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3D-Printed Oral Solid Dosage forms: Current Status, Regulatory Challenges, and Future Prospects

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Abstract:
Three-dimensional (3D) printing, or additive manufacturing, is an emerging pharmaceutical manufacturing approach in which oral solid dosage forms are fabricated layer by layer from a digital design. Unlike conventional tablet compression, 3D printing can modify dose, geometry, internal architecture and drug-release characteristics with comparatively little change to physical tooling. These features make the technology attractive for personalized medicine, pediatric and geriatric therapy, polypills and small-batch or on-demand manufacturing. The regulatory relevance of pharmaceutical 3D printing was established in 2015 with FDA approval of SPRITAM® (levetiracetam), manufactured using Aprecia Pharmaceuticals' ZipDose® technology. Recent literature shows continued development of fused deposition modelling, semi-solid extrusion, selective laser sintering, stereolithography, inkjet printing and powder-bed/binder-jet approaches. However, translation from laboratory research to routine pharmaceutical manufacturing remains limited by material variability, thermal or photochemical drug degradation, printer-to-printer variability, content uniformity, process validation, stability, cleaning, digital-file integrity and regulatory uncertainty. Recent EMA guidance activity in 2026 specifically addresses implementation of 3D printing for solid oral dosage forms. This review summarizes the current status of 3D-printed oral solid dosage forms, major technologies, formulation and quality considerations, regulatory challenges and future opportunities.

Keywords: 3D printing; additive manufacturing; oral solid dosage forms; printlets; personalized medicine; FDM; binder jetting; quality by design; process analytical technology; regulatory science.

Introduction

Oral solid dosage forms (OSDFs), particularly tablets and capsules, remain the dominant pharmaceutical dosage forms because of their stability, convenience, portability and suitability for large-scale manufacture. Conventional tableting is highly optimized for standardized products, but it is less flexible when individualized dose strengths, unusual geometries, multiple release profiles or small production volumes are required. This limitation has become increasingly important with the movement toward patient-centered and personalized therapy.

3D printing provides an alternative manufacturing concept in which a physical dosage form is generated from a digital model. The digital design may control external dimensions as well as internal structures such as pores, channels, layers, compartments and infill patterns. Consequently, the geometry of a dosage form can become a functional formulation variable. Recent reviews emphasize that drug-release performance should not be attributed to geometry alone; it results from interactions among material properties, printing conditions and geometry [9, 11].

The landmark regulatory event occurred in 2015, when the U.S. Food and Drug Administration approved SPRITAM® (levetiracetam), the first 3D-printed prescription drug. The highly porous dosage form was designed for rapid disintegration and easier administration, demonstrating that additive manufacturing could satisfy conventional pharmaceutical quality requirements [4, 13].

Despite this milestone, commercial adoption has remained limited, and current literature continues to describe 3D printing as a promising but developing technology [3].

Table 1: Major 3D-Printing Technologies

Technology	Principle	Major Pharmaceutical Opportunity	Key Limitation
Binder jetting	Liquid binder is selectively deposited onto a powder bed.	Highly porous, rapidly disintegrating tablets.	Powder/binder control and mechanical strength.
FDM/FFF	Drug-loaded thermoplastic filament is heated and extruded.	Complex geometry, modified release and polypills.	Thermal exposure and filament quality.
Semi-solid extrusion	Paste/gel is deposited through a nozzle.	Low-temperature processing and pediatric formulations.	Rheology, drying and nozzle control.
SLS	Laser selectively sinters powder particles.	Porous structures without conventional binders.	Thermal degradation and laser-process control.
SLA/DLP	Light polymerizes a photosensitive formulation.	High-resolution architectures.	Photoinitiators, residual monomer and API stability.
Inkjet printing	Small liquid droplets are deposited digitally.	Low-dose precision and patterned drug loading.	Viscosity, nozzle clogging and drying.

Fused deposition modelling has received extensive attention because it is flexible and can manufacture multilayer and compartmentalized dosage forms, but it usually requires thermoplastic processing. Semi-solid extrusion can reduce thermal stress and is therefore attractive for heat-sensitive drugs. Powder-bed and binder-jet methods can generate highly porous products, while stereolithography offers high resolution but introduces additional concerns about photoreactive materials. The choice of process must therefore be based on the API, excipient system, target product profile and required quality attributes rather than on printer availability alone [1, 3].

Formulation and Quality Considerations

A successful 3D-printed oral dosage form requires a formulation that is not only pharmaceutically acceptable but also printable. Critical material attributes may include particle size, flowability, moisture content, viscosity or rheology, filament diameter, thermal properties and drug-excipient compatibility. Critical process parameters can include nozzle temperature, printing speed, layer height, extrusion pressure, laser energy, binder concentration, drying conditions and infill density. Quality by Design (QbD) provides a useful framework for connecting these variables with critical quality attributes (CQAs). Relevant CQAs include assay, content uniformity, mass, dimensions, mechanical strength, friability, disintegration, dissolution, moisture, solid-state form and degradation products. Recent FDA-associated research stresses the importance of understanding material attributes and process parameters and developing analytical tools for real-time assessment [11].

Table 2:

CQA	Important Influencing Variables	Typical Evaluation
Dose/content uniformity	API distribution, feedstock homogeneity, deposition	Assay and unit-dose testing
Dissolution	Geometry, porosity, polymer, infill, process conditions	Dissolution profile
Mechanical integrity	Polymer, infill, layer adhesion, moisture	Hardness/friability/mechanical testing
Disintegration	Porosity, hydrophilicity, binder level	Disintegration test
Solid-state stability	Temperature, light, drying and storage	XRPD, DSC, chromatography
Dimensions/geometry	Layer height, speed, material flow	Imaging, microscopy or dimensional analysis

Applications in Oral Drug Delivery

The principal attraction of 3D printing is the possibility of producing dosage forms that are difficult or inefficient to manufacture by conventional methods. Patient-specific dosing is particularly relevant to pediatric and geriatric populations, where commercially available strengths may not correspond to the required dose. 3D printing can also create different shapes and sizes to improve acceptability and swallowing.

Another major application is the polypill. Multiple active pharmaceutical ingredients can be placed in separate layers or compartments and designed to release at different rates. This approach could reduce

pill burden in patients receiving several medicines. However, drug-drug compatibility, content uniformity and the reproducibility of each release profile must be demonstrated.

Modified-release products represent another important area. Porosity, shell thickness, infill pattern, polymer composition and compartmentalization can be varied to change liquid penetration and drug diffusion. Current evidence suggests that geometry is most useful when it is considered together with the material and process window; changing geometry alone does not guarantee predictable release [0].

Regulatory Challenges

Regulatory translation is one of the largest barriers to widespread pharmaceutical 3D printing. Conventional pharmaceutical regulation is based on demonstrated control of product identity, strength, quality, purity and manufacturing consistency. 3D printing introduces additional variables because the manufacturing instruction may be partly represented by a digital file and because individualized products may vary intentionally from one unit to another.

Important regulatory questions include the definition of a batch, qualification of printers and feedstocks, validation of digital design and slicing software, printer-to-printer comparability, process validation, cleaning and cross-contamination control, stability, cybersecurity and release testing. The regulatory challenge is therefore not simply to approve a printer; the complete digital-to-dosage-form process must be controlled.

The FDA approval of SPRITAM® demonstrates that 3D printing can operate within a conventional pharmaceutical quality framework. However, SPRITAM® is a defined commercial product rather than an unrestricted personalized manufacturing platform. Recent literature continues to identify regulatory uncertainty and quality assurance as major translational barriers [0, 1].

A significant recent development is the European Medicines Agency's Questions and Answers document on implementation of 3D-printing/additive-manufacturing technology for solid oral dosage forms, published in March 2026. The document places 3D printing within established pharmaceutical quality and GMP expectations while addressing technology-specific considerations [7].

Quality by Design and Process Analytical Technology

QbD can help establish a scientifically justified design space for 3D-printed dosage forms. The development process should begin with a Quality Target Product Profile, followed by identification of CQAs, CMAs and critical process parameters. Risk assessment and design-of-experiments approaches can then identify interactions among formulation and printing variables.

Process Analytical Technology (PAT) is particularly relevant to 3D printing because personalized manufacturing may involve very small production runs. Near-infrared and Raman spectroscopy, machine vision, temperature monitoring, pressure monitoring and weight measurements may provide real-time information. Non-destructive verification of drug content has already been investigated for 3D-printed drug products [11].

In the future, PAT could support closed-loop manufacturing in which sensor data automatically detect process deviations and adjust printing conditions. However, analytical models themselves require validation, calibration-transfer procedures and lifecycle management.

Future Prospects

Future pharmaceutical 3D printing is likely to develop through the convergence of additive manufacturing, digital pharmacy, artificial intelligence and real-time quality control. AI may assist in selecting printable polymers, predicting formulation performance and optimizing process parameters. Closed-loop printers could combine sensors with validated control algorithms to maintain dose and geometry during production.

Point-of-care manufacturing is another long-term possibility. A hospital pharmacy or specialized facility could theoretically receive an authorized digital prescription and produce a validated personalized dosage form. Such a model would require controlled pharmaceutical-grade materials, qualified equipment, environmental monitoring, secure digital files, trained personnel and a clearly defined release process. It should not be equated with ordinary consumer 3D printing.

For India, the technology may eventually be relevant to pediatric medicines, rare diseases, clinical trials and hospital-based personalized therapy. Translation should proceed in stages: laboratory feasibility, formulation and process understanding, GMP pilot manufacturing, regulatory consultation, clinical evaluation and only then controlled decentralized production.

Conclusion

3D printing has established itself as a credible platform for the development of advanced oral solid dosage forms and has demonstrated regulatory feasibility through the approval of SPRITAM®. Its major advantages are digital flexibility, personalization, complex geometry, multi-drug integration and potential on-demand production. Nevertheless, the technology is not a universal replacement for conventional tablet manufacturing,

which remains highly efficient for standardized high-volume products.

The next stage of pharmaceutical 3D printing will depend less on demonstrating that a tablet can be printed and more on proving that the complete process can repeatedly produce safe, effective, stable and traceable medicines. Standardized material specifications, validated digital workflows, QbD, PAT, process validation, cybersecurity and regulatory harmonization will be essential. With these controls, 3D printing has the potential to complement conventional manufacturing and become an enabling technology for patient-centered oral drug delivery.

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