

3D PRINTING TECHNOLOGY IN PHARMACEUTICAL DRUG DELIVERY: RECENT DEVELOPMENTS, INSTRUMENTATION, ARTIFICIAL INTELLIGENCE AND FUTURE PROSPECTS

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ABSTRACT

Three-dimensional (3D) printing, commonly referred to as additive manufacturing, has emerged as an innovative approach in the pharmaceutical field, particularly for the development of personalized drug delivery systems. In this technology, pharmaceutical materials are processed in successive layers to generate dosage forms with predetermined dimensions, structures, drug content, and release characteristics. Several techniques, including fused deposition modelling (FDM), stereolithography (SLA), selective laser sintering (SLS), inkjet printing, powder-based printing, and semi-solid extrusion, have been explored for manufacturing customized pharmaceutical products.^[1-6] These approaches have enable the development of a wide variety of drug delivery systems, including immediate-release, sustained-release, delayed-release, pulsatile-release, transdermal, vaginal, implantable, and combination dosage

forms.^[2-8] The regulatory approval of Spritam® (levetiracetam) represented an important milestone in pharmaceutical 3D printing and encouraged further research into patient-specific drug delivery.^[3,4] The major benefits of this technology include flexible dose adjustment, complex product design, controlled drug release, incorporation of multiple active pharmaceutical ingredients, and potential for on-demand production.^[1-8] Nevertheless, limitations associated with equipment cost, material selection, drug stability, process

reproducibility, scale-up, quality assurance, and regulatory compliance continue to restrict widespread implementation. The incorporation of artificial intelligence (AI), machine learning (ML), and Internet of Things (IoT) technologies may further improve formulation development, printing-process optimization, real-time monitoring, and product-quality prediction. This review discusses the fundamental principles, major printing methods, instrumentation, benefits, limitations, pharmaceutical applications, current products, and future opportunities of 3D printing, with particular emphasis on the emerging role of AI in pharmaceutical manufacturing.

KEYWORDS: Three-dimensional printing; Personalized medicine; Pharmaceutical drug delivery; Customized dosage forms; Fused deposition modelling; Selective laser sintering; Artificial intelligence; Controlled drug release.

1. INTRODUCTION

Three-dimensional printing is a digitally controlled additive manufacturing process in which a physical object is constructed progressively by depositing, binding, or solidifying materials in successive layers.^[1] Initially developed for applications in engineering and rapid prototyping, the technology has gradually expanded into biomedical research, tissue engineering, dentistry, prosthetic development, and pharmaceutical manufacturing. Its ability to provide precise control over product architecture and material placement has made it an attractive alternative for designing advanced drug delivery systems.^[1,5]

Conventional pharmaceutical manufacturing generally involves large-scale production of dosage forms with predetermined strengths and standardized physical characteristics. Such a manufacturing model may not adequately address the diverse therapeutic requirements of individual patients. Differences in age, body weight, physiological conditions, disease severity, and medication requirements can result in the need for different drug doses and release patterns. Pharmaceutical 3D printing offers a potential solution by enabling the preparation of dosage forms that can be customized according to individual therapeutic needs.^[2,6,8]

The approval of Spritam® (levetiracetam) as the first FDA-approved 3D-printed medicine demonstrated the practical potential of additive manufacturing in pharmaceutical applications.^[3,4] Following this development, research activities have expanded toward the fabrication of various pharmaceutical products, including tablets, printlets, implants, vaginal

delivery systems, transdermal devices, microneedles, and other specialized drug delivery platforms.^[3,7,8]

One of the important features of 3D printing is the ability to control the distribution of active pharmaceutical ingredients (APIs) and excipients within the printed structure. Modification of parameters such as product geometry, dimensions, internal channels, infill pattern, material composition, and printing conditions can influence the rate and mechanism of drug release.^[4,8] Furthermore, different drugs can potentially be incorporated into a single dosage form, allowing the development of polypills that may help reduce the number of individual medicines taken by patients.^[2,14]

The technology has particular relevance to patient-centered and precision-based healthcare. Customized formulations may be beneficial for pediatric and geriatric patients and for individuals who experience difficulty swallowing conventional dosage forms.^[2,8] Moreover, combining 3D printing with AI, ML, and IoT technologies could facilitate automated formulation optimization, intelligent process control, quality assessment, and potentially decentralized medicine production.^[15]

2. ADVANTAGES OF 3D PRINTING IN PHARMACEUTICAL DRUG DELIVERY

2.1 Personalized Dose Preparation

One of the most important benefits of pharmaceutical 3D printing is its ability to produce dosage forms containing customized amounts of drugs. This approach may be especially useful when standard commercial strengths are unsuitable for pediatric, geriatric, or other patients who require individualized dosing.^[2,6]

2.2 Regulation of Drug Release

The drug-release characteristics of a printed dosage form can be modified by adjusting its geometry, surface area, internal architecture, porosity, and polymeric composition. Consequently, 3D printing can be explored for the preparation of immediate-, sustained-, delayed-, and pulsatile-release systems.^[1,4,8]

2.3 Incorporation of Multiple Active Ingredients

Several APIs may be incorporated within one printed dosage form, either by placing them in separate compartments or by designing individual regions with different release

characteristics. This strategy may reduce the daily pill burden and potentially improve treatment adherence in patients receiving multiple medications.^[2,14]

2.4 Fabrication of Complex Structures

3D printing allows the creation of intricate geometries that may be difficult or impractical to manufacture using traditional pharmaceutical processes. Hollow structures, internal channels, multilayer systems, and customized shapes can be designed using digital modelling tools.^[4,8]

2.5 On-Demand Production

The digital nature of 3D printing creates the possibility of producing medicines when and where they are required. In the future, this may support customized production in selected hospitals, pharmacies, or specialized healthcare facilities, although appropriate regulatory and quality systems will be essential.^[1,16]

2.6 Adaptable Dosage-Form Characteristics

Important characteristics such as drug strength, dimensions, shape, appearance, texture, and release behaviour can potentially be modified by changing the digital design or formulation parameters. This provides greater flexibility during dosage-form development.^[14]

2.7 Potential Reduction in Material Waste

Since 3D printing is based on an additive manufacturing principle, material is generally placed only in the regions required to construct the product. This may provide an opportunity to reduce unnecessary material consumption compared with certain conventional manufacturing processes.^[1]

2.8 Development of Advanced Drug Delivery Platforms

The versatility of 3D printing has enabled research into several pharmaceutical delivery systems, including oral tablets, mini-tablets, implants, vaginal rings, intrauterine devices, microneedles, and transdermal systems.^[3,7,8]

3. DISADVANTAGES AND LIMITATIONS OF 3D PRINTING

3.1 High Initial Investment

Pharmaceutical-grade 3D printing may require specialized printers, processing equipment, software, and quality-control instruments. The initial investment may therefore be relatively high.

3.2 Restrictions in Material Selection

A pharmaceutical material cannot necessarily be used with every printing technique. The formulation must possess appropriate characteristics such as viscosity, flow properties, mechanical strength, thermal stability, or photoreactivity, depending on the selected technology.^[5,6]

3.3 Risk of Drug Degradation Due to Heat

FDM-based printing involves elevated temperatures during filament preparation and printing. Therefore, drugs that are sensitive to heat may experience degradation or loss of potency during processing.^[14]

3.4 Lower Manufacturing Speed

Some 3D printing systems require considerable time to fabricate individual dosage forms. Consequently, their production capacity may be lower than that of conventional high-speed pharmaceutical manufacturing equipment.

3.5 Variability and Reproducibility

Differences in material characteristics, printer performance, environmental conditions, and processing parameters can influence the physical quality and drug-release behaviour of the final product. Maintaining consistent results is therefore an important challenge.^[5,6]

3.6 Regulatory Difficulties

Personalized and decentralized manufacturing models introduce new regulatory considerations. Validation, quality assurance, process monitoring, product consistency, and control of individualized production must be carefully addressed before widespread implementation.^[5,16]

3.7 Challenges in Industrial Scale-Up

A printing process that performs successfully at laboratory scale may not always be directly transferable to large-scale production. Maintaining uniformity and reproducibility during scale-up remains a significant concern.

3.8 Drug Stability Problems

Depending on the printing technique, pharmaceutical ingredients may be exposed to heat, light, solvents, or laser energy. Such conditions may negatively affect drugs that are sensitive to these processing environments.

3.9 Requirement for Skilled Personnel

Effective pharmaceutical 3D printing requires multidisciplinary knowledge involving pharmaceutics, materials science, computer-aided design, digital manufacturing, printer operation, and quality evaluation.

4. MAJOR 3D PRINTING METHODS USED IN PHARMACEUTICAL APPLICATIONS

4.1 Fused Deposition Modelling (FDM)

Fused deposition modelling is one of the extensively studied extrusion-based technologies for pharmaceutical applications. In this approach, a drug-containing polymer filament is heated until it reaches a suitable state for extrusion. The softened material is then forced through a nozzle and deposited in successive layers based on a computer-generated digital model.^[4,5,14]

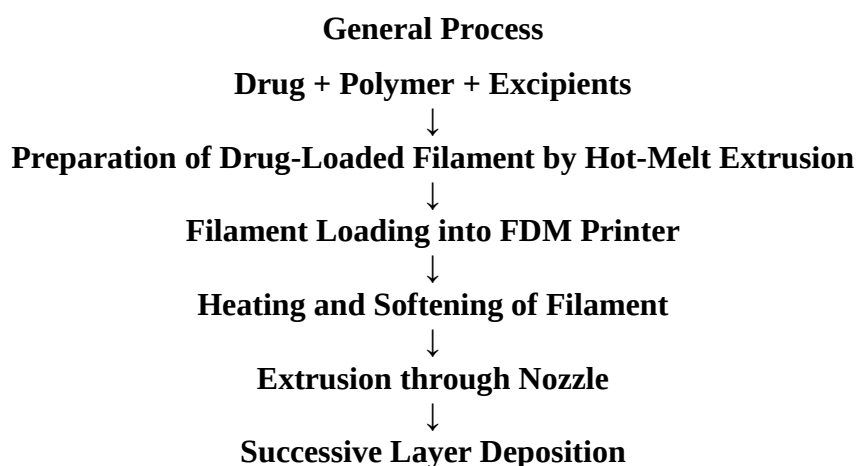


Fig 1: Fused Deposition Modelling (FDM)

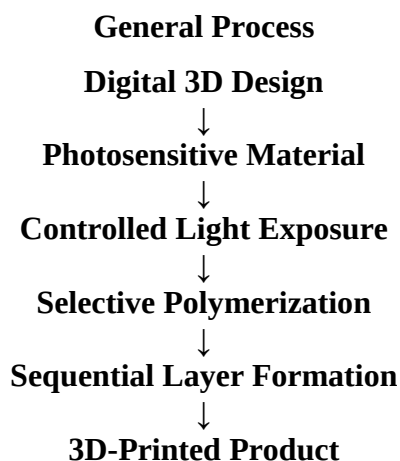
↓

Final 3D-Printed Dosage Form

FDM has been investigated for the preparation of tablets, mini-tablets, implants, polypills, intrauterine devices, and other drug delivery systems. However, the elevated processing temperature can restrict its use for heat-sensitive pharmaceutical ingredients.^[5,14]

4.2 Stereolithography (SLA)

Stereolithography is a light-assisted printing process in which a photosensitive liquid material is selectively polymerized using a light source, commonly ultraviolet radiation. The desired three-dimensional structure is generated by repeatedly curing individual layers according to a digital model.^[5,6]



SLA is capable of producing highly detailed and complex structures. However, the limited availability of suitable pharmaceutical-grade photopolymers and possible concerns related to photoinitiators may restrict its wider use in drug delivery.^[5,6]

4.3 Selective Laser Sintering (SLS)

Selective laser sintering is a powder-based additive manufacturing method. A thin layer of drug-containing powder or polymeric material is spread over the printing surface. A laser selectively fuses the desired regions, after which another powder layer is applied. Repetition of this process results in the formation of the complete three-dimensional product.^[5,6]

SLS can generate porous structures and may provide opportunities to modify drug-release characteristics by controlling the porosity and processing conditions. However, exposure to laser energy must be carefully considered when processing sensitive pharmaceutical compounds.

4.4 Inkjet Printing

Inkjet printing involves the controlled deposition of very small quantities of drug-containing liquid onto a selected surface. The location and amount of deposited material can be accurately controlled through digital instructions. This technique is particularly useful when precise placement of small drug quantities is required.^[3,4]

For successful printing, the formulation must possess suitable physicochemical properties, including appropriate viscosity and surface tension. Therefore, formulation optimization is an important consideration for this method.



Fig 2: Inkjet printing.

4.5 Semi-Solid Extrusion (SSE)

Semi-solid extrusion is an extrusion-based technology in which a semi-solid formulation is pushed through a nozzle and deposited in successive layers to construct the desired dosage form. Hydrogels, pastes, and other semi-solid formulations can be processed using this approach.^[3,8]

The method offers considerable formulation flexibility and has attracted interest in the development of customized chewable dosage forms and other patient-specific pharmaceutical products.

4.6 Powder-Based Printing

Powder-based printing involves the selective binding of powder particles using a suitable liquid binder or another binding mechanism. Repeated application and binding of powder layers results in the formation of the final dosage form.

The technique can be used to create complex structures and may be particularly useful for designing dosage forms that require rapid disintegration.

5. INSTRUMENTATION USED IN PHARMACEUTICAL 3D PRINTING

A typical pharmaceutical 3D printing system consists of several interconnected components that collectively convert a digital design into a physical dosage form.

5.1 Computer-Aided Design (CAD) System

CAD software is used to create and modify the digital model of the required dosage form. Parameters such as dimensions, shape, internal architecture, and geometry can be specified during the design stage.^[7]

5.2 Digital Printer-Control System

The digital model is converted into machine-readable instructions that determine the movement of the printer and the deposition or solidification of the selected material.

5.3 Material or Drug-Formulation Reservoir

Depending on the printing technique, this unit stores the drug-loaded filament, powder, liquid ink, polymer solution, or semi-solid formulation required for manufacturing.

5.4 Printing or Extrusion Nozzle

In extrusion-based systems such as FDM and SSE, the nozzle delivers the formulation onto the printing platform in a controlled manner to create successive layers.

5.5 Heating Unit

FDM systems generally contain a heating element that softens or melts the polymer filament before it is extruded through the nozzle.

5.6 Printing Platform

The printing platform acts as the base on which the dosage form is constructed during the printing process.

5.7 Light or Laser Source

SLA systems use a controlled light source to polymerize photosensitive materials, whereas SLS systems use a laser to selectively fuse powder particles.

5.8 Motion-Control Mechanism

Motors and mechanical components control the movement of the print head, nozzle, or printing platform to achieve accurate material deposition.

5.9 Software and Process-Control Unit

The software regulates important printing parameters, including layer height, printing speed, infill pattern, temperature, extrusion rate, and nozzle movement.

6. ROLE OF ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL 3D PRINTING

Artificial intelligence has the potential to strengthen pharmaceutical 3D printing by supporting formulation design, process optimization, quality assessment, and personalized medicine. However, AI should be viewed as a complementary tool that assists pharmaceutical professionals rather than replacing scientific expertise and established quality-control systems.

6.1 AI-Based Formulation Optimization

AI and machine learning algorithms can evaluate relationships between formulation variables and the resulting properties of printed products. Variables such as polymer concentration, drug content, viscosity, and excipient selection may be analyzed to predict their influence on printability and drug release.

6.2 Optimization of Printing Conditions

AI-based predictive models may assist in selecting suitable printing conditions, including:

- Printing speed
- Nozzle temperature
- Layer thickness
- Infill density
- Printing orientation
- Extrusion rate
- Laser power
- Laser scanning speed

Appropriate optimization of these variables may improve the quality and consistency of printed pharmaceutical products.

6.3 Prediction of Drug-Release Profiles

Machine learning models may be developed to establish relationships between formulation composition, product geometry, and drug-release behavior. This approach could help reduce the number of experimental trials required during formulation development.

6.4 AI-Assisted Quality Assessment

Computer-vision systems supported by AI may be capable of identifying manufacturing defects, including cracks, dimensional deviations, incomplete structures, and surface abnormalities. Such systems may support real-time monitoring of the printing process.

6.5 Support for Personalized Medicine

Integration of patient-specific information with digital manufacturing platforms may facilitate the preparation of individualized dosage forms. This could be beneficial for patients who require uncommon drug strengths or complex therapeutic regimens.^[2,15]

6.6 Integration of AI, 3D Printing, and IoT

The combination of AI, ML, IoT, and 3D printing may lead to more intelligent pharmaceutical manufacturing systems. Such integrated platforms could continuously monitor production conditions, identify potential process deviations, predict quality problems, and support automatic adjustment of selected printing parameters.^[15]

7. CURRENT 3D-PRINTED PHARMACEUTICAL PRODUCTS AND APPLICATIONS

7.1 Spritam® (Levetiracetam)

Spritam® is recognized as the first FDA-approved 3D-printed pharmaceutical product. The levetiracetam-containing product was manufactured using ZipDose® technology and demonstrated the feasibility of using 3D printing to produce rapidly disintegrating pharmaceutical dosage forms.^[3,4]

7.2 Personalized 3D-Printed Tablets

Customized tablets with different drug strengths, dimensions, shapes, and release characteristics have been investigated. Such dosage forms may provide an alternative to standardized commercial strengths for patients requiring individualized treatment.^[2,6,8]

7.3 3D-Printed Polypills

The ability to place several APIs within a single printed dosage form has encouraged the development of polypill concepts. Different drugs can potentially be positioned in separate regions and designed to release at different rates, which may help decrease the number of individual tablets required by patients.^[2,14]

7.4 3D-Printed Mini-Tablets

Customized spherical and other geometrically designed mini-tablets have been studied as personalized dosage forms. Modifying the formulation and structural characteristics can influence drug loading and dissolution behavior.^[15]

7.5 3D-Printed Drug-Loaded Implants

Additive manufacturing has been explored for producing biodegradable and drug-loaded implants designed to provide prolonged drug release. Intravitreal implants represent one area where this approach has been investigated.^[17]

7.6 3D-Printed Vaginal Drug Delivery Systems

Researchers have explored the use of 3D printing to manufacture vaginal rings, intravaginal inserts, and biodegradable microdevices. These systems may allow drug loading and release characteristics to be tailored according to therapeutic requirements.^[3]

7.7 3D-Printed Intrauterine Drug Delivery Devices

Drug-loaded intrauterine devices containing anticancer agents have been investigated for localized treatment of uterine cancer. Fused filament fabrication provides opportunities to customize both the geometry and drug dosage of these devices.^[18]

7.8 3D-Printed Microneedles

3D printing has also been investigated for manufacturing microneedle systems designed for transdermal drug delivery. Advanced printing approaches can produce microneedles with customized shapes and dimensions, allowing controlled penetration into the skin.^[19]

7.9 3D-Printed Drug-Adsorbing Biosponge Systems

3D-printed porous biosponge devices have been explored as a strategy for capturing excess chemotherapy drugs within the body. Such systems are intended to reduce exposure of healthy tissues to unbound anticancer drugs and potentially minimize off-target toxicity.^[20]

7.10 3D-Printed Bilayer Controlled-Release Tablets

The combination of hot-melt extrusion and FDM printing has been investigated for preparing bilayer tablets with adjustable drug-release behavior. Modification of the relative proportions of individual layers and their geometric arrangement can influence the resulting dissolution profiles.^[21]

8. Future Perspectives

The continued development of pharmaceutical 3D printing is expected to contribute significantly to personalized and precision medicine. Digital manufacturing may eventually allow patient-specific dosage forms to be produced in selected hospitals, pharmacies, and specialized manufacturing facilities. The integration of AI and machine learning could further support formulation development, optimization of printing parameters, continuous process monitoring, and prediction of product quality.^[15,16]

Future research should prioritize the identification of safe and printable pharmaceutical materials, improvement of manufacturing speed, enhancement of reproducibility, and development of standardized quality-control procedures. Appropriate regulatory frameworks will also be essential for ensuring the safety, efficacy, and consistency of personalized and on-demand 3D-printed medicines.

The integration of 3D printing with AI, IoT, digital healthcare, and advanced analytical technologies may contribute to the development of intelligent manufacturing platforms capable of producing patient-centered pharmaceutical products. Such developments could potentially transform conventional pharmaceutical manufacturing from standardized mass production toward more individualized and flexible approaches.

9. CONCLUSION

Three-dimensional printing has emerged as a promising technology for the development of innovative pharmaceutical dosage forms and personalized drug delivery systems. Its ability to modify drug content, product geometry, internal structure, material composition, and release behaviour provides significant flexibility compared with conventional manufacturing approaches. Technologies such as FDM, SLA, SLS, inkjet printing, powder-based printing, and semi-solid extrusion have each demonstrated potential for producing customized pharmaceutical products.

The development and approval of Spritam® provided an important milestone for pharmaceutical 3D printing, while subsequent research has expanded the technology toward personalized tablets, polypills, mini-tablets, drug-loaded implants, microneedles, vaginal delivery systems, intrauterine devices, and controlled-release dosage forms.^[3,8,18–21] Nevertheless, challenges involving material selection, drug stability, reproducibility,

production capacity, cost, quality assurance, and regulatory approval must be addressed before widespread clinical and commercial adoption.

The future combination of 3D printing with AI, machine learning, and IoT technologies may provide new opportunities for intelligent formulation design, automated process optimization, real-time quality monitoring, and individualized medicine production. Therefore, the integration of additive manufacturing with emerging digital technologies has the potential to support a transition toward more personalized, flexible, and patient-centered pharmaceutical drug delivery systems.

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