FORMULATIONS

As with bilayer and other complex oral dosage forms, a systematic, risk-based QbD approach is increasingly applied to 3D-printed formulation development to build quality into the printed product by design.^{1,2}

11.1 CQAs, CMAs, and CPPs Specific to Additive Manufacturing



Print-specific CQAs include dimensional accuracy, drug content uniformity across the printed object, mechanical integrity, and release-profile conformity to the designed geometry. CMAs include filament/resin/powder material properties (viscosity, particle size, thermal behavior), while CPPs are technology-specific as outlined in Table 3 (Section 6.2).^{7,8}

11.2 DoE Approaches for Print-Parameter Optimization

Design of Experiments methodology—mapping the relationship between CPPs (e.g., nozzle temperature and print speed for FDM, or laser power and scan speed for SLS) and CQAs (e.g., dissolution profile, hardness)—supports construction of a validated design space for a given printed dosage form, mirroring the DoE approach already established for bilayer and other complex tablet systems.

11.3 PAT and In-Line Monitoring

Process analytical technology integrated directly into the print process (e.g., in-line imaging or spectroscopic monitoring of each printed layer) is an emerging area of interest for real-time verification of dose and structural conformity during fabrication, extending the PAT concepts already used in bilayer tablet manufacture to a layer-by-layer printed context.

12. ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING INTEGRATION

AI/ML approaches have begun to be applied directly to the design of multi-layer, multi-drug 3D-printed dosage forms, using predictive models to guide material selection, infill geometry, and print parameters toward a target controlled-release profile, rather than relying solely on iterative trial-and-error formulation development.¹¹

Such AI-driven design of customized multi-layer architectures illustrates how machine learning can compress the design-space exploration process for complex, personalized-medicine-oriented printed dosage forms.¹¹

Looking forward, digital twin models—virtual, continuously updated representations of the physical print process—and closed-loop print optimization, in which real-time in-line monitoring data feeds back into AI-adjusted process parameters, represent a natural extension of this integration as pharmaceutical 3D printing matures toward routine clinical and point-of-care use.

13. REGULATORY AND INTELLECTUAL PROPERTY LANDSCAPE

13.1 Regulatory Guidance

The Spritam approval demonstrated that 3D-printed pharmaceuticals can be evaluated under existing FDA drug-approval pathways rather than requiring an entirely new regulatory category, though agencies continue to develop more specific guidance addressing the unique quality-control and batch-definition questions raised by additive manufacturing, particularly for point-of-care or decentralized printing scenarios.^{4,5}

13.2 Point-of-Care/Hospital Pharmacy Printing

The prospect of printing patient-specific doses at the point of care (e.g., hospital or specialty pharmacy) raises distinct regulatory questions regarding who is accountable for quality assurance of the final printed unit—the device/software manufacturer, the material supplier, or the printing site—an area of active regulatory policy development.^{1,2}

13.3 Intellectual Property Landscape



Patent activity spans both the printer/device level (e.g., Aprecia's proprietary ZipDose Technology platform) and the formulation level (drug-polymer systems optimized for specific print technologies), reflecting the continued commercial value of proprietary pharmaceutical AM platforms.^{4,5,6}

14. FUTURE PERSPECTIVES

14.1 Point-of-Care and Decentralized Manufacturing

Compact, qualified pharmaceutical 3D printers located in hospital or specialty pharmacies could enable on-demand fabrication of patient-specific doses at the point of care, reducing dependence on centralized large-batch manufacturing for personalized therapy.^{1,2,3}

14.2 Personalized Polypills for Chronic Disease Management

Multi-material printing of compartmentalized, multi-drug polypills—extending the IR/SR bilayer concept to a fully individualized, multi-API format—is positioned as a key application for chronic, multi-drug disease management, reducing pill burden while enabling patient-specific dose ratios.^{10,11}

14.3 4D Printing (Stimuli-Responsive Printed Dosage Forms)

4D printing extends 3D-printed structures with materials engineered to change shape or release behavior in response to a physiological stimulus (e.g., pH, temperature, moisture) after fabrication, representing an active frontier explored alongside FDM, SLS, and SLA platforms using stimuli-responsive polymer systems.⁷

14.4 Integration with Digital Health and Telemedicine

Coupling patient-specific prescribing data (from telemedicine or electronic health records) directly to print-file generation could, in principle, close the loop between individualized dose determination and on-demand fabrication, though this remains a largely prospective direction requiring further regulatory and technical development.^{1,2}

14.5 Sustainable/Green Additive Manufacturing

Reduced material waste relative to subtractive or blend-based conventional manufacturing, and the potential for solvent-free processing routes (e.g., FDM, SLS), position pharmaceutical 3D printing as a potentially more sustainable manufacturing paradigm, meriting further life-cycle assessment as the technology scales.^{7,8}

15. CONCLUSION

Three-dimensional printing has progressed from a research curiosity to a clinically validated pharmaceutical manufacturing platform, anchored by the 2015 FDA approval of Spritam and its ZipDose binder-jetting technology. Across FDM, SLA/DLP, SLS, binder jetting, and semi-solid extrusion, pharmaceutical 3D printing offers a fundamentally different value proposition from conventional tableting: the ability to engineer dose, geometry, and release profile digitally and individually, rather than through fixed-batch formulation and tooling. Realizing this potential at scale requires continued progress on throughput, GMP-compatible quality control, expansion of the qualified pharmaceutical materials library, and regulatory frameworks suited to individualized manufacturing—challenges increasingly being addressed through QbD-based development and AI-assisted print-parameter optimization. As these barriers are addressed, pharmaceutical 3D printing is well positioned to become a cornerstone



technology for personalized medicine, point-of-care manufacturing, and next-generation multi-drug dosage form design.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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