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# THE ERA OF DIGITAL PHARMACY: 3D PRINTING IN THE PHARMACEUTICAL INDUSTRY

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**ABSTRACT**

3D printing, also called additive manufacturing technology, is an innovative technology for building three-dimensional objects by laying down successive layers of material under the control of a computer software. It is entering pharmacy mainly because of its revolutionary potential to provide individualized dosage forms that meet the needs of each patient, due to the possibility to produce objects of many different sizes and shapes. An important aspect of personalized 3D tablets is the possibility to include several active substances in one dosage form, which would reduce the daily number of medications and the frequency of their administration and improve patient compliance. Another advantage of 3D printing is the possibility of producing small batches or even individual drugs for each patient. Despite the many advantages, 3D printing has several technological challenges to overcome before it becomes widely applicable in pharmacy. Five basic technologies are currently applied in pharmaceutical practice: powder-based printing, selective laser sintering, stereolithography, extrusion moulding printing, and electrohydrodynamic 3D printing.

**KEYWORDS:** 3D printing; FDM; SLA; pharmaceuticals.

## INTRODUCTION

In contrast to the traditional manufacturing techniques of “subtractive manufacturing”, 3D printing is an “additive manufacturing” technology, where a model is constructed using computer-aided design software, sliced, and transferred to a printer, and the 3D product is then constructed layer by layer using the principle of layered manufacturing.[1,2] With the research and development of 3D printing technology, many new 3D printing technologies have emerged one after another. As each 3D printing technology uses different materials, deposition techniques, layering manufacturing mechanisms, and final product characteristics, the American Society for Testing and Materials classified 3D printing technologies into seven categories according to their technical principles.[3,4], namely material extrusion, binder jetting, powder bed fusion, vat photopolymerization, material jetting, directed energy deposition, and sheet lamination.

Three-dimensional printing technology is widely used in automotive, construction, aerospace, medical, and many other fields. In the pharmaceutical sector, research into 3D printing technology is currently experiencing a global boom.[5,6] Compared to traditional preparation technologies, 3D printing offers flexibility in the design of complex 3D structures within drugs, the adjustment of drug doses and combinations, and rapid manufacturing and prototyping, enabling precise control of drug release to meet a wide range of clinical needs, a high degree of flexibility and creativity to personalise pharmaceuticals, and a significant reduction in preparation development time, driving a breakthrough in drug manufacturing technology and transforming the way we design, manufacture, and use drugs.[7,8,9] Three-dimensional printing technologies have been used to manufacture a variety of medicinal products, such as immediate-release tablets, controlled-release tablets, dispersible films, microneedles, implants, and transdermal patches.[10] The main 3D printing technologies used in pharmaceuticals are BJ-3DP, FDM, SSE, and MED in material extrusion and SLA.[11]

Owing to the recent development and uptake of non-invasive drug and disease-monitoring strategies (e.g. smart wearable devices combined with artificial intelligence [AI]) and electronic prescriptions, 3D printing provides a unique platform that can produce medicines in response to changing situations and patient needs in a rapid, digital and decentralised manner [12] Several studies have highlighted the potential for 3D printing technologies to be combined with AI for a multitude of benefits, including AI determining printability, as well as ensuring the quality and safety of the final printed drug product. [13-17] This concept could lead to a new era of digital pharmacy, enabling electronic prescriptions to be sent to a decentralised 3D printer location for real-time personalised medicine dispensing (Figure 1). A wide range of stakeholders, including academic researchers, clinical pharmacists, doctors, biotech start-ups, large pharmaceutical companies and research funding bodies, are exploring this vision globally.[18]

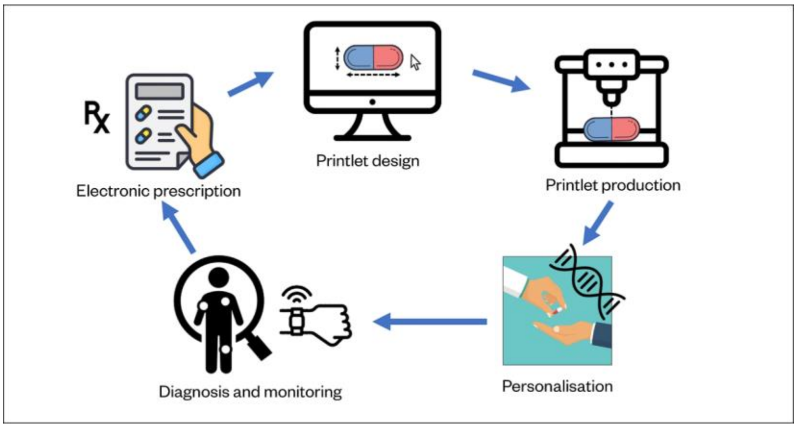



**Figure 1**: **The five components of a digital pharmacy era.**

**TYPES OF PHARMACEUTICAL 3D PRINTING SYSYTEMS**

In 1986, 3D printing technology was developed and commercialised by Charles Hull; since then, several different 3D printing methods have been introduced [19-21]. The over-arching term ‘3D printing’ is now used to describe a wide range of printing technologies. Generally, all of these 3D printing technologies follow a common process for printlet production, described as the ‘3 Ds of 3D printing’ and provide a pathway for the future use and integration of this technology into clinical practice.[22]

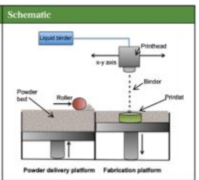
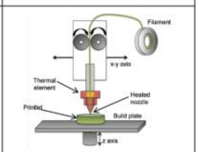
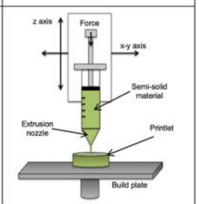
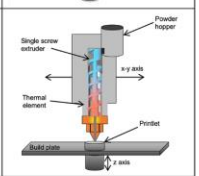
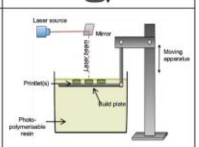
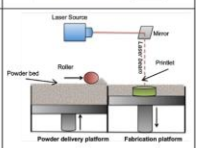
**Design:** Using digital computer-aided design software, the pharmacist can design the formulation — for example, selecting the printlet geometry (shape and size) that can be targeted to the pre-clinical or clinical requirements. The designed formulation is then digitally transferred to the selected 3D printer;

**Develop:** Printlets are developed by inserting the required 'ink' cartridge (composed of a mix of drug and excipients) into the selected 3D printer. The most appropriate printing parameters are selected (e.g. resolution, temperature, printing time), which are typically based on the printer type, drug characteristics and desired outcomes;

**Dispense:** The 3D printer is then ready to automatically prepare the printed formulations layer by layer, which are then ready for 'dispensing' by the pharmacist.

There are six main types of 3D printing methods explored in pharmaceuticals, described in Table 1.
To date, fused deposition modelling (FDM), selective laser sintering (SLS), stereolithography (SLA), binder jet (BJ) printing, direct powder extrusion (DPE) and semi-solid extrusion (SSE) have all been explored for the production of pharmaceuticals [35-39] Each technology comes with unique technical requirements and produces personalised drug products with a variety of characteristics — ranging from rapidly dissolving and orally disintegrating drug products to delayed and sustained release preparations. Table 1 details each technology, the types of drug products that can be produced and provides a schematic showcasing the technologies mode of action.[23-49]

**Table 1: The six main 3D printing technologies used in pharmaceuticals.**

| 3D printer | Mode of action | Advantages | Disadvantages | Schematic |
|---|---|---|---|---|
| **Binder jet printing** | A nozzle containing a binder liquid moves along an x-y axis depositing the liquid onto a flat powder surface. The liquid binds the powder particles together, causing layer solidification. The fabrication build plate is then moved down along the vertical z-axis. A thin powder layer is distributed on top and the process is repeated sequentially to fabricate a 3D-printed medicine | • Capable of producing delayed release and zero order release (a drug released at a constant rate) formulations; • Used to develop the world's first US Food and Drug Administration (FDA)-approved 3D printed medicine; • Capable of producing immediate- and sustained-release formulations; • High resolution enables the formation of complex geometries. | • Expensive process; • Lack of portable equipment. |  |
| **Fused deposition modelling** | A drug-loaded filament is extruded through a heated nozzle. The printer head is moved along the x-y axis to release the molten extrudate, which solidifies at room temperature onto a build plate. The build plate is sequentially lowered along the vertical z-axis to enable a layer-by-layer fabrication of a 3D-printed medicine | • Capable of producing immediate and sustained-release formulations; • Can improve solubility of poorly soluble drugs (by producing amorphous solid dispersions); • Ability for multi-nozzle printing (production of multi-drug combinations); • Cheap system; • Portable, compact and user friendly. | • May be unsuitable for thermosensitive drugs; • Can be challenging to formulate the initial filament feedstock; • Challenging to scale up; • Low drug loading. |  |
| **Semi-solid extrusion** | A drug-loaded semi-solid material (e.g. gel or paste) is extruded using a syringe-based tool head. The printer head is moved along the x-y-z axis to release the extrudate, which solidifies at room temperature onto a build plate | • Suitable for production of chewable and palatable formulations; • Capable of producing a range of formulation types, including immediate-release and controlled-release dosage forms, polypills and oral films. | • Low resolution compared to other 3D printing technologies; • Only suitable for drugs that can be formulated as a semi-solid; • Low throughput. |  |
| **Direct powder extrusion** | An extrusion-based process, a drug-loaded formulation blend is inserted into a powder hopper. The hopper feeds into a heated single screw extruder in the print head, creating a molten extrudate, which solidifies at room temperature onto a build plate. The build plate is sequentially lowered along the vertical z-axis to enable a layer-by-layer fabrication of a 3D-printed medicine | • Capable of producing immediate- and sustained-release formulations • Can improve solubility of poorly soluble drugs (by producing amorphous solid dispersions); • Capable for scale up (demonstrated by Triastek, which developed a FDA investigational new drug application clearance for a formulation prepared using a similar technology). | • May be unsuitable for thermosensitive drugs; • Relatively new 3D printing technology in pharmaceuticals. |  |
| **Stereo-lithography** | The process involves exposing a photopolymerisable resin to high-energy light (e.g. UV light) to induce polymerisation and solidification of the material. Each time, the resin is solidified to a defined depth, the platform is moved down vertically along the z-axis and the built layer is recoated with resin. The process is repeated to create a 3D-printed medicine | • Widely explored for the production of sustained-release drug products and medical devices; • High resolution and accuracy (superior to other 3D printing technologies) enabling the production of complex geometries; • Can improve solubility of poorly soluble drugs; • Suitable for the production of multi-layered polypills. | • May be unsuitable for photosensitive drugs; • Potential issues around material toxicity. |  |
| **Selective laser sintering** | This process employs a laser that is directed to draw a specific pattern on the powder bed, causing selective partial or full melting to bind powder particles. Once the layer is sintered, a roller distributes a fresh layer of powder on top of the sintered material. The process is repeated layer-by-layer to fabricate a 3D-printed medicine | • Capable of forming highly porous dosage forms (rapidly dissolving); • Capable of producing a range of formulation types, including immediate-release through to controlled-release dosage forms and medical devices; • High resolution process enabling the production of complex geometries; • Suitable for the production of polypills. | • May be unsuitable for photosensitive and thermosensitive drugs; • Requires precise control over powder flow characteristics; • Post-processing required. |  |

## THE FUTURE OF PHARMACY: A ROADMAP TO 3D PRINTING INTEGRATION

There are many published research papers demonstrating the potential and role of 3D printing technologies for medicines manufacture and patient care.[50] Figure 2 shows a timeline of 3D printing in pharmaceuticals and highlights the major milestones of this technology in the sector.

Major strides have been made towards overcoming these challenges. Now days 3D Printing technology use for various clinical application in research institute.[51] Previously, commercially available 3D printers were not standardised or fit for purpose to produce pharmaceutical products (i.e. not validated to good manufacturing practice [GMP]). Today, a wide variety of 3D-printed objects in biotechnology—ranging from miniaturized cultivation chambers to microfluidic lab-on-a-chip devices for diagnostics—are already being deployed in labs across the world.[52] Among the various 3D printing technologies under investigation for pharmaceutical applications, fused deposition modeling (FDM) stands out as a particularly promising candidate for pediatric medicine production.[53] Pharmaceutical industries continue developing for better and increase effectivity for formulation of fast dissolving tablets using binder jetting (BJ) technology.[54]

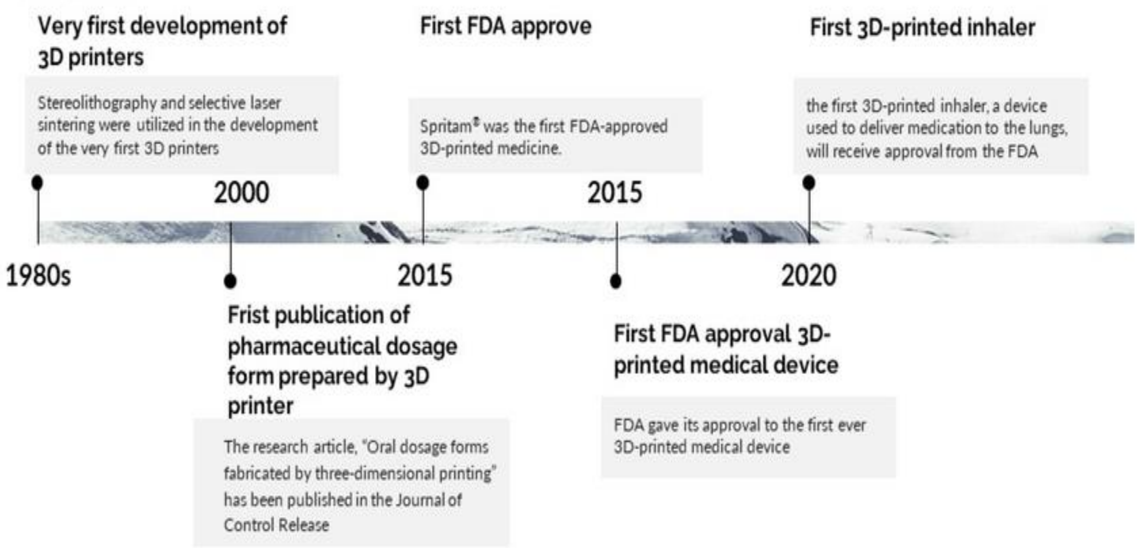



**Figure 2: Graphical timeline of the advances in 3D printed medicines.[55-57]**

## APPLICATIONS OF 3D PRINTING IN PHARMACY

3D printing offers significant potential in pharmaceuticals, enabling personalized medicine, rapid prototyping, and complex dosage form creation, with applications ranging from customized implants and drug delivery systems to rapid dissolving tablets and multi-drug combinations.

Here's a breakdown of key applications:

- **Personalized Medicine:**
- **Tailored Doses:** 3D printing allows for the creation of dosage forms specifically designed for individual patient needs, such as low-dose medications for children or specific formulations for elderly patients with swallowing difficulties.
- **Complex Dosage Forms:** It enables the production of complex, multi-layered tablets or implants with controlled release properties, addressing limitations of conventional manufacturing methods.

- **Polypharmacy:** 3D printing can combine multiple drugs into a single tablet, improving medication adherence and reducing the risk of errors.
- **Patient-Specific Implants:** 3D printing can create customized implants, such as drug-eluting implants, for targeted drug delivery and improved treatment outcomes.
- **Drug Delivery Systems:**
- **Oral Drug Delivery:** 3D printing facilitates the creation of various oral dosage forms, including rapidly dissolving tablets, controlled-release formulations, and gastro-retentive tablets.
- **Transdermal Drug Delivery:** It enables the fabrication of complex geometries for transdermal patches and implants, allowing for local and systemic drug delivery.
- **Microneedles:** 3D printing can produce microneedles for painless and effective drug delivery through the skin.
- **Buccal Films:** 3D printing can create mucoadhesive buccal films for local or systemic drug delivery.
- **Other Applications:**
- **Rapid Prototyping:** 3D printing allows for the rapid development and testing of new drug formulations and dosage forms.
- **Tele pharmacy:** The portability of 3D printers enables on-demand medication production in remote locations or healthcare settings, improving access to medications.
- **Medical Devices:** 3D printing can be used to create medical devices, such as patient-specific prosthetics or surgical tools.
- **Tissue Engineering:** 3D printing plays a role in the development of 3D-printed scaffolds for tissue regeneration.
- **Specific examples of 3D printed pharmaceuticals:**
- **FabRx**: in the UK prepares personalized drugs for children with maple diabetes.
- **SSE printers**: have been placed in the pharmacy of a Spanish hospital and conducted clinical trials on the subject.

## ADVANTAGES AND LIMITATIONS

The use of 3D printing in the pharmaceutical industry is accelerating as a result of the numerous benefits that it offers. However, several constraints are associated with the use of 3D printing in the production of pharmaceuticals. The advantages and disadvantages of 3D printing in pharmaceutical applications are outlined in **Table 2**.

**Table 2: Advantages and limitations of 3D printing in pharmaceutical applications.**

| Advantages | Limitations |
|---|---|
| Customization and personalization—3D printing allows for the production of customized and personalized products that are tailored to the specific needs of individual patients to improve the effectiveness and safety of the treatment.[58,59,60] | Regulation and quality control—Regulatory and quality control issues must be addressed to ensure the safety and efficacy of 3D-printed pharmaceutical products.[58,61] |
| Complex structures and geometries—3D printing allows for the production of complex structures and geometries that are not possible with traditional manufacturing methods and that can enable the development of new and innovative drug delivery systems.[62,63,64,65,66] | Material selection and compatibility—The selection of materials suitable for use in 3D printing in the pharmaceutical industry is limited, and compatibility issues exist with certain drugs or formulations.[58] |
| Cost and efficiency—3D printing can potentially reduce the cost and increase the efficiency of the manufacturing process by enabling the production of small batches of products on demand and reducing the need for large-scale production and inventory management. [63,67 | Scaling up production—Technical challenges exist in scaling up the production of 3D-printed products to meet the demand of the market.[58,68]. |

## CONCLUSION

3D printing has the potential to revolutionise clinical pharmacy practice. It can transition conventional means of medicine mass manufacture towards the production of small batches of highly flexible and personalised dosage forms on-demand. This technology provides benefits for patients, pharmacists and the pharmaceutical industry alike by providing unique advantages such as making treatments safer and more effective. Healthcare professionals, including pharmacists, doctors, and nurses, are of paramount importance in enabling the integration of this technology and will be key to advising academics, the pharmaceutical industry and biotech companies on strategies to innovate the sector using 3D printing.

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