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INTERNATIONAL JOURNAL OF PROGRESSIVE RESEARCH IN ENGINEERING MANAGEMENT AND SCIENCE (IJPREMS)
(Int Peer Reviewed Journal)
Vol. 05, Issue 10, October 2025, pp : 319-324

e-ISSN : 2583-1062
Impact Factor : 7.001

A REVIEW ON 3D PRINTING

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DOI: https://www.doi.org/10.58257/IJPREMS44129

ABSTRACT

In the past few decades, the pharmaceutical industry has been limited by the extent of cutting-edge research in pharmaceutical sciences, because the development of new drugs is a long and complex process accompanied by high risks and high costs . In other words, the current field of drug research and development (R&D) requires significant productivity improvements to shorten the cycle time and cost of drug development. Technologies 3D printing (3DP), is a method of manufacture whereby an object is built up layer by layer It includes multiple techniques, such as fused deposition modelling (FDM), hot melt extrusion (HME), solid state extrusion (SSE), stereolithography apparatus (SLA), digital light processing (DLP), selective laser sintering (SLS), vat polymerisation and binder jetting such as network pharmacology, RNA-sequencing (RNA-seq), high-throughput screening (HTS), or virtual screening (VS) have all accelerated the discovery of new targets, as well as new drugs to some extent Nevertheless, these technologies have rarely been significant contributors to the current process of new drug discovery. Thus, there is an urgent need for new technology to drive the development of new drugs

Keywords: Additive Manufacturing, 3D Printing, Fused Deposition Modelling.

1. INTRODUCTION

Additive manufacturing (AM), or commonly known as 3D printing (3DP), is a method of manufacture whereby an object is built up layer by layer [[1], [2], [3]]. It includes multiple techniques, such as fused deposition modelling (FDM), hot melt extrusion (HME), solid state extrusion (SSE), stereolithography apparatus (SLA), digital light processing (DLP), selective laser sintering (SLS), vat polymerisation and binder jetting [4]. Although widely used in other industries, such as automobile and aerospace, its use in the pharmaceutical field is still in its infancy [5]. Recently, many AM patents have expired [6], which has made this new technology readily available and led to its wide applications in various fields.

The use of AM has brought the pharmaceutical industry a whole step closer to the era of personalised medicine [[7], [8], [9], [10], [11], [12]]. Even when given the same dose, there may be significant inter-individual differences in drug responses [13]. Personalised medicine could result in a lower risk of adverse effects or subtherapeutic benefits due to these dosages outside the therapeutic window [14,15] and could lead to increased adherence and greater satisfaction for patients [16,17]. Personalised medicine also includes suitable dosage forms for special populations, such as paediatric, geriatric, or dysphagic patients so that they are able to utilise medication [18]. While available forms on the market can be altered via breaking/crushing tablets and opening capsules, there may be concerns about inaccurate dosing or inconvenience/ability of the patient to carry out such modifications regularly. Traditional manufacture methods do not provide personalised patient dosing as it is not cost-effective and impractical whereas AM has high accuracy [6], a highly adaptable nature [17] and can be used as an alternative manufacture tool. In a study by Tian et al., a series of tablets containing warfarin were produced, with the dose being varied by changing the tablet size [19]. The resultant tablets had accurate dosage and met the standards required for friability and hardness. In the future, AM technology may be able to produce medications on-demand and be used as a means to increase the accessibility to medicines for those living in remote areas [8,20].

AM can be used to produce complex geometries, which has made the production of certain oral dosage forms and medical devices possible [17,21]. Although its manufacturing speed compared to conventional pharmaceutical mass production is slow, it has its own advantages, such as individualization and relatively low cost for small batch production [22]. Certain AM technologies, e.g., DLP and SLA, are able to create products high in accuracy, making it possible to produce microscale drug delivery systems, such as microneedles (MNs) [23]. Recently, Khaled et al. showed that AM was capable of printing high dose paracetamol tablets, which is not possible by using conventional manufacture methods due to limitations involved in material blending and tabletting compression [24].

However, AM has its own set of constraints, namely, the limited materials suitable for pharmaceutical purposes, difficulties associated with high drug loaded filaments [25], inefficiency to be used for large scale production [6,26]. For instance, high drug loading in pharmaceutical manufacturing is preferred because it can reduce the use of

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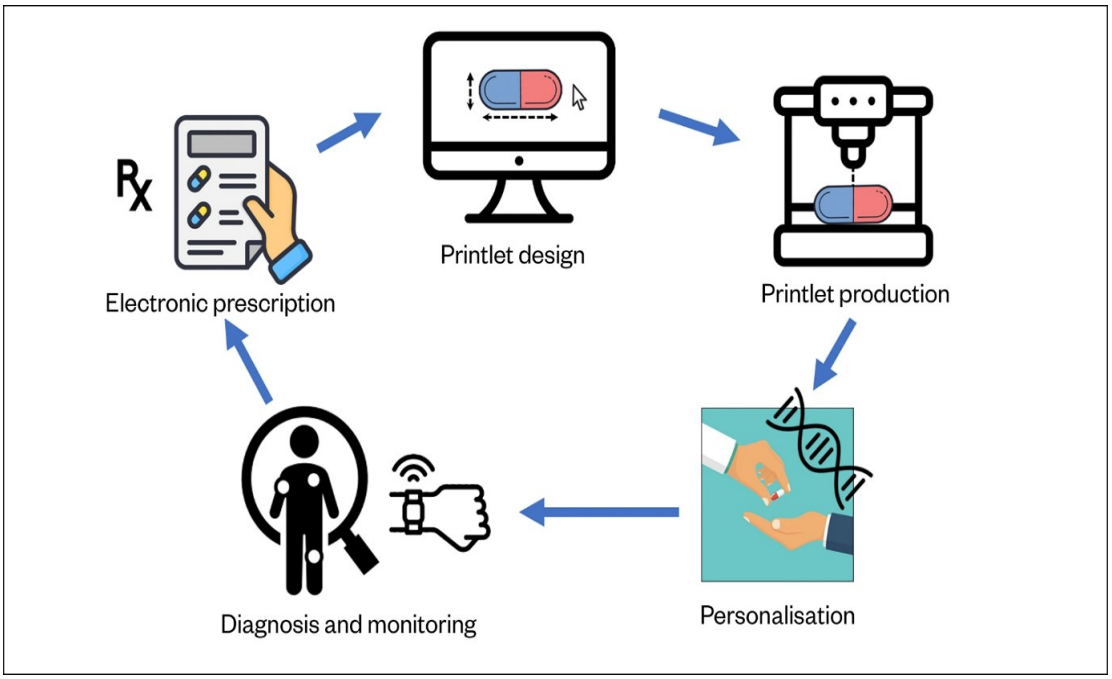
excipient and avoid potential material mixing issues. However, increased drug loading can compromise the printability of the materials and result in faulty products [27]. Moreover, as AM is an emerging field with fast growing rate, regulations have not yet been clearly put forth, but it is very likely that there will be issues related to product quality control, privacy concerns and intellectual property rights [8,21,28,29].

It will also summarise the remaining challenges to integration and discuss the critical role of healthcare staff as innovators in developing and integrating 3D printing into the pharmaceutical sector.



Types of pharmaceutical 3D printing systems

In 1986, 3D printing technology was developed and commercialised by Charles Hull; since then, several different 3D printing methods have been introduced[47–49]. 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[15]:

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(50-54). 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[38–64]. A full size version of this table can be found here.

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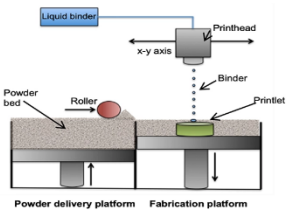
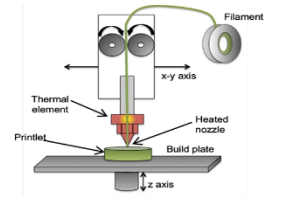
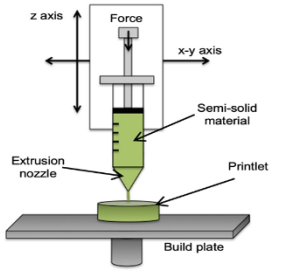
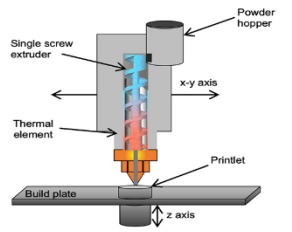
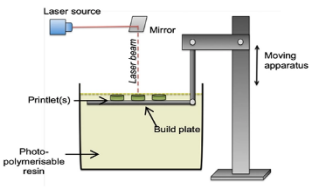
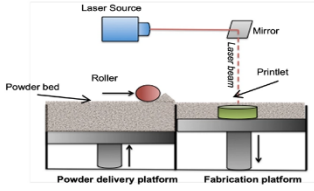
Table 1: The six main 3D printing technologies used in pharmaceuticals, detailing the mode of action, types of formulations produced and a diagram of the printing process for medicines production

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.	

Motivations for 3D printing medicines

The potential to personalise therapies in an automated and decentralised manner means that 3D printing provides various opportunities to patients, pharmacists, clinicians and the pharmaceutical industry alike.

Benefits to patients

A major benefit of 3D printing medicines is the ability to truly personalise a treatment based on a patient's therapeutic or individual requirements. In the future, patients could be asked to select a formulation type from a catalogue; enabling the selection of characteristics such as formulation flavour, texture, colour, shape and size, leading to increased patient autonomy and engagement with treatment pathways and improved medicines adherence[15]. Enabling the production of medicines with exact dosages, or even containing flexible dosages of more than one drug to create a 3D printed polyprintlet, can also improve treatment efficacy while reducing the risk of adverse effects owing to inaccurate dosing[26,27].

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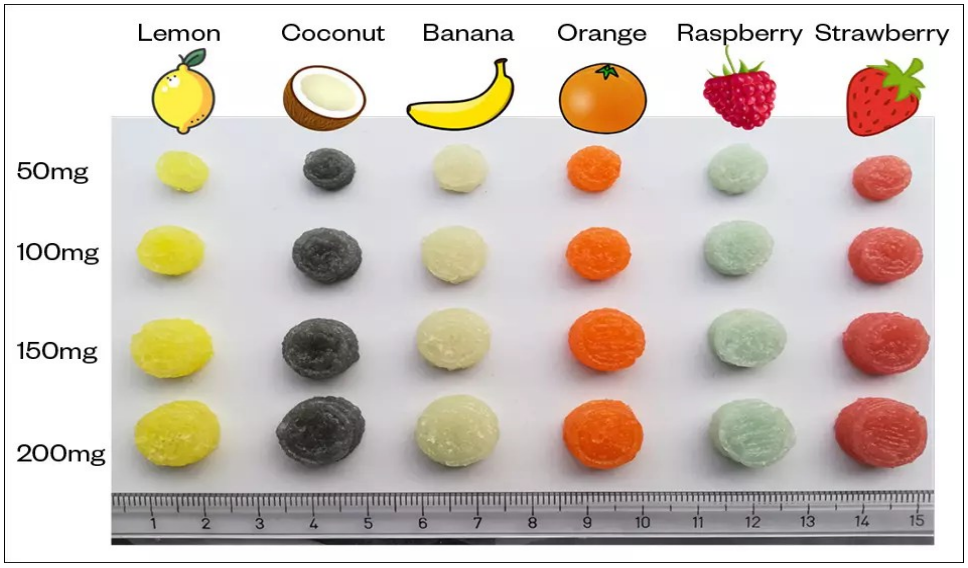
Paediatrics

The ability to produce medicines with personalised dosage, flavour, shape and size can provide many benefits to paediatric populations, for whom conventional mass-produced formulations may not be suitable (e.g. owing to poor palatability or unsuitable dosages)[65,66]. Several studies have focused on producing child-acceptable formulations using 3D printing, including the production of chewable and even chocolate-based formulations[67,68].

For example, a 2018 study by Scoutaris *et al*. produced 'candy-like' formulations of several drugs, including indomethacin, that imitated Haribo Starmix® sweets using FDM[69]. However, while 3D printing can create formulations that are palatable to children, it is important to balance this against the risk of the formulations being too desirable and creating unintended risks to patient safety. In 2020, Januskaite *et al*. evaluated the visual preferences of children aged 4–11 years of placebo printlets produced using four different 3D printing technologies, including digital light processing (DLP), the concept of which is similar to SLA, SLS, SSE and FDM[70]. Printlets were judged based on their familiarity, appearance, perceived taste and texture. Around 62% of children considered DLP printlets to be the most visually appealing, followed by SLS printlets, and FDM and SSE printlets. However, when the children were informed that the SSE printlet was chewable, the majority (79%) changed their original choice, which highlights children's preference for chewable dosage forms[70].



In 2019, a world-first clinical study was carried out using a 3D printer to prepare personalised therapies in a hospital pharmacy setting[71,72]. This technology was integrated into the Clinic Hospital at University De Santiago de Compostela, Spain, to produce personalised medicines to treat children aged 3–16 years with maple syrup urine disease — a severe metabolic disease that stops the body from processing certain amino acids, causing a harmful build-up of substances in the blood and urine.

Chewable isoleucine printlets with six different flavours and colours, and four different dosages, were prepared using SSE, and researchers evaluated isoleucine blood levels as well as the acceptability of each formulation (see Figure 2). After six months of treatment, the 3D printed formulations demonstrated more desirable pharmacokinetic profiles of isoleucine and improved medicine acceptability among the participants, compared to standard isoleucine therapy. All of the formulations with different flavours and colours of the printlets were well accepted by patients, but flavour preference differed according to individuals[72]. Research is ongoing at Alder Hey Hospital in Liverpool for the production of personalised 3D printed hydrocortisone preparations for paediatrics[7Figure 2: Chewable printlets in different flavours, colours and with different doses of isoleucine for the world-first clinical study using 3D printed chewable tablets to treat children with maple syrup urine disease (71, 72)

Older people

3D printing may be beneficial to older populations or for those on complex dosing regimens where polypharmacy is common, leading to a high tablet burden. Studies have highlighted that polypharmacy can lead to non-adherence and confusion for patients, posing a risk of dosing errors[74].

There is value in combining multiple drugs, dosages and/or drug-release profiles into a single formulation that could improve medication adherence and reduce administration errors; however, conventional manufacturing processes do not currently support individualisation of 'polypills', producing only fixed-dose combinations. Owing to the flexibility and capabilities for accurate spatial distribution of drugs, 3D printing could be used to produce 'polyprintlets'[75].

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Several papers have demonstrated the production of polyprintlets using a range of technologies[75–78]. For example, in 2019 Robles-Martinez *et al*. prepared 3D printed polyprintlets using SLA, containing six different drugs (naproxen, aspirin, paracetamol, caffeine, chloramphenicol and prednisolone) separated into six different compartments, enabling the reduction of pill burden from six tablets to just one[26].

A 2015 study used FDM 3D printing to produce low-dose antihypertensive polypills containing atenolol, ramipril, pravastatin, aspirin and hydrochlorothiazide[22]. It should be noted that, while the printing of polypills is feasible using 3D printing, this will likely only be suitable for drugs with a low therapeutic dosage (microgram to milligram dose strength) to ensure the size of the formulation is a suitable size for administration.

In June 2021, FabRx (a spin-out biotech company from University College London [UCL]) and Gustave Roussy, a world-leading oncology hospital in Paris, announced a collaboration aiming to translate multi-drug 3D printed formulations into the clinic[46]. As part of this collaboration, personalised, multi-drug 3D printed dosage forms will be developed for the treatment of early-stage breast cancer patients, combining anticancer therapy with anti-side effect treatment into a single tablet. The printed medicines will be tested in a multi-centre clinical study to assess the effectiveness for improving acceptability, adherence and ultimately patient outcomes compared with the standard treatment regime.

3D printing technologies may improve medicines independence. SLS has been employed to prepare orally disintegrating printlets with Braille and moon patterns

Benefits for Patients and Healthcare

- **Personalized Medicine:**

Tailors medications to individual patient profiles, including age, weight, and disease state, with custom doses and flavors to improve adherence.

- **Complex Formulations:**

Creates single pills with multiple drugs (poly-pills) to simplify complex medication regimens.

- **Controlled Release:**

Designs internal structures to control the timing and rate of drug release in the body, improving therapeutic effects and reducing side effects.

- **Reduced Waste:**

On-demand printing minimizes waste from overproduction and reduces the need for excess inventory.

- **Faster Drug Development:**

Allows for the rapid prototyping and testing of new drug formulations.

Applications in Pharmacy

- **Community Pharmacies:**

On-site production of customized medications reduces reliance on large-scale manufacturing and shortens lead times.

- **Hospitals:**

Enables rapid production of needed medications, including pediatric and geriatric doses and fixed-dose combination products.

- **Research:**

Facilitates the rapid testing and development of innovative drug delivery systems and patient-specific treatments.

2. 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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