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3D Printing in Pharmaceuticals: From Personalized Dosage Forms to Regulatory Challenges

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Abstract:

Three-dimensional (3D) printing has become a transformative technology in pharmaceutical sciences, allowing the creation of customized drug delivery systems with precise control over shape, dosage, and release profiles. This review offers a thorough overview of 3D printing methods used in pharmaceuticals, including their materials, design strategies, characterization techniques, and current clinical and regulatory environments. Applications encompass personalized medicine, polypills, controlled-release implants, and new pediatric formulations. Despite its significant potential, 3D printing faces challenges related to scalability, quality control, and regulatory approval. Recent FDA approvals, notably of the first 3D-printed drug Spritam®, represent important milestones. Future advancements depend on unified guidelines, digital manufacturing integration, and AI-driven formulation improvements.

Keywords: 3D printing, additive manufacturing, personalized medicine, pharmaceutical formulation, regulatory challenges, Spritam®, fused deposition modeling.

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1. Introduction

The pharmaceutical industry has long relied on conventional mass production methods, a system built on standardization rather than personalization. While this "one-size-fits-all" approach was revolutionary in ensuring widespread access to medicines, it has clear limitations in addressing the diverse and complex therapeutic needs of individual patients [1]. In recent years, the growing focus on precision medicine, coupled with rapid technological innovation, has opened the door for more flexible, patient-centered drug manufacturing strategies. One of the most promising

advancements in this regard is 3D printing, which is steadily reshaping the landscape of modern pharmaceutics [2]. Traditional dosage forms are typically produced in fixed strengths and standard shapes, leaving very little room for personalization. While this works for the average patient, it fails to accommodate variability in metabolism, pharmacogenomics, and co-medication regimens, which can drastically alter drug efficacy and safety. This lack of flexibility often results in suboptimal therapeutic outcomes, side effects due to under- or overdosing, and decreased patient adherence, especially in vulnerable populations like children, the elderly, and patients on multiple medications [3]. Moreover, manual compounding to meet individual needs is time-consuming, error-prone, and difficult to scale, further emphasizing the inadequacy of conventional systems in modern healthcare. 3D printing, or additive manufacturing, offers a disruptive solution to these long-standing limitations. By building dosage forms layer by layer from digital blueprints, this technology enables precise control over drug content, shape, porosity, and release kinetics. Unlike traditional batch production, 3D printing allows for on-demand fabrication of customized oral tablets, transdermal patches, implants, and even polypills that can combine multiple active ingredients in a single unit [4]. The real game-changer is its ability to tailor each dosage form according to patient-specific requirements, enhancing therapeutic outcomes and improving compliance. This patient-centric model aligns perfectly with the principles of personalized medicine, making drug therapy smarter and more efficient. The idea of 3D printing in pharmaceuticals surfaced in the early 2010s, but it truly gained momentum in 2015 when the U.S. FDA approved Spritam® (levetiracetam), developed by Aprecia Pharmaceuticals, as the world's first 3D-printed oral solid dosage form using ZipDose® technology [5]. This landmark approval not only validated the feasibility of additive manufacturing for drug products but also sparked a global wave of research and innovation in pharmaceutical 3D printing. Since then, the field has evolved rapidly, with advancements in printer technology, printable formulations, regulatory considerations, and clinical applications. Today, 3D printing stands at the crossroads of digital manufacturing and precision therapeutics, poised to redefine how medicines are designed, produced, and delivered in the future [6].

2. Classification of 3D Printing Techniques in Pharmaceuticals

3D printing in pharmaceuticals isn't a one-size-fits-all approach; it's a versatile toolbox of techniques, each adapted from engineering and tailored to meet pharmaceutical needs. What makes this technology stand out is its ability to fine-tune dosage forms by controlling process parameters, formulation properties, and structural designs [7]. Unlike conventional manufacturing, where dosage customization is limited, these advanced methods enable personalized drug delivery systems with precision and efficiency. One of the most explored techniques is Fused Deposition Modeling (FDM), which uses thermoplastic polymers like PVA, PLA, and HPMC that are melted and extruded layer by layer to create solid oral dosage forms and implants [8]. It's efficient but not suitable for heat-sensitive drugs. Another popular method is Inkjet Printing, where drug-loaded liquid droplets are deposited onto substrates, allowing for precise microdosing and multi-drug combinations, ideal for orodispersible films and fast-dissolving formulations. Then there's Stereolithography (SLA), a laser or UV-based process that produces high-precision structures from photopolymerizable resins, though it's limited to photostable

compounds [9]. Selective Laser Sintering (SLS) uses laser energy to fuse powdered materials without solvents, enabling porous and complex geometries that support controlled release. Binder Jetting applies a binder to a powder bed to form tablets, famously used in Spritam®, the first FDA-approved 3D-printed drug. Lastly, Pressure-Assisted and Semi-Solid Extrusion cater to thermolabile drugs and biopolymers, allowing soft matrices and bio-ink printing for sensitive compounds and biologics [10]. Together, these methods form the backbone of pharmaceutical additive manufacturing, giving formulators the flexibility to design patient-centric therapies with tailored release profiles, shapes, and dosages that traditional manufacturing cannot achieve [11]

Table 1: Comparison of 3D Printing Techniques in Pharmaceuticals

Printing Method	Material State	Advantages	Limitations	Typical Applications	Reference
FDM	Thermoplastic filament	Simple, low-cost, customizable	Heat-sensitive drugs degrade	Tablets, implants	12
Inkjet	Solution/suspension	High precision microdosing	Limited viscosity range	Films, transdermal patches	13
SLA	Photopolymer resin	Excellent resolution	Photodegradation risk	Implants, microneedles	14
SLS	Powder bed	Solvent-free, porous structures	High equipment cost	Controlled-release tablets	15
Binder Jetting	Powder + binder	Fast, scalable	Binder toxicity possible	Fast-dissolving tablets (*Spritam*®)	16
Semi-solid extrusion	Gel/paste	For thermolabile actives	Viscosity control needed	Biopharmaceuticals, hydrogels	17

3. Materials in 3D Printed Pharmaceuticals

In pharmaceutical 3D printing, the choice of excipients is absolutely crucial; they don't just sit passively in the formulation, they control everything from printability and mechanical strength to dissolution, stability, and drug release behavior. Unlike traditional dosage forms, where excipients mainly act as fillers or stabilizers, in 3D printing, they also determine how well a structure can be made, how strong it will be, and how it performs in the body. Smart material selection transforms a digital blueprint into a precise, patient-specific drug delivery system. Polymers form the backbone of most 3D printed dosage forms, and different types serve different printing techniques. Thermoplastic polymers, such as polyvinyl alcohol (PVA), polylactic acid (PLA), polycaprolactone (PCL), and hydroxypropyl methylcellulose (HPMC),

are commonly used in Fused Deposition Modeling (FDM) because they melt and solidify easily, allowing for strong, layered structures [18]. Hydrogels, like polyethylene glycol (PEG), alginate, gelatin, and chitosan, work well with semi-solid and extrusion printing since they stay flexible and biocompatible, making them ideal for temperature-sensitive drugs and bio-inks. For SLA-based systems, photopolymerizable materials such as PEG diacrylate (PEGDA) enable precise, light-curing of complex geometries suitable for implants or customized drug delivery devices. To make the printed structures more flexible and prevent cracking during or after printing, plasticizers and binders like PEG, triethyl citrate, and glycerol are added [19]. They improve flow properties, reduce brittleness, and strengthen the mechanical stability of the final product. These excipients play a subtle but powerful role in ensuring print quality and durability of the dosage form. 3D printing isn't picky about APIs; almost every major drug class has been tested. From antiepileptics and antihypertensives to antimicrobials and hormones, APIs are evaluated for stability during printing and release behavior afterward. This flexibility allows 3D printing to handle both small molecules and biologics, opening the door to personalized polypharmacy, where multiple active ingredients can be printed in a single unit [20]. Additives give 3D printed formulations their functional flair. Colorants help make them visually distinctive, taste-masking agents improve palatability (especially for pediatric use), and enteric coatings protect drugs from breaking down in the stomach or enable targeted release. These can be applied either during printing or in post-processing, adding an extra layer of customization and control [21]. (Figure 1)

Figure 1: Schematic of 3D Printing Workflow in Pharmaceuticals

4. Physicochemical Characterization of 3D Printed Dosage Forms

Analytical characterization ensures reproducibility and regulatory compliance. (Table 2)

Table 2: Analytical Techniques for 3D Printed Formulations

Technique	Purpose	Example Readouts	Reference
SEM/TEM	Surface morphology and layer uniformity	Porosity, surface roughness	22
DSC/TGA	Thermal transitions	Drug–polymer interaction, stability	23
XRD	Crystallinity/amorphization	Drug solid-state form	24
FTIR	Chemical compatibility	Absence of degradation	25
Dissolution testing	In vitro release profiling	Controlled vs. immediate release	26
Mechanical testing	Hardness, friability	Tablet robustness	27

5. Applications of 3D Printing in Pharmaceuticals

The real magic of pharmaceutical 3D printing lies not just in the advanced technology but in what it allows us to do with medicines. This isn't just a new manufacturing trick; it's a paradigm shift in how drugs can be designed, personalized, and delivered [28]. From patient-specific dosages to complex release systems, 3D printing opens doors that traditional manufacturing could never even knock on. Personalization is the crown jewel of 3D printing in pharmaceutics. By tweaking tablet size, geometry, infill pattern, or layer thickness, the dose and release profile can be precisely tailored to each patient's needs [29]. Imagine walking into a hospital or pharmacy and having your medication printed on demand, based on your prescription and clinical data. This eliminates the need to cut or split tablets, reduces dosing errors, and aligns perfectly with precision medicine strategies. One of the most game-changing applications is the creation of polypills—single tablets containing multiple active drugs, each separated by carefully designed barriers or compartments to prevent interactions [30]. This simplifies complex regimens, improves adherence in chronic conditions like diabetes, hypertension, or cardiovascular diseases, and can even allow different drugs to be released at different times within the same pill. 3D printing is a lifesaver for populations often overlooked in drug design, children, and the elderly. For kids, taste-masking and fun shapes can make medication less of a daily battle. For older adults, easily chewable, rapidly dissolving, or low-dose formulations can make adherence much easier, especially for those with swallowing difficulties or polypharmacy issues [31]. The customizable nature of 3D printing makes it perfect for tailoring formulations for these sensitive groups. Unlike conventional tablets, where release profiles are fixed, 3D printing allows precise manipulation of release kinetics. By adjusting parameters like infill percentage, shell thickness, or channel patterns, formulators can control diffusion and erosion rates to achieve sustained, delayed, pulsatile, or even zero-order release. This level of control enables steady therapeutic levels of drugs over extended periods, reducing dosing frequency and side effects [32]. 3D printing isn't limited to oral dosage forms. Using biocompatible polymers and hydrogels, it's possible to fabricate implantable devices and microneedle arrays for localized or transdermal drug delivery. These systems are especially useful in oncology, pain management, and hormonal therapies,

where controlled and targeted delivery is crucial. Such devices can be custom-shaped to fit individual anatomy, ensuring better comfort and therapeutic outcomes [33]. (Table 3)

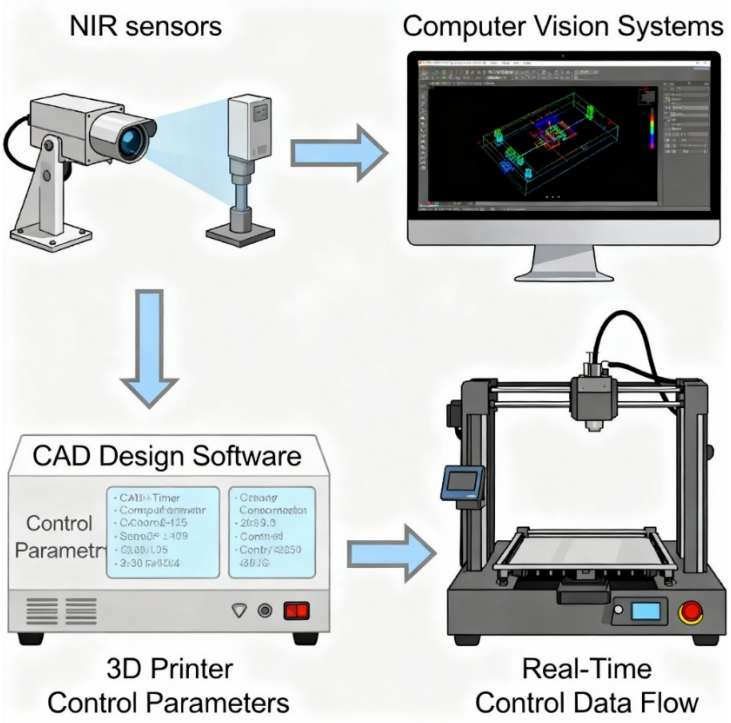
Table 3: Examples of 3D-Printed Pharmaceutical Applications

Product Type	API	Objective	Printing Method	Reference
Spritam®	Levetiracetam	Rapid disintegration	Binder jetting	34
Personalized polypill	5-ASA, lisinopril, metformin	Combination therapy	FDM	35
Pediatric ODF	Ibuprofen	Taste-masked oral film	Inkjet	36
Implant	Antibiotics	Local infection control	SLA	37
Microneedle	Insulin	Transdermal delivery	SLA/Extrusion	38

6. Quality Control, Reproducibility, and Process Validation

When it comes to pharmaceuticals, innovation is only as reliable as its quality assurance, and 3D printing, being a completely new challenge, disrupts the traditional QC approach. Unlike conventional manufacturing, where fixed batch processes enable predictable quality checks, 3D printing involves on-demand, highly customized production, which requires smarter, real-time, and more adaptable quality control strategies [39]. The first line of defense is in-process monitoring, where advanced tools like Near-Infrared (NIR) spectroscopy and computer vision systems are used to closely observe dose uniformity, layer deposition, geometry, and structural accuracy while the product is being printed. This real-time oversight helps catch deviations before they turn into defects, ensuring consistent performance even in personalized, small-batch runs. Once printing is complete, post-print validation steps assess mechanical strength, dimensional stability, and dissolution uniformity—key parameters to confirm that every tablet or implant meets pharmaceutical standards. Unlike traditional tablets, printed dosage forms can vary from one unit to another, making these tests essential for maintaining therapeutic reliability [40]. On the regulatory side, adjustments are also underway. Instead of following the rigid "test it after making it" model, agencies are promoting Process Analytical Technology (PAT) and Quality by Design (QbD) frameworks, which embed quality into the process itself. This approach allows manufacturers to maintain reproducibility and compliance, even with highly flexible and personalized production lines [41]**.** (Figure 2)

Figure 2: PAT Integration in 3D Printed Drug Manufacturing



7. Clinical Translation and Regulatory Challenges

While 3D printing is making significant waves in pharmaceutical research labs, transitioning from the benchtop to clinical use isn't exactly straightforward. The clinical application of 3D printed dosage forms introduces new manufacturing, regulatory, stability, and data security challenges that traditional pharma has never faced at this scale [42]. To fully realize the technology's potential, these issues require smart, coordinated solutions. Unlike conventional manufacturing lines that produce millions of identical tablets continuously, 3D printing is inherently patient-specific and batch-oriented. This means traditional scale-up methods don't quite apply here. To meet clinical or commercial demand, companies must rely on parallel production (using multiple printers simultaneously) or invest in high-throughput, automated printing systems. Additionally, GMP-compliant 3D printers are still relatively scarce, which complicates regulatory approval and large-scale production efforts [43]. The regulatory landscape is still adapting to this rapidly evolving technology. The U.S. FDA has issued initial guidance for additive manufacturing in medical devices, but a harmonized framework for pharmaceuticals is still in development. Meanwhile, the European Medicines Agency (EMA) is exploring risk-based strategies to ensure safety and consistency. Until comprehensive, globally recognized guidelines are in place, regulatory pathways for 3D printed drugs remain complex and case-specific, hindering clinical translation. Stability is not just a minor concern; it's one of the biggest hurdles [44]. Many 3D printed dosage forms are sensitive to moisture, mechanically fragile, or susceptible to API degradation over time. These vulnerabilities can compromise efficacy and safety, making packaging, polymer choice, and storage conditions critical. Unlike mass-produced tablets with years of validated shelf-life data, printed medicines require tailored

stability protocols based on their formulation and structure [45]. And here's where things get increasingly digital. 3D printing introduces new concerns for IP and data security. Instead of merely protecting a chemical formula, companies must safeguard digital CAD files, printer calibration data, and prescription-based print instructions. If these files fall into the wrong hands, counterfeiting and illegal replication become serious threats. Maintaining data integrity, cybersecurity, and IP protection is just as crucial as ensuring the quality of the finished product [46].

Table 4: Regulatory Milestones and Current Status

Year	Milestone	Regulatory Body	Significance	Reference
2015	Approval of *Spritam*®	U.S. FDA	First 3D-printed oral drug	47
2017	FDA guidance on additive manufacturing	U.S. FDA	Framework for 3D-printed devices and drugs	48
2021–2024	Pilot studies for point-of-care printing	EMA/FDA collaborations	Exploring decentralized manufacturing	49

8. Future Perspectives

The story of 3D printing in pharmaceuticals is still being written, and the next chapters promise to be bold, digital, and deeply transformative. What began as a novel fabrication tool is rapidly evolving into a cornerstone of personalized healthcare, driven by advancements in AI, bioprinting, and regulatory science [50]. The vision? A future where medicines are printed as easily as documents, tailored to the patient, not the other way around.

Picture this: a hospital or community pharmacy where, instead of waiting for a batch from a central plant, your personalized medicine is printed on the spot in just a few minutes [51]. This isn't science fiction anymore; it's an emerging reality backed by pilot programs and regulatory sandbox models. These point-of-care manufacturing units could revolutionize access by enabling dose adjustments, rapid formulation changes, and immediate responses to clinical needs, all while reducing supply chain delays. 3D printing relies on precision, and nothing enhances precision like artificial intelligence [52]. Machine learning models are being developed to predict and optimize printing parameters from infill geometry and extrusion temperature to excipient ratios—allowing for tailored drug release profiles and mechanical properties before the first layer is printed. This integration of AI transforms 3D printing from trial-and-error fabrication into a smart, data-driven design system, making personalized medicine faster, cheaper, and more

reliable. But the future extends beyond pills. 3D bioprinting is paving the way for living tissue constructs, which can be used in drug screening, regenerative medicine, and disease modeling. Imagine testing a cancer therapy not on animals or generalized models but on a miniaturized, patient-specific organ-on-chip [53]. This approach could dramatically accelerate drug discovery, improve clinical relevance, and reduce reliance on traditional preclinical testing models. As the technology advances, regulatory science must keep pace. The future will depend on building collaborative frameworks that define acceptable tolerances for dosage accuracy, layer adhesion, drug distribution uniformity, and overall product quality. Standardization will be essential to ensure reproducibility, safety, and global regulatory alignment, paving the way for full-scale clinical adoption [54].

9. Conclusion

3D printing represents a paradigm shift in pharmaceutical manufacturing, moving from bulk production to personalized, data-driven fabrication. The journey from *Spritam*® to prototype polypills demonstrates remarkable flexibility in designing tailored therapies. Yet, clinical translation is constrained by technical, regulatory, and ethical complexities. Overcoming these challenges demands multidisciplinary collaboration among pharmacists, engineers, data scientists, and regulators. The ultimate vision of on-demand, personalized medicine integrated into healthcare infrastructure is no longer futuristic; it's the next industrial revolution in pharmacy.

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