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Controlled Release Drug Delivery Using 3D Printing Techniques: A Current Scenario in Personalized Medicine

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Abstract

Three-dimensional (3D) printing is particularly influencing the pharmaceutical manufacturing sector in the creation of controlled release drug delivery systems. This technology enables the precise fabrication of personalized medicines with tailored drug release profiles, dosages, and geometries, marking a significant advancement over traditional mass production methods. An array of 3D printing techniques, including extrusion-based, powder-based, and others, can be used to build complex dosage forms that regulate drug release through processes like dissolution, diffusion, osmosis, and erosion. By adjusting the composition and size of these shells, drug release rates can be finely tuned, supporting the goals of personalized medicine and improved patient compliance. While 3D printing offers significant advantages including on-demand manufacturing, dose personalization, and the ability to create multidrug or multi-compartment dosage forms – it also faces challenges related to material selection, production capacity, regulatory standards, and quality control. On-going advancements in materials science, process optimization, and regulatory frameworks are expected to further expand the clinical applications and market growth of 3D printed controlled release pharmaceuticals in the coming years. This current review describes briefly the materials and methods, design strategy and applications of 3D printing technique for controlled release drug delivery.

Keywords: 3D printing techniques, personalized medicine, extrusion-based printing, drug delivery, liquid-based and powder-based system

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INTRODUCTION

Three-dimensional (3D) printing is revolutionizing pharmaceutical manufacturing by enabling the production of personalized medicines with precise control over drug release profiles, dosage, and formulation geometry [1–3]. Unlike traditional mass production, 3D printing allows for on-demand, patient-specific drug products, marking a significant shift in clinical pharmacy practice [1, 2]. The capacity to customize drugs to meet the needs of each patient solves long-standing issues with drug therapy, including complex dose schedules, polypharmacy, and varied patient reactions [2, 4]. Dosage forms that contain many medications, release them at different speeds, or target specific body parts can all be made with 3D printing. This improves patient adherence and enhances therapeutic efficacy by simplifying medication regimes and reducing side effects [2–4].

Moreover, 3D printing enables the creation of intricate internal structures and geometries-such as multi-layered tablets, compartmentalized capsules, and implants that are difficult or impossible to achieve with conventional manufacturing techniques [1, 2, 4]. New opportunities for creative drug delivery systems are created by these sophisticated designs, which enable regulated, prolonged, or even pulsatile drug release.

OVERVIEW OF 3D PRINTING TECHNIQUES IN PHARMACEUTICS

Additive manufacturing, also referred to as 3D printing, is radically altering the pharmaceutical industry by making it possible to create customized medications with precise doses, geometries, and drug release profiles [1–2, 4].

Unlike traditional manufacturing, which relies on large-scale, inflexible processes, 3D printing offers compact equipment, fewer production steps, and rapid integration of digital design and manufacturing, making it especially suitable for both small-batch and on-demand production [3–8].

Various 3D Printing Techniques in Pharmaceutics

- Binder Jet 3D Printing (BJ-3DP).
- Fused Deposition Modelling (FDM).
- Semi-Solid Extrusion (SSE).
- Stereo lithography (SLA).
- Selective Laser Sintering (SLS).
- Melt Extrusion Deposition (MED).

Binder Jet 3D Printing (BJ-3DP)

In the pharmaceutical industry, additive manufacturing, the process of building drug goods layer by layer from digital designs, is the foundation of 3D printing. With this method, the interior structure, shape, and drug distribution of the dosage form may all be precisely controlled. For the creation of intricate and customized drug delivery systems, pharmaceutical grade materials and active ingredients are processed using a variety of 3D printing technologies, including fused deposition modelling (FDM), binder jetting, stereolithography (SLA), and selective laser sintering (SLS) [3–9].

Fused Deposition Modelling (FDM)

Fused deposition modelling (FDM) is an extrusion-based 3D printing technique where a drug-loaded thermoplastic filament is heated and extruded through a nozzle to build dosage forms layer by layer. The process is governed by a digital design, allowing for precise control over the geometry and internal structure of the final product. The filament is typically prepared via hot-melt extrusion, ensuring uniform drug distribution before printing [3, 10–11].

Semi-Solid Extrusion (SSE)

Semi-solid extrusion is a 3D printing process where a viscous, paste-like mixture containing the drug and excipients is extruded through a nozzle, layer by layer, to form the final dosage form. The process is typically performed at room or slightly elevated temperatures, making it suitable for heat-sensitive drugs. The mixture's rheology (flow properties) is carefully optimized to ensure smooth extrusion and shape retention after deposition [3, 12].

Stereo Lithography (SLA)

Stereo lithography (SLA) is a vat photo polymerization 3D printing process that uses a focused ultraviolet (UV) laser or light source to selectively cure and solidify layers of liquid photopolymer resin. The digitally regulated technique allows for the accurate layer-by-layer construction of complex structures at room temperature. This method of high resolution is perfect for creating complex and precise pharmaceutical dosage forms [3, 13].

Selective Laser Sintering (SLS)

Selective laser sintering (SLS), a powder bed fusion 3D printing technology, applies a thin layer of pharmaceutical powder (such as a polymer, excipient, or drug blend) to a build platform. The object is constructed layer by layer using a powerful laser that selectively scans and fuses the powder particles in accordance with a digital design. Excess powder is eliminated after printing and serves as support for intricate geometries [3, 14].

Melt Extrusion Deposition (MED)

Melt extrusion deposition (MED) is an advanced 3D printing technology specifically tailored for pharmaceuticals. In MED, pharmaceutical powders including active pharmaceutical ingredients (APIs) and excipients are directly fed into a heated chamber. The final dosage form is created by melting the mixture and then extruding it via a nozzle in accordance with a computerized design, depositing the material layer by layer. This method eliminates the need for prior filament or paste preparation, distinguishing MED from fused deposition modelling (FDM) and semi-solid extrusion (SSE) [3, 15].

Common Applications for 3D Printing Techniques

- *Personalized Medicine:* 3D printing allows for the creation of tailored dosage forms, adjusting drug dose, size, and shape to individual patient needs, which is particularly beneficial for pediatric, geriatric, and special patient populations.
- *Polypills:* The technology enables the fabrication of multi-compartment tablets that can deliver multiple drugs with different release profiles in a single dosage form, simplifying medication regimens for patients with chronic diseases.
- *On-Demand Manufacturing:* By producing medications on-site, pharmacies and hospitals may be able to increase accessibility and cut down on waste.
- *Complex Drug Release Profiles:* The design flexibility allows to produce tablets with immediate, delayed, or controlled release characteristics, as well as spatially separated drug zones [3, 9].

Specific Applications of Semi Solid Extrusion Techniques

- *Thermo-Sensitive and Biologic Drugs:* Because it operates at low temperatures, SSE is suitable for drugs and biologics that are unstable at high temperatures.
- *Rapid Prototyping and Clinical Trials:* SSE enables quick formulation changes and small-batch production, supporting early-phase clinical studies and orphan drug development [3, 12].

Specific Applications of Stereo Lithography Techniques

- *Medical Devices and Implants:* The technology is utilized to create highly accurate and biocompatible customized implants and medical devices, including micro needles and anatomical models.
- *Immediate Soluble Drugs:* SLA can be utilized to produce quickly dissolving dosage forms, like "zip-dose" tablets, which are particularly advantageous for patients who are dysphagic, elderly, or pediatric [13].

Specific Applications for Selective Laser Sintering Techniques

- *Orally Disintegrating Tablets (ODTs):* SLS can produce extremely porous tablets that quickly dissolve in the mouth, increasing patient compliance for those who have trouble swallowing.
- *Amorphous Solid Dispersions:* SLS can produce amorphous forms of poorly soluble drugs, enhancing their solubility and bioavailability.

Specific Applications for Melt Extrusion Deposition Techniques

Modified and Controlled Release Tablets

By modifying the design and content, MED can create dosage forms with delayed, sustained, or fast release properties.

Common Benefits and Motivations of 3D Printing Techniques

3D Printing in Pharmaceutics Enables

The creation of medicines tailored to patient-specific therapeutic requirements (dose, combination, release profile) as well as personal preferences (shape, size, texture, flavor). Rapid prototyping and expedited development, reducing time and costs in drug development and clinical trials. Adaptable, on-demand production in pharmacies and hospitals, among other healthcare facilities [16, 17].

In conclusion, pharmaceutical innovation is being driven by 3D printing technologies including BJ-3DP, FDM, SSE, SLS, SLA, and MED, which offer the accuracy and adaptability required for the upcoming generation of controlled release and customized medications.

ADVANTAGES OF 3D PRINTING IN CONTROLLED DRUG DELIVERY

3D printing offers a transformative set of advantages for controlled drug delivery, fundamentally shifting pharmaceutical manufacturing from mass production to personalized, patient-centric solutions [18–22].

- *Personalized Medicine:* 3D printing enables the design and production of medicines tailored to individual patient needs, including specific dosages, drug combinations, release profiles, and even preferences for shape, size, texture, and flavor. This is particularly beneficial for pediatric, geriatric, and polypharmacy patients, improving compliance and therapeutic outcomes [18].
- *Precise Control of Drug Release:* The technology allows for sophisticated control over drug release kinetics by adjusting formulation geometry, internal structure, and material composition. This precision is difficult to achieve with traditional manufacturing methods, enabling the creation of complex controlled-release profiles and multi-drug tablets [19].
- *On-Demand and Decentralized Manufacturing:* Compact, user-friendly 3D printers can be integrated into hospitals, clinics, and community pharmacies, allowing for rapid, on-demand production of personalized medicines. Service access is improved and wait times are reduced, which is especially beneficial in emergencies or resource-constrained situations [6, 20].
- *Reduced Waste and Cost Efficiency:* 3D printing minimizes drug and excipient waste by producing only what is needed, reducing costs – especially for expensive or unstable drugs – and lowering environmental impact. Medicines can be produced as needed, reducing the need for large inventories and cold-chain storage [6, 19].
- *Expedited Development and Flexibility:* The digital and automated nature of 3D printing accelerates the development of new formulations, supports rapid prototyping, and allows for easy modifications in clinical trials or small-batch production. Patients and pharmaceutical businesses both gain from this flexibility [7, 18]. It can create durable, mechanical sound tablets with customized release profiles.
- *Enhanced Safety and Medication Accuracy:* 3D printing enhances medicine accuracy and safety by facilitating accurate administration and eliminating the need to split or crush pills, especially for medications with limited therapeutic windows or those needing intricate regimens.
- *Improved Patient Experience:* Customizable dosage forms, such as chewable tablets with flavors for children or porous, easy-to-swallow forms for the elderly, enhance patient acceptability and adherence [7, 21].
- *Potential for Digital Integration:* 3D printing can be linked with digital health technologies, such as electronic prescriptions and AI-driven quality assurance, paving the way for a new era of digital pharmacy and real-time personalized medicine dispensing [6, 19].

APPLICATIONS AND CASE STUDIES

3D printing has found diverse and impactful applications in controlled release drug delivery, especially in personalized medicine, hospital pharmacy compounding, and complex dosage form fabrication. Several case studies highlight its practical use and benefits [7–8, 23].

- Personalized medicines in hospitals and pharmacies.
- Advanced drug delivery devices.

- Decentralized and on-demand manufacturing.

Personalized Medicines in Hospitals and Pharmacies

- *Pediatric Personalized Therapies:* At the Clinic University Hospital in Spain, 3D printing was used to produce chewable isoleucine tablets ("printlets") with multiple flavors and doses for children with maple syrup urine disease, a rare metabolic disorder. These printlets allowed precise dose adjustments and improved patient acceptability compared to conventional capsules. The successful control of isoleucine blood levels showed clinical efficacy (7, 8, 24).
- *Polypills for Polypharmacy:* Fused deposition modelling (FDM) has been employed to create polypills-single tablets containing multiple drugs with bespoke release profiles to simplify medication regimens for patients with multiple conditions, improving adherence and reducing pill burden (8).
- *Warfarin Dose Adjustment:* 3D printing techniques, such as FDM and semi-solid extrusion (SSE), have been used to produce warfarin tablets and films with highly accurate, personalized doses, addressing the drug's narrow therapeutic window and reducing dosing errors [8].
- *Rapidly Disintegrating Tablets:* 3D printing technologies have revolutionized the development of RDTs by enabling personalized dosing, innovative internal architectures, and rapid prototyping of formulations that meet individual patient needs. Binder jet 3D printing (BJ-3DP) was used to produce Spritam, the first FDA-approved 3D printed drug, which rapidly disintegrates and is suitable for patients with swallowing difficulties [25].
- *Orally Disintegrating Tablets for Patients with Visual Impairments:* Orally disintegrating tablets featuring Braille and moon patterns have been produced using selective laser sintering (SLS), allowing visually impaired patients to safely identify their prescriptions [26].

Advanced Drug Delivery Devices

- *Wearable Drug Delivery:* It is Customized 3D printed orthodontic retainers loaded with clonidine hydrochloride have been developed for sustained local drug release, demonstrating the potential for personalized, site-specific delivery systems [27].
- *Multi-Drug Combinations for Cancer Therapy:* It is Collaborations between biotech companies and oncology hospitals are underway to produce 3D printed multi-drug tablets combining anticancer agents with supportive therapies, aiming to improve adherence and treatment outcome [8].

Decentralized and On-Demand Manufacturing

- *Hospital Pharmacy Integration:* 3D printers have been successfully integrated into hospital pharmacies to produce tailored doses of medications such as spironolactone for pediatric inpatients, enhancing precision, safety, and patient satisfaction.
- *Tele Pharmacy and Community Pharmacies:* The compact and user-friendly nature of 3D printers, like FDM and SSE supports their use in community and hospital pharmacies, enabling on-demand production of personalized medicines and rapid response to changing patient needs (Table 1) [28].

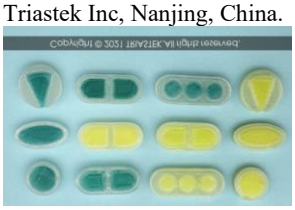
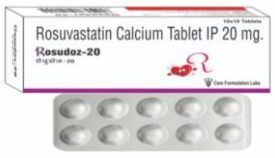
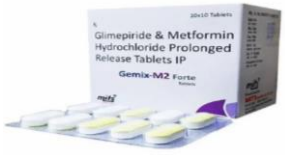
CREATING DESIGN PLANS FOR CONTROLLED DRUG RELEASE USING 3D PRINTING TECHNIQUES

3D printing enables unprecedented control over drug release profiles through innovative design strategies. By working with expanding frontiers, process-led innovations, patient-specific customization, and geometry architectural design [29–31].

Below are key design approaches validated in pharmaceutical research.

- Geometric architecture design
- Process-led innovations
- Patient-specific customization,
- Emerging frontiers

Table 1. Marketed available 3D-printed drugs delivery system & drugs.

S.N.	Drug/Disease	Drug Delivery System/Device	3D Printing Technique	Product Name (Dosage Form), Company, Image
1	Levetiracetam/antiepileptic, seizures (Figure 1).	Flash dispersing technology, tablet for oral suspension	Powder-based Binder Jet 3D Printing.	Aprecia Pharmaceuticals, Aminabad, Lucknow, Uttar Pradesh.  **Figure 1.** Spiritam.
2	Tofacitinib/Chronotherapeutic system for rheumatoid arthritis (Figure 2)	Chrono-therapeutic oral dosage form	Melt Extrusion Deposition (MED)	Triastek Inc, Nanjing, China.  **Figure 2.** Triastek T19.
3	Triastek T21/Site-specific delivery for ulcerative colitis (Figure 3)	Targeted oral dosage form	MED	Triastek Inc, Nanjing, China.  **Figure 3.** Triastek T21.
4	Multiple drugs (e.g., aspirin, hydrochlorothiazide, etc.) (Figure 4)	Multi-compartment, controlled-release tablet	FDM, Extrusion-based	Cadila Pharmaceuticals Ltd. in India. Polycap/Polypill.  **Figure 4.** Polycap.
5	Glimepiride, rosuvastatin (diabetes, hyperlipidemia) (Figure 5)	Multicompartment, self-nano emulsifying system	Extrusion-based 3D printing	Care Formulation Labs Pvt Ltd, Narela, New Delhi, India Rosudoz-20 Self-nano emulsifying drug delivery system [SNEDDS tablets].  **Figure 5.** Rosudoz-20.
6	Metformin (SR), glimepiride (IR) (diabetes) (Figure 6)	Bilayered, personalized release tablet	FDM	MITS Life Science Pvt Ltd, Haryana, India Gemix-M2 forte/Bilayered tablets  **Figure 6.** Gemix-M2 forte.

Geometric Architecture Design

Geometric architecture design is central to optimizing drug release in 3D-printed pharmaceuticals. Researchers may accurately control how a medication is released over time by adjusting the internal and external geometries, including compartmentalization, surface area-to-volume ratio, infill pattern, and shell thickness [9, 10].

For instance, immediate-release tablets can be changed into sustained-release systems using 3D-printed cellulose acetate shells that have pore-forming chemicals like D-mannitol and varying ratios of rate-controlling polymers. Dissolution and release kinetics are directly impacted by the shape of the shell, including the space between the tablet and shell wall [9].

- *Complex Core-Shell Structures:* Multi-layered implants with drug-loaded cores and rate-controlling polymer shells enable delayed or sustained release. The shell acts as a programmable barrier, and its composition and thickness can be tuned for desired release profiles [8–10].
- *Porous and Lattice Designs:* Theophylline tablets and other oral dose forms exhibit gyroid, radiator-like, or modular lattice architectures that enhance surface area and permit varying release rates.
- *Hollow Compartments:* By shielding delicate active pharmaceutical ingredients (APIs) from external elements (such as moisture and stomach acid) until the time of release, hollow compartments can improve the stability and effectiveness of drugs [8]. Complex treatment regimens can be supported by multi-drug polypills having distinct reservoirs that enable sequential or site-specific drug release from a single unit [8, 10].

Process-Led Innovations

Process-led innovations in 3D printing are transforming pharmaceutical manufacturing by introducing new levels of flexibility, precision, and efficiency throughout the drug development and production pipeline. Unlike traditional large-scale manufacturing – which relies on fixed, high-capacity equipment and lengthy changeover processes – 3D printing enables rapid integration of production, small-batch customization, and seamless adaptation to new formulations or patient needs [32, 33].

- *Coating Systems:* 3D-printed external shells (e.g., PVA-based) convert immediate-release tablets into modified-release formulations. By precisely controlling the shell's thickness, porosity, and composition, researchers can tailor the rate at which the drug diffuses out of the core tablet. Without changing the original medication formulation, this method enables the conversion of conventional, quickly dissolving tablets into sustained- or delayed-release systems [9].
- *Microfluidic Encapsulation:* Ultrasonic-enhanced emulsification in printed devices creates API-loaded micro particles. These devices fabricated using technologies, such as fused deposition modelling (FDM) or liquid crystal display (LCD) 3D printing, feature intricate channel designs that enable controlled mixing and emulsification of materials for the medication and its carrier. For instance, homogenous liposomes or polymeric microspheres containing active pharmaceutical ingredients (APIs) can be created via ultrasonic-enhanced emulsification inside these printed micro channels [8].
- *Semi-Solid Extrusion:* Dual-printing (FDM + paste extrusion) enables combi-pills with distinct release profiles. In this dual-printing approach, FDM is used to print the structural components or shells from thermoplastic polymers [8]. SSE allows for the deposition of semi-solid, drug-loaded pastes or gels into specific compartments within the printed structure. This technique enables the integration of multiple drugs or formulations with different release characteristics, such as immediate, sustained, or pulsatile release, within a single dosage form.

Patient-Specific Customization

Pharmaceutical care is undergoing a paradigm shift away from the conventional "one-size-fits-all" approach and toward fully customized medication with the use of 3D printing for patient-specific customization. This customization is achieved by tailoring the dosage form, drug combination, release profile, and even sensory attributes (such as shape, color, texture, and flavor) to the unique needs and preferences of each patient [34, 35].

- *Anatomical Matching:* 3D printing enables the fabrication of patient-specific vaginal rings tailored in shape, size, and drug load to optimize comfort, fitness, and drug release. For instance, fused deposition modelling (FDM) has been used to produce vaginal rings loaded with progesterone, using polymers like polylactic acid (PLA) and polycaprolactone (PCL).
- *Dose Titration:* 3D printing allows precise control over tablet porosity and internal structure, enabling dose titration is especially important in pediatric populations. For example, chewable amlodipine tablets have been fabricated with adjustable porosity to tailor drug release rates and doses according to the child's therapeutic requirements.
- *Implants:* 3D-printed implantable drug delivery devices provide site-specific, long-term release of antibiotics such as ciprofloxacin, reducing systemic exposure and addressing localized infections. Implants can be precisely fashioned to match anatomical areas and filled with pharmacological dosages using biocompatible and biodegradable polymers.

Emerging Frontiers

Emerging frontiers in 3D printing for pharmaceuticals are rapidly expanding the boundaries of what is possible in drug development, manufacturing, and patient care. These innovations are not only transforming the technical landscape but also reshaping the pharmaceutical ecosystem, regulatory frameworks, and healthcare delivery models [36, 37].

- *Enzyme-Activated Systems:* Enzyme-activated systems represent an innovative frontier in 3D-printed drug delivery, leveraging the body's own biochemical environment to trigger or modulate drug release in a highly targeted and controlled manner.
- *Cryogenic Printing:* Cryogenic printing is a 3D printing technique that involves depositing materials at sub-zero temperatures, causing rapid freezing and solidification of the printed layers.
- *LEGO-Inspired Designs:* LEGO-inspired designs in 3D printing refer to modular, interlocking components modelled after LEGO bricks that can be assembled in various configurations to create complex, customizable structures.

These strategies demonstrate how 3D printing transcends traditional manufacturing constraints, enabling smart drug delivery systems with precise spatiotemporal control. Future work focuses on AI-driven design automation and regulatory standardization.

POLYMERIC MATERIALS USED IN CONTROLLED RELEASE 3D PRINTING

The selection of materials is crucial for the successful fabrication of controlled release drug delivery systems using 3D printing [1, 2]. The materials-primarily polymers and excipients-directly influence the mechanical properties, printability, and drug release kinetics of the final dosage form [7, 8, 38].

Key Materials Used

- Rate-Controlling Polymers.
- Pore-Forming Agents.
- Biodegradable Polymers.

Rate-Controlling Polymers [2, 4]

- *Cellulose Acetate:* To enable sustained and controlled release profiles, cellulose acetate is frequently utilized as the main matrix material for 3D printed shells that enclose immediate-release tablets. The ratio of cellulose acetate to other excipients can be adjusted to fine-tune the release rate of the enclosed drug.
- *Polylactic Acid (PLA):* It is employed as a structural material for outer compartments in 3D-printed tablets, providing mechanical strength and contributing to controlled release characteristics. Because of PLA's unique features, it is possible to precisely manage the shape, structure, and function of drug delivery systems and bespoke biomedical devices.
- *Polyvinyl Alcohol (PVA):* It is used for its good printability and ability to create tablets with multiple release profiles depending on internal geometry. PVA can be used as a soluble shell filled with

drug-containing gels at ambient temperature to avoid the degradation of sensitive active ingredients caused by high-temperature processing.

- *Hydroxypropyl Methylcellulose (HPMC):* Hydroxypropyl methylcellulose (HPMC) is widely used in extrusion-based printing due to its gel-forming and long-lasting releasing properties. Hydroxypropyl Methylcellulose (HPMC) is a water-soluble, multipurpose polymer that is mostly utilized in 3D printing technology as a matrix forming, support material, and rheology modifier in engineering and pharmaceutical applications.

Pore-Forming Agents [2, 4]

- *D-Mannitol:* It is added to the polymer matrix to increase porosity, thus accelerating drug release by enhancing shell permeability. In 3D pharmaceutical printing, D-Mannitol is a highly valued excipient that facilitates the development of strong, pleasant, and quickly dissolving oral dosage forms designed for patient-centered treatments.
- *Polyethylene Glycol (PEG 6000):* It is employed as a pore-former and plasticizer to increase the printed shell's flexibility and control the release rate. PEG 6000 is a multifunctional excipient in pharmaceutical 3D printing, improving filament processing, mechanical properties, and drug release characteristics, thereby enabling the fabrication of personalized and effective drug delivery systems.

Biodegradable Polymers [1, 2]

Biodegradable Polyesters (e.g., PLA, PGA, PLGA): It is used in vat polymerization and melt-based 3D printing to fabricate implants and devices that degrade over time, eliminating the need for surgical removal and enabling long-term controlled release.

Solvents and Processing Aids [2, 4]

In 3D printing, solvents and processing aids are crucial, particularly for creating hydrogels, soft biomaterials, and composite structures. They are essential in establishing the final characteristics, printability, and structural integrity of the printed structures.

Active Pharmaceutical Ingredients (APIs) [2]

The API, the primary therapeutic agent in 3D-printed pharmaceuticals, must integrate, stabilize, and release for additive printing-enabled tailored drug delivery systems to be effective. Drugs that are hydrophilic or hydrophobic can be added, and the ratio of excipients and polymer matrix can be used to customize the release profile.

Material engineering strategies in 3D-printed pharmaceuticals focus on optimizing the selection, formulation, and processing of materials to achieve desired drug release profiles, mechanical strength, stability, and patient-specific customization (Table 2) [39, 40].

Material Selection Considerations

- To preserve drug stability and effectiveness both before and after printing, the medicine must be compatible with the selected polymer and excipients.
- The ratio of rate-controlling polymer to pore-forming agent is a key lever to modulate drug release kinetics, as demonstrated by varying cellulose acetate and D-mannitol ratios for propranolol HCl tablets.
- The printability and mechanical properties of the material must be suitable for the selected 3D printing technique such as extrusion, fused deposition modelling, or vat polymerization (Figure 10) [7–8, 41].

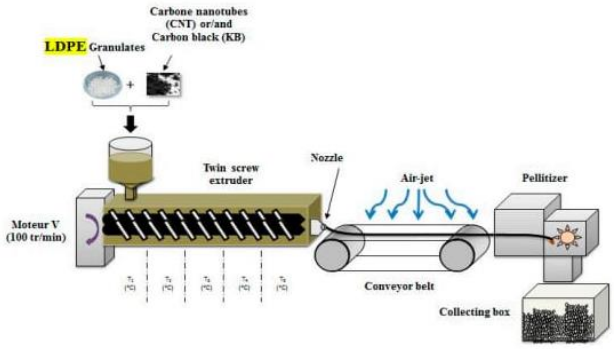
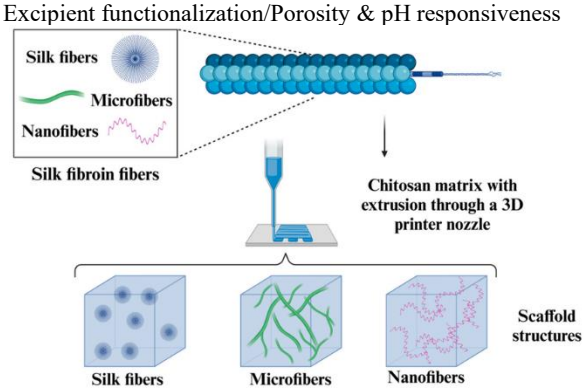
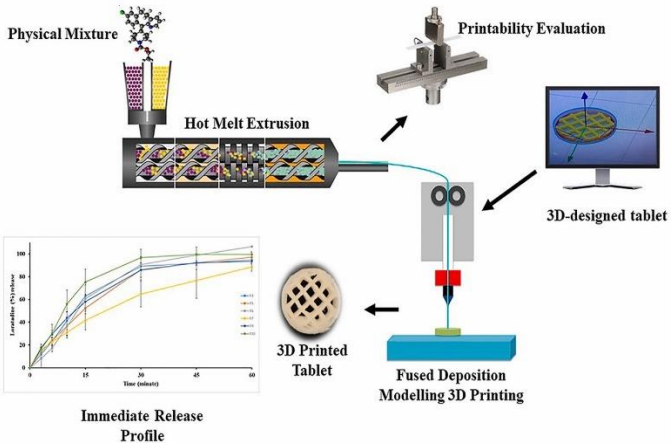
ECONOMY RECENT SURVEY – TABLE

Recent market surveys highlight the rapid growth, regional trends, and technological advancements in the 3D printed drug sector.

- The global 3D printed drugs market is projected to grow rapidly, with estimates ranging from $374 million to over $1 billion by 2033–2035.

- North America currently dominates the market, but Asia-Pacific is the fastest-growing region, driven by healthcare investments and collaborations.
- Integration of AI and digital tools is accelerating innovation and quality control in 3D printed drug manufacturing.
- The main drivers include demand for personalized medicine, rapid on-demand manufacturing, and the ability to produce complex drug delivery systems that are not possible with traditional methods (Figure 11).

Table 2. Various material engineering strategies.

S.N.	Strategy / Mechanism	Application Example	Source
1	Polymer blender/ Adjusting hydrophilicity-rheology  **Figure 7.** Polymer blender.	PEO-PCL matrices for sustained theophylline release (Figure 7).	[9]
2	Excipient functionalization/Porosity & pH responsiveness  **Figure 8.** Chitosan - based 3D printing.	Carboxylated chitosan microspheres in cervical implants (Figure 8).	[10]
3	Hot–melt extrusion morphous solid dispersions  **Figure 9.** Hot Melt extrusion process.	Improved lopinavir bioavailability via SLS printing (Figure 9).	[10]

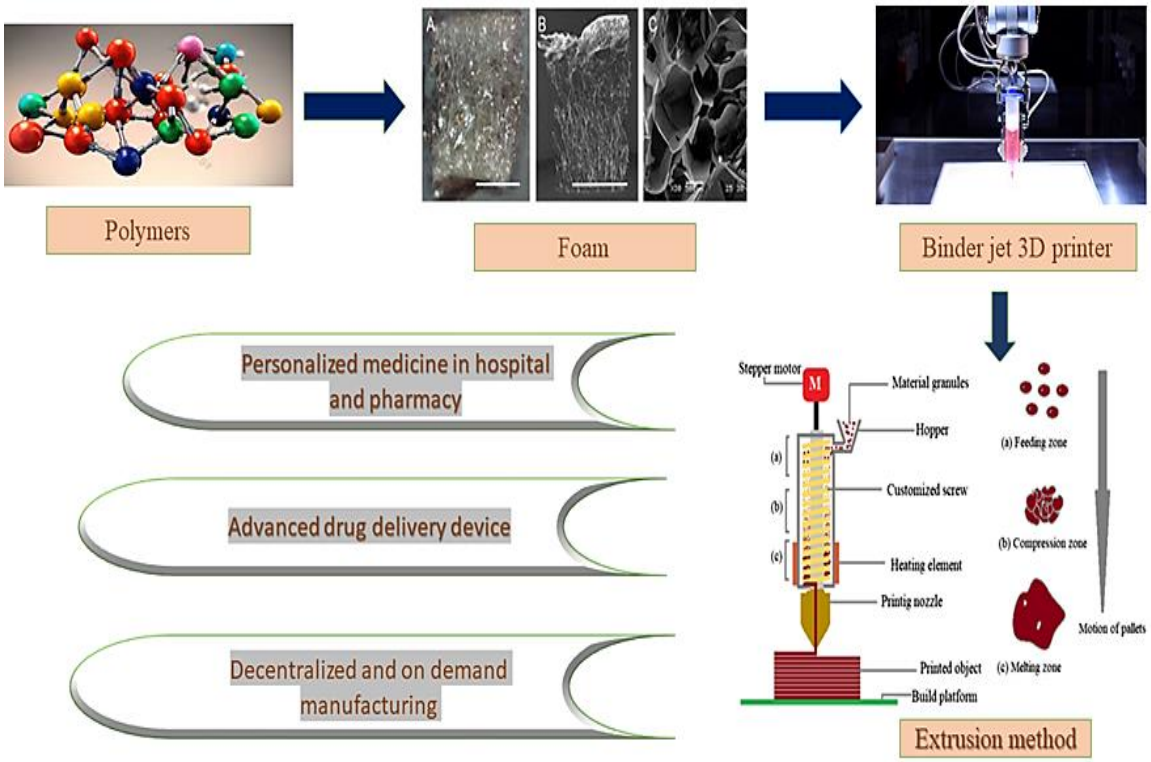


Figure 10. Common 3D printing techniques.

The following Table 3 summarizes key findings from leading industry reports [6].

Table 3. Economical recent market surveys show in the 3D printed drug sector.

Attribute/Region	2024 Market Size (USD Million)	2025 Market Size (USD Million)	2034/2035 Projected Size (USD Million)	CAGR (%)	Key Insights
Global (Future Market Insights)	363.7	396.9	1,014.8 (2035)	9.8 (2025–2035)	Personalized medicine, complex drug delivery, US and China fastest growth [11].
Global (Straits Research)	106.46	122.43	374.52 (2033)	15 (2025–2033)	North America largest, Asia-Pacific fastest growing, rising adoption for rare diseases [12].
Global (Precedence Research)	338.28	368.18	789.2 (2034)	8.84 (2025–2034)	Rapid delivery of novel medicines, focus on bespoke and rare disease treatments [13].
Global (Roots Analysis)	281.63	—	605.09 (2035)	7.2 (2024–2035)	North America dominates, Asia-Pacific shows high growth, tailored drugs for elderly/pediatrics [14].
Global (Towards Healthcare)	113.77	131.25	461.31 (2034)	15.35 (2025–2034)	AI integration, precision manufacturing, rapid adoption for personalized medicines [15].
United States	96.41	—	—	11.4 (2025–2035)	Leading R&D, innovation, and adoption of personalized 3D printed drugs [12].
China	—	—	—	12.7 (2025–2035)	Fastest growth due to collaborations and healthcare infrastructure investments [12].

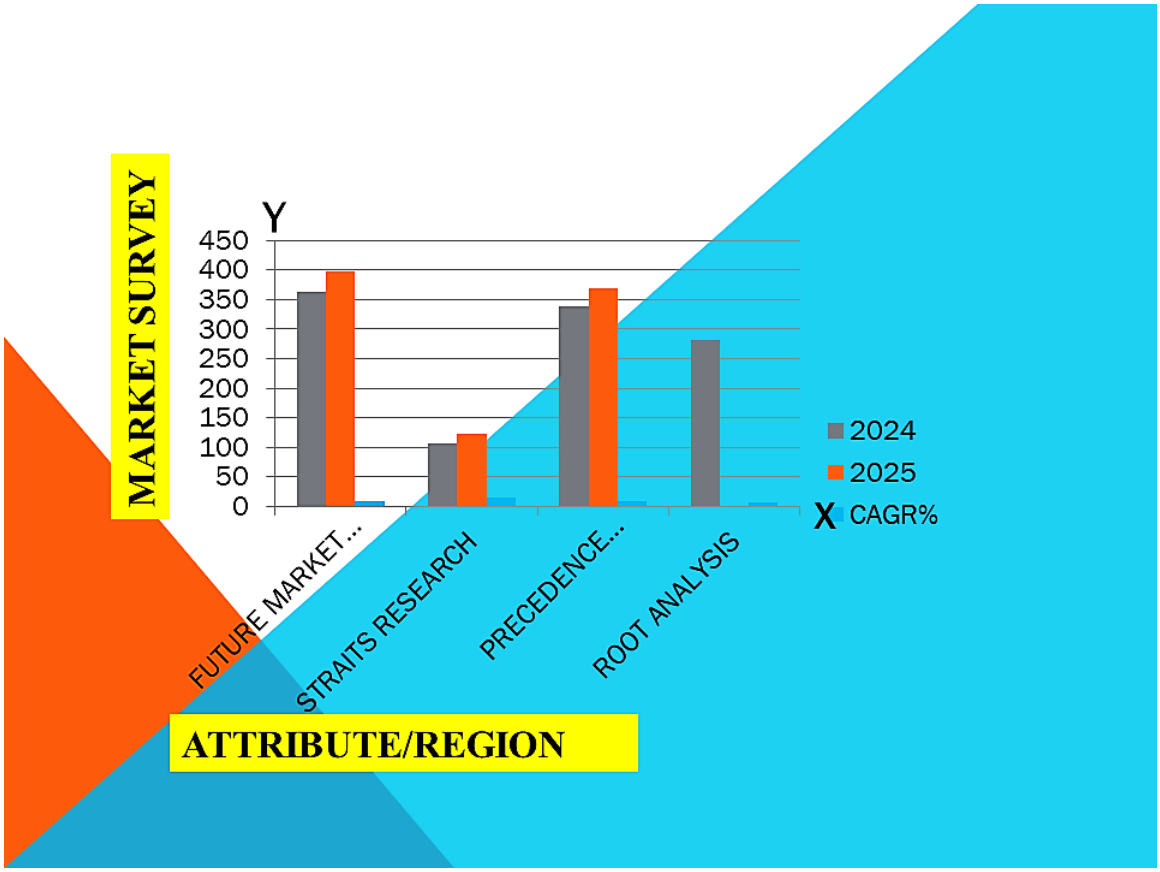


Figure 11. Bar graph showing economical recent market surveys in 3D printed drug sector.

CHALLENGES AND LIMITATIONS

Despite its promise, 3D printing in controlled drug delivery faces several significant challenges and limitations that must be addressed for broader clinical adoption [42–44].

- *Regulatory Barriers:* The lack of precise regulatory guidance is a major barrier for drugs that are 3D printed. There are currently no comprehensive regulations for drug goods, despite the FDA and other authorities issuing guidelines for 3D-printed medical items. The use of 3D-printed drugs in healthcare systems is limited by this statutory ambiguity, which further complicates clearance processes [45, 46].
- *Material Selection and Printability:* Choosing suitable materials is complex, requiring careful consideration of biocompatibility, stability, and regulatory approval. Issues, such as nozzle clogging, layer adhesion, and print accuracy, can impact the quality and consistency of printed drugs. The small number of pharmaceutically approved polymers further restricts formulation options [47].
- *Quality Control and Dose Uniformity:* Ensuring uniform drug dosage and consistent product quality is challenging due to potential variability in the printing process. For real-time evaluation at production sites, trustworthy, non-destructive quality control techniques (such as NIR and Raman spectroscopy) are still being developed [46].
- *Scalability and Mass Production:* While 3D printing excels at personalized, small-batch manufacturing, scaling up for mass production remains difficult. Production time, cost-effectiveness, and maintaining regulatory compliance at larger scales are on-going concerns [48].
- *Technological Complexities:* The use of heat, solvents, and light in various 3D printing techniques can affect drug stability and product performance. Barriers also come from technical concerns including reproducibility, process optimization, and equipment maintenance [8, 49].
- *Intellectual Property and Legal Issues:* Patent infringement, technology licensing, and protection of proprietary formulations add complexity to the development and commercialization of 3D-printed pharmaceuticals [8, 48].

- *Ethical and Data Privacy Concerns:* The use of patient-specific data for personalized drug design raises ethical issues related to data privacy and informed consent, which must be addressed as technology advances [50, 51].
- *Good Manufacturing Practice (GMP) Compliance:* For clinical application, 3D printing techniques and equipment must adhere to GMP regulations. Compact, GMP-compliant printers are still under development, and widespread adoption will require robust quality assurance systems [6, 52].

FUTURE DIRECTIONS

3D printing's future in controlled release drug administration is characterized by swift technological development, evolving regulations, and growing clinical use. Numerous significant trends and orientations are influencing the next ten years [53, 54].

- *Distributed and Point-of-Care Manufacturing:* Distributed manufacturing frameworks will be made possible by new rules, like those that the UK will implement in 2025, which will allow 3D printing of pharmaceutical items right in community and hospital pharmacies [55]. This shift reduces production time and increases access to personalized medicines by enabling small-batch, on-demand production that is tailored to each patient's needs [6].
- *Automation and Digital Integration:* Integration of automation, artificial intelligence (AI), and digital health tools is expected to optimize compounding, reduce pharmacist workload, and ensure real-time quality control. Pharmacy processes can be streamlined and human error reduced by using automated devices to monitor bulk homogeneity and process parameters [56].
- *Advancements in Materials and Bioprinting:* New polymers, bio-inks, and excipients that facilitate more intricate, accurate, and biocompatible drug delivery systems are being developed, thanks to ongoing material science and bioprinting research. Even more customization of dose formulations and release profiles will be possible because to these advancements [8, 55].
- *Regulatory Progress and Global Adoption:* Regulatory agencies are becoming more receptive to the concept as protocols for the effective and safe use of 3D-printed medications advance. This regulatory progress is expected to accelerate global adoption, especially as more countries invest in healthcare innovation and supportive policies [6, 57].
- *Sustainability and Waste Reduction:* Pharmaceutical waste may be decreased by 3D printing since it enables just-in-time manufacturing and reduces excess inventory. This is consistent with more general trends in resource optimization and sustainability in healthcare [6, 58].
- *Expansion into New Therapeutic Areas:* The versatility of 3D printing will drive its application in new domains, such as oncology, rare diseases, and pediatric care, where individualized dosing and complex drug regimens are critical [59, 60].

CONCLUSIONS

3D printing is fundamentally reshaping the landscape of controlled release drug delivery by enabling the creation of highly personalized, complex, and patient-centric pharmaceutical products. This technology allows precise modulation of drug release profiles, multi-drug combinations, and on-demand manufacturing-capabilities that are difficult to achieve with traditional pharmaceutical methods. The rapid growth of the global 3D printed drugs market, with projections ranging from $374 million to over $1 billion by 2033–2035 and strong double-digit CAGR, underscores the increasing adoption and clinical relevance of this approach. North America currently leads the market, while Asia-Pacific is emerging as the fastest-growing region, driven by investments in healthcare innovation and regulatory advancements. Despite notable challenges, such as regulatory uncertainty, material limitations, and scalability ongoing progress in automation, material science, and digital integration is paving the way for broader clinical implementation. In regulated medication delivery, decentralized, automated, and sustainable production is the way of the future for 3D printing, which will bring personalized medicine closer to routine clinical practice. In summary, 3D printing stands at the forefront of pharmaceutical innovation, offering transformative potential to improve therapeutic outcomes, patient adherence, and healthcare efficiency worldwide.

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