

## AN OVERVIEW OF 3D PRINTING TECHNOLOGY: A CURRENT SCENARIO

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### ABSTRACT

Three-dimensional printing [3DP], also known as additive manufacturing, is rapidly emerging as a transformative technology within the pharmaceutical industry. Its application in drug delivery systems has significantly expanded due to its ability to customize medications in precise, individually adjusted doses. By enabling the accurate deposition of medicaments and excipients, 3DP is poised to revolutionize drug formulation, production, and application, spanning the entire medication development process from preclinical stages to clinical trials and frontline healthcare. Beyond pharmaceuticals, 3D printers convert digital templates into tangible objects, layer by layer, utilizing a variety of materials such as plastic, metal, and nylon. This technology has proven beneficial across multiple sectors, including manufacturing, industrial design, aerospace, and medicine, offering a

fast and cost-effective solution for diverse applications. The ongoing advancements in 3DP technologies continue to demonstrate their feasibility for commercial drug production, supported by regulatory assessments. In summary, 3D printing represents an exciting frontier in both drug delivery and broader manufacturing processes, with potential implications that extend well beyond its current applications.

**KEYWORD:** 3D Printing, Additive Manufacturing, Personalized Medicine, Drug Formulation, Pharmaceutical Innovation.

### INTRODUCTION

3D printing technology [3DP] has its roots in the early 1980s when Charles Hull invented the method, initially applied in engineering and various non-clinical sectors such as automotive,

aviation, and consumer goods. However, it gained significant traction starting in 2012, driven by rapid advancements and the development of flexible, biocompatible materials that opened new avenues for its application in pharmaceuticals. The pharmaceutical industry began exploring 3D printing more deeply in the early 1990s at the Massachusetts Institute of Technology [MIT], where a strategy known as "three-dimensional printing methods" was developed and licensed by Sachs et al. This innovation demonstrated the potential of 3D printing to create various pharmaceutical formulations, particularly those involving poorly water-soluble drugs and proteins.<sup>[2]</sup>

A landmark moment in pharmacy printing occurred in August 2015 when the USFDA approved Spiroatom® [levetiracetam] as the first commercial 3D-printed tablet. This breakthrough marked a significant milestone, allowing for high-dose administration and rapid onset of action, thus opening new possibilities in drug manufacturing.<sup>[2]</sup> This innovative technology allows for the creation of objects layer by layer, integrating design, manufacturing, electronics, materials, and business into a single process.<sup>[4]</sup>

Transdermal drug delivery systems [TDDS] have evolved significantly from their early iterations to sophisticated modern methods. Their primary function is to deliver drug molecules through the skin layers to the underlying dermis, where they can enter the systemic circulation via the rich capillary network. This route offers several advantages, including improved patient compliance, bypassing the first-pass metabolism, and the ability for controlled release of drugs.<sup>[5]</sup>

The advantages of 3D printing are particularly pronounced in the pharmaceutical sector, where it enables the production of tailor-made medicines. Traditional manufacturing methods often rely on high-chain polymeric materials or waxy lipids for drug embedding, which can lead to issues such as accidental burst releases and associated toxicity. In contrast, 3D printing offers flexibility in creating complex geometries for oral dosage forms, potentially overcoming the limitations of conventional modified release systems.<sup>[3]</sup>

Moreover, the fabrication steps involved in 3D printing are clean and generate minimal material waste, allowing for the exploration of previously discarded raw materials. This not only enhances drug compliance and accessibility but also supports the rapid production of medications. Utilizing computer-aided design [CAD], manufacturers can produce medicines quickly, addressing stability issues during production and enabling immediate use.<sup>[3]</sup>

Despite its promise, 3D printing technology remains in its early stages of development. The need for specialized technologies in pharmaceutical production presents challenges, as many of these technologies are not widely available in the industry.<sup>[3]</sup> Nonetheless, adherence to Good Manufacturing Practices [GMP] is essential to ensure that 3D-printed medical products meet the same quality and standards as conventional dosage forms.<sup>[3]</sup>

## TYPES OF 3D PRINTING TECHNIQUES

- **Laser-Based Writing Systems:** Laser-based writing systems are critical in the field of 3D printing, enabling the creation of highly detailed and complex geometries for various applications, including rapid prototyping and low-volume production. The most prominent laser-based 3D printing techniques are Stereolithography [SLA] and Selective Laser Sintering [SLS], each with distinct mechanisms, advantages, and applications.
- **Stereolithography [SLA]:** SLA is a pioneering technology in the realm of 3D printing, originally developed as the first laser-based liquid resin polymerization method. In this process, a computer-regulated laser beam is used to selectively harden a liquid polymer or resin into solid structures, layer by layer, by initiating photopolymerization. This technology is widely used in rapid prototyping due to its precision, offering a high resolution that enables the creation of intricate structures.<sup>[6]</sup>

One of the key advantages of SLA is its ability to avoid thermal techniques, which could otherwise degrade sensitive pharmaceutical compounds. This makes SLA highly suitable for manufacturing thermo-labile pharmaceuticals. The SLA process is especially beneficial for applications requiring high detail and smooth surface finishes, making it a go-to technology for producing medical devices and other precision components.<sup>[1]</sup>

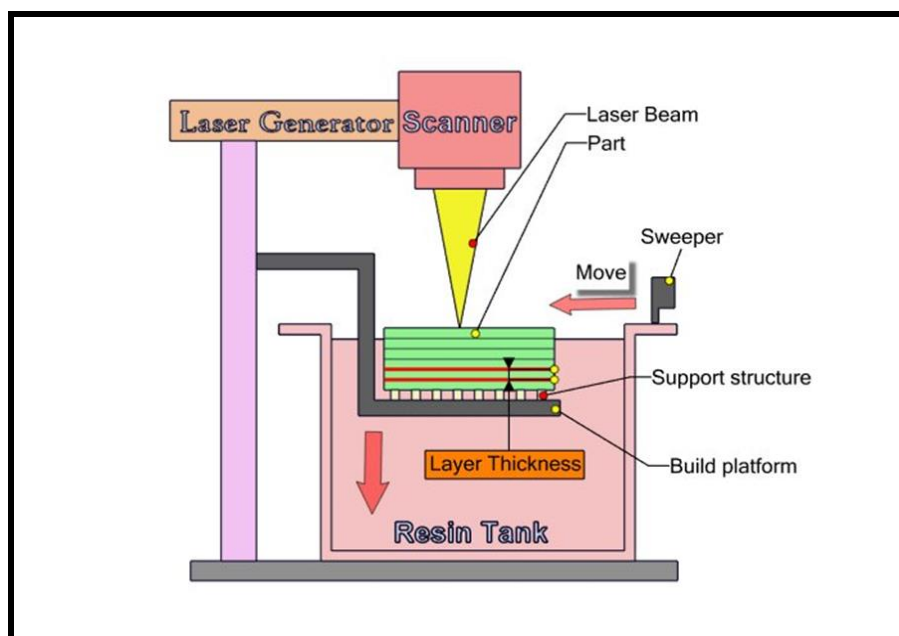


Fig 1.1

## Stereolithography

### • Selective Laser Sintering [SLS]

Selective Laser Sintering [SLS] was developed in the mid-1980s by Dr. Carl Deckard and Dr. Joe Beaman at the University of Texas at Austin.<sup>[28],[2]</sup> This technique eliminates the need for liquid resins, as used in SLA, by employing powdered materials such as thermoplastics, ceramics, metals, and glass. A high-powered laser selectively melts areas of the powder bed, fusing them layer by layer to form the desired structure. The SLS process involves a powder bed, a spreading platform, and a laser system. A roller levels the powder in the bed, and the laser beam scans the surface according to the CAD model, melting the powder to form the object. After each layer is sintered, the powder bed moves downward, and a new layer of powder is applied on top, repeating the process until the object is complete. SLS offers various advantages, including the ability to reuse leftover powder, minimal waste, and the elimination of the need for support structures during printing.<sup>[8],[9]</sup> The minimum layer thickness is 0.020 mm. The material can be: stainless steel, Co-Cr, Inconel 625-718, titanium Ti64.<sup>[27]</sup> This method has been demonstrated to deliver close to the exact shape components up to 99.9% relative thickness.<sup>[7]</sup> SLS has a wide range of applications, especially in the production of solid oral dosage forms [SODFs]. Various materials like Kollidon VA 64, Eudragit L100-55, Eudragit RL, and Kollicoat IR are commonly used powders for creating pharmaceutical dosage forms with tailored drug release profiles. However, one limitation of SLS is the potential for drug degradation due to the high temperatures generated by the laser.

Compared to Selective Laser Melting [SLM], another additive manufacturing process, SLS is more focused on sintering materials rather than fully melting them. This allows for better control of porosity and other material properties, making SLS ideal for low-volume production of parts and prototypes. Although initially designed for rapid prototyping, SLS is now expanding into broader production roles as the commercialization of additive manufacturing continues to grow.<sup>[5]</sup>

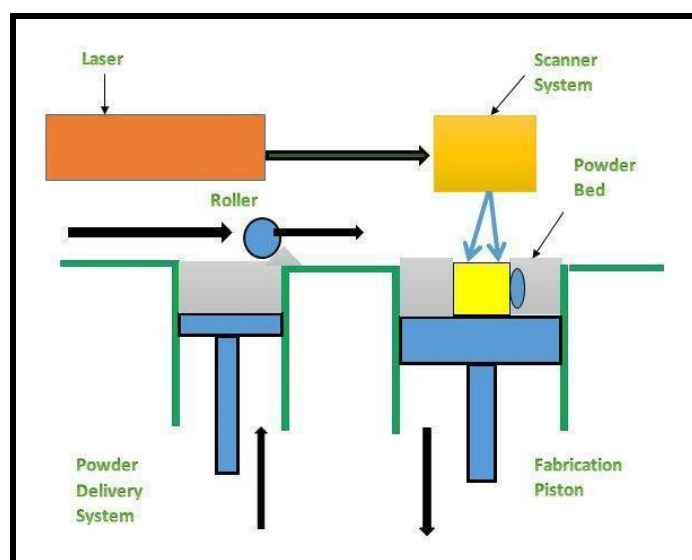


Fig 1.2

### Selective laser Sintering technique in 3D printing

- **Inkjet printing technology**

originally developed for computer-operated inkjet printing, has been adapted for pharmaceutical applications by replacing ink with drug-containing solutions and using edible substrates instead of paper. This method allows precise control over drug dosages by adjusting the number of printed layers or altering the printed area. Two key types of inkjet printing systems used in pharmaceuticals are thermal inkjet printers and piezoelectric inkjet printers. These methods enable drugs to be printed as microdots onto substrates, providing flexibility in drug design and dosage.<sup>[3]</sup>

Inkjet printing encompasses two main techniques: Continuous Inkjet Printing [CIP] and Drop-on-Demand [DoD] Printing. In CIP, a high-pressure pump pushes liquid ink through a small nozzle, where piezoelectric crystals break it into droplets that are directed to the substrate by an electrostatic field.<sup>[2]</sup> DoD, on the other hand, only ejects droplets when needed. It operates with either a thermal print head, which heats the ink to create bubbles, or

a piezoelectric print head, which generates pressure pulses to release ink.<sup>[2,1]</sup> The DoD method offers finer control, producing droplets of 10–50  $\mu\text{m}$  and volumes of 1–70 pL, ideal for high-resolution, accurate drug printing. However, the thermal method is limited to volatile liquids, while the piezoelectric method is more versatile. Inkjet printing's main advantages in pharmaceuticals include precise dosage control, reduced drug waste, and low production costs, making it an efficient and reproducible method for producing solid oral dosage forms [SODs].<sup>[1,2]</sup>

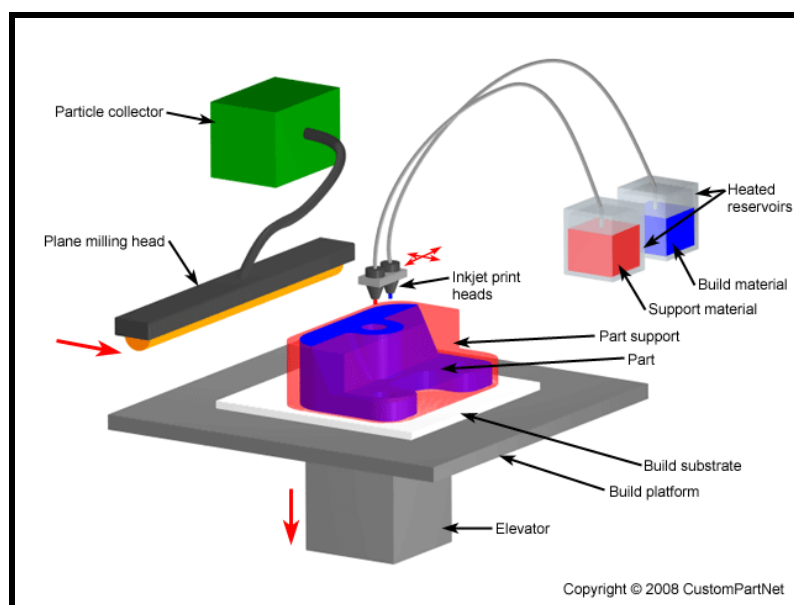


Fig 1.3

### Inkjet printing in 3D printing

- **Nozzle-Based Deposition in 3D Printing**

Nozzle-based deposition systems are widely recognized as a promising technology in pharmaceutical 3D printing due to their ability to create precise, customized dosage forms. This technology involves the controlled deposition of materials through a nozzle, layer by layer, to build a three-dimensional object. Two major nozzle-based systems, Fused Deposition Modeling [FDM] and Pressure-Assisted Micro syringe [PAM], play key roles in pharmaceutical applications.<sup>[1][2]</sup>

- **Fused Deposition Modeling [FDM]**

FDM is one of the most well-known extrusion-based 3D printing technologies, especially in the pharmaceutical industry. This method involves the use of thermoplastic filament, which is heated to its melting point and then extruded layer by layer through a nozzle to build a 3D

object. The FDM technology was first introduced in the early 1990s by Scott Crump and later commercialized by Stratasys, Inc. In FDM printing, the filament is heated above its glass transition temperature inside the print head, then deposited onto a platform, where it solidifies as the temperature decreases. The building platform is gradually lowered after each layer is deposited, allowing for the creation of complex three-dimensional structures. This method is particularly useful in pharmaceuticals because it can be used to produce various dosage forms such as implants, zero-order release tablets, and personalized drug-loaded objects.<sup>[2]</sup> printing.<sup>20</sup> Fused deposition modeling 3D printing helps in manufacturing delayed release print lets without an outer enteric coating and also provides personalized medicines dose.<sup>[25]</sup>

#### Advantages of FDM

Cost-Effective: Printers range from £500 to £2000.

Customizable Parameters: Easily adjustable layer thickness and infill percentages for different geometries and release profiles.

#### Limitations of FDM.

High temperatures can degrade thermolabile drugs.

Limited to certain pharmaceutical-grade thermoplastic polymers.

Drug loading typically results in low yields, primarily suited for low-dose drugs.

A variant, Dual FDM, uses multiple print heads to print complex dosage forms with multiple APIs, enhancing medication management for patients.

#### ● **Pressure-Assisted Micro syringe [PAM]**

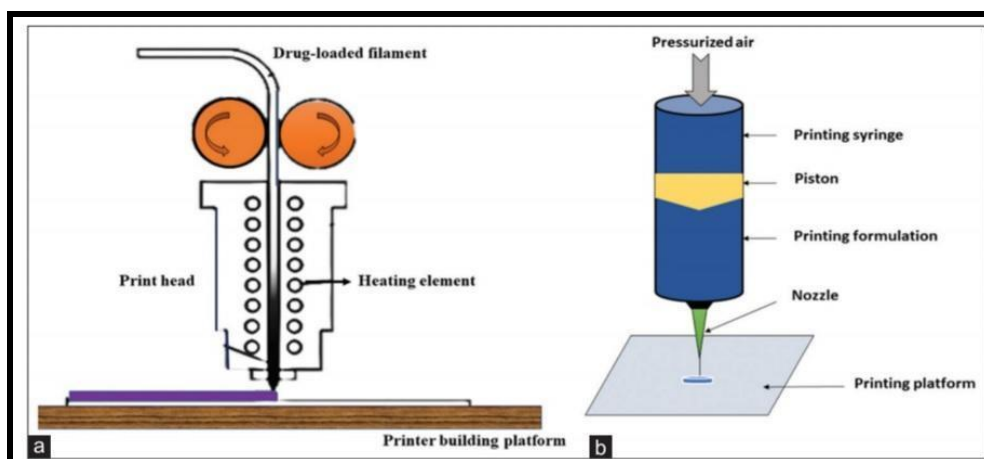
PAM is another extrusion-based 3D printing technology, but unlike FDM, it does not require a melting stage. Instead, PAM uses a micro syringe to extrude viscous or semi-liquid materials through a nozzle onto a build platform. This extrusion process is driven by mechanical, pneumatic, or solenoid pistons, allowing for layer-by-layer deposition. This Technology Is Particularly beneficial for thermolabile drugs that might otherwise degrade in FDM. PAM also allows for the use of a wider variety of materials, such as hydrogels and epoxy resins, as well as the creation of dosage forms with high drug loading. This makes it a versatile tool for developing combination drug therapies.<sup>[3]</sup>

#### Limitation of PAM.

Often requires organic solvents, which can be harmful.

Slower printing speeds and lower resolution due to nozzle diameter variability.



**Fig 1.4****Schematic representations of FDM [a] and PAM [b]****APPLICATIONS IN DRUG DOSING**

- 1) Companies that use 3D printing for commercial medical applications have also emerged. These include: Helices, Ultimateker, and Organovo, a company that uses 3D printing to fabricate living human tissue.<sup>[12]</sup>
- 2) The application of 3D food printing in military foods due to the several reasons. 1) this technology allows for the production of meals on demand in the battlefield; 2) meals can be personalized and customized depending on individual soldier's nutrition and energy requirements.<sup>[11]</sup>
- 3) Polymer materials with low melting point or in liquid state are widely used in 3D printing industry due to their low weight, low cost and processing flexibility. Although 3D printed polymer products could have geometric complexity, lack of mechanical strength and functionality is a big challenge for their wide applications.<sup>[42]</sup>
- 4) Orthopedics and traumatology have been among the first medical fields to use 3DP technology to build PS models, along with maxillofacial surgery. This stems from the straightforward elaboration required by radiological images of the involved structures. Bone structures are well-contrasted with respect to the surrounding structures; thus, they can be simply segmented from medical images using automatic or semi-automatic algorithms. Moreover, the advent of selective laser sintering [SLS], an AM technology able to process metal and ceramic powder, allowed the production of personalized prostheses, to be tailored to the specific geometry of each clinical case. The introduction of materials for 3D printers which can be sterilized also paved the way to the prototyping of personalized instrumentation for orthopedic and traumatology surgery.<sup>[44]</sup>



- 5) Study of osteoporotic conditions: following a pharmacological treatment, 3D printing is useful in validating the results achieved by the patient. This enables a more accurate estimation of patient's bone condition and a better decision on the surgical treatment.<sup>[43]</sup>
- 6) Surgical planning is the pre-visualization of a surgical intervention using virtual or visual aids such as Computed Tomography [CT]/Magnetic Resonance Imaging [MRI] images, and 3D models in order to ensure that the surgical steps are well planned and predefined so as to aid in a smooth surgery.<sup>[40]</sup>
- 7) 3D printing has existed for over a decade in the medical field, but, until recently, its use was limited mostly to dentistry and orthopedics. However, as printers and software become more widely available, there is a rapid increase in the use of 3D printing in medicine.<sup>[41]</sup>
- 8) Aerospace industry 3D printing technology allows for unprecedented design freedom in components and production. In the aircraft industry, 3D printing technology has the ability to produce lightweight parts with better and complicated geometry, reducing energy requirements and resources. At the same time, adopting 3D printing technology can save fuel by reducing the amount of material necessary to build aircraft parts. Furthermore, 3D printing technology has been widely used to make spare parts for some aeronautical components, such as engines. The engine section is readily damaged, necessitating frequent repair. As a result, 3D printing technology is an excellent choice for procuring such spare parts. Nickel-based alloys are chosen in the aerospace sector because of their tensile qualities and resistance to oxidation and corrosion.<sup>[13]</sup>
- 9) 3D printing has been used in various healthcare settings, including cardiothoracic surgery, cardiology, gastroenterology, neurosurgery, oral and maxillofacial surgery, ophthalmology, otolaryngology, orthopedic surgery, plastic surgery, podiatry, pulmonology, radiation oncology, transplant surgery, urology, and vascular surgery.<sup>[14]</sup>
- 10) It is commonly utilized in creating personalized implant trays. In the future, 3D printing personalized trays can be promoted in therapeutic settings.<sup>[15]</sup>

## MATERIALS USED IN 3D PRINTING TECHNOLOGY

### ● Fused Deposition Modeling [FDM]

1. ABS: Acrylonitrile butadiene styrene [ABS] [chemical formula  $[C_8H_8]$ ,  $[CH]_y$  [C, H, N]] is a popular thermoplastic polymer. The glass transition temperature is at 105 degrees Celsius [221 degrees Fahrenheit]. ABS is amorphous; hence it has no true melting point. CH<sub>2</sub> H<sub>2</sub>CABS is a terpolymer produced by polymerizing styrene and acrylonitrile in the

presence of polybutadiene. The quantities can range from 15% to 35% acrylonitrile, 5% to 30% butadiene, and 40-60% styrene. The end result is a long chain of polybutadiene intertwined with shorter chains of poly[styrene-co-acrylonitrile].<sup>[16]</sup> The polar nitrile groups from nearby chains attract and bond the chains together, making ABS stronger than pure polystyrene.<sup>[20]</sup> The styrene gives the plastic its shiny, impermeable surface. Polybutadiene, a rubbery material, offers tenacity even at low temperatures. ABS may be utilized in most applications between -20 and 80 °C [-4 and 176 °F], as its mechanical qualities change with temperature. The qualities are achieved by rubber toughening, which distributes small particles of elastomer throughout the hard matrix.<sup>[16]</sup>

2. PLA: Poly [lactic acid] is a biodegradable and bioactive thermoplastic aliphatic polyester generated from renewable resources such as maize starch, tapioca roots, chips of starch, or sugarcane.<sup>[20]</sup> In 2010, PLA had the second highest global consumption of any bioplastic. The name "polylactic acid" does not fit with IUPAC standard nomenclature, and is possibly ambiguous or confusing, because PLA is a polyester, not a placid [polyelectrolyte].<sup>[16]</sup>

#### ● MATERIALS USED IN INKJET

Water, phosphoric acid, citric acid, PVA, and poly-DL-lactide [PDLLA] are some of the most used binding materials for inkjet 3D printing. A variety of powdered materials, including polymers and composites, are used in medical and tissue engineering applications. Finished 3D printed products are frequently post-processed to improve their mechanical qualities. Wang et al. utilized phosphoric acid and PVA as binding solutions to bind HA/ $\beta$ -TCP powders for bone tissue regeneration. The precision and mechanical strength of constructions printed with phosphoric acid were higher than those printed with PVA.

Sandler et al. created accurate and tailored dose forms by combining concentrated paracetamol, theophylline, and caffeine. Uddin et al. surface coated metallic transdermal needles with chemotherapeutic drugs using Soluplus, a copolymer of PVC, PVA, and PEG, for transdermal drug administration.<sup>[17]</sup>

#### ● MATERIALS USED IN PRESSURE ASSISTED MICROSYRINGE [PAM]

A.C.E.F. s.p.a. supplied corn starch [CS] and glycerol [Gly] from Fiorenzuola d'Arda, Italy. Sigma-Aldrich [Milano, Italy] supplied the alginic acid sodium salt from algae [marine], MW 216.12, M/G [mannuronic acid/guluronic acid] [ratio = 1.56; viscosity 1% in water 15-25

cps]. Antica Spezieria Bavicchi [Perugia, Italy] sold barley seeds grown at Monteleone di Spoleto. The MilliQ system Millipore [Rome, Italy] was used to obtain ultrapure water through the reverse osmosis process. Other reagents and solvents were analytical grade and did not require further purification. The simulated wound fluid [SWF], pH 6.5, was created by dissolving 8.30 g of NaCl and 0.28 g of CaCl<sub>2</sub> in 1000 mL of ultrapure water.<sup>[18]</sup>

#### ● MATERIALS USED IN SLA AND SLS

Stereolithography [SLA] uses liquid solidification technology. SLA is the oldest technology, using a liquid in a vat solidified with an ultraviolet [UV] laser controlled by lenses and mirror reflection, while a construction platform is moved down for layer-by-layer manufacturing. A lattice structure is constructed to support the object.<sup>[19]</sup>

Powder solidification: Finally, powder materials can be cemented by selective laser sintering. SLS creates an object's surface by sintering powder using a laser. When a layer is completed, the build plate is stepped down and a new coating of powder is applied with rollers to maintain a consistent thickness. At the end of the operation, all powder is extracted using compressed air and recycled. A variety of materials are available for SLS, and no scaffolding or support material is necessary because the unsintered powder supports the product during 3D printing.<sup>[19]</sup> This method allows for the combination of a powder and a liquid with sufficient viscosity to form droplets.

#### OTHER MATERIALS USED

Wood filaments: composed of ground wood material with PLA or another plastic. Spools of wood filament were manufactured with an extruder nozzle diameter of 0.6mm and no blockages or miss-feeds. The material qualities are similar to PLA, but the objects are significantly softer and weaker.<sup>[20]</sup> Printable waxes, Waxes, similar to those used in thermojet printers, might be printed. Thermo-jet uses thermoplastic waxes composed of hydrocarbons, amides, and esters.<sup>[16]</sup>

Liquid materials: Stereolithography and inkjet printers use UV curable resins made of thermosetting plastic, which have very different properties than the thermoplastics used in extrusion-based printers, including mechanical properties such as tensile and impact strengths and glass transition temperatures.<sup>[20]</sup>

## CHALLENGES & LIMITATIONS

Despite the potential advantages of 3D printing [3DP] technology in pharmaceutical formulation development, several challenges and limitations hinder its broader application. These challenges can be categorized into several key areas: excipient availability, software and equipment optimization, mechanical properties, regulatory issues, and quality control.

The limited availability of suitable excipients poses a significant barrier to the design of specialized dosage forms. For 3DP applications, excipients must be non-toxic, biodegradable, biocompatible, and stable. The current scarcity of such excipients restricts the range of formulations that can be developed using 3DP technology, thus necessitating further research and development in this area.<sup>[21]</sup>

### 2. Software and Equipment Development

As the complexity of dosage forms increases, there is a need for continuous updates to modeling and slicing software to ensure precise design and production. Current printing equipment and operating procedures often require optimization to avoid issues such as clogging and to enhance product uniformity. This includes refining adhesive nozzles and improving the control systems of printers to ensure consistency in manufacturing.

### 3. Mechanical Properties Optimization

The mechanical properties of 3D-printed products are influenced by various factors, including the viscosity and surface tension of adhesives and the fineness of the printing nozzles. To improve the mechanical behavior of printed products, it is essential to optimize the printing process parameters and the equipment used. This may involve adjusting settings such as drying methods, drying time, and temperature, which significantly affect the final product's appearance and quality.

### 4. Regulatory Landscape

Regulatory challenges remain a significant hurdle in the adoption of 3DP in pharmaceuticals. Although the FDA issued guidance on 3D-printed medical devices in 2017, this guidance does not universally apply to all 3D-printed pharmaceuticals. Issues arise concerning whether customized products should be classified as manufacturing or compounding, which affects the regulatory framework governing them. Additionally, while the FDA has authorized the first 3D-printed tablets, there is a notable absence of specific regulations or guidelines for 3D-printed medicines.

## 5. Quality Control

Ensuring the reproducibility of 3D-printed formulations is critical. This involves establishing stringent quality control parameters to assess the performance and safety of the products. The FDA's Office of Testing and Research is actively addressing how to measure the performance of 3D-printed pharmaceuticals and develop appropriate quality control measures.<sup>[22]</sup>

## CURRENT RESEARCH & INNOVATION

As 3D printing technology accelerating day by day, some recent research and developments has been made on 3D printer for fixing damaged cartilage in knees, noses and ears through 3D bio print the shape of an ear using human cells which build up cartilage, they have successfully tested it in a vivo mouse model in March 16,2016.<sup>[23]</sup> Versatile Drug Release Achieved by 3D Printing 3D printing enables precise control of drug release rates through innovative mechanisms like modulating surface areas and layering, bypassing the need for complex coatings. It facilitates site-specific release, including targeted delivery to the colon for treating conditions like inflammatory bowel diseases. Gastroprotective dosage forms, made buoyant or expandable, enable prolonged drug release in the stomach for better dissolution or absorption. 3D printing also allows combining immediate and extended-release drugs or multiple drugs with varying pharmacokinetics in a single dosage. This technology revolutionizes dosage form design with unparalleled versatility.<sup>[34]</sup>

While traditional pharmaceutical manufacturing has matured over time and excels in large-scale industrial production, 3D printing introduces transformative possibilities that address some of its limitations. This innovative technology enables precise shaping of diverse materials and supports the creation of intricate formulations, opening new doors for personalized drug delivery systems. By expanding the scope of pharmaceutical research, 3D printing fosters advancements in multi-drug formulations and offers a more tailored approach to patient care. Although technical and regulatory hurdles remain, ongoing innovation is expected to overcome these challenges. Ultimately, 3D printing is set to revolutionize medicine, paving the way for more personalized, precise, and intelligent drug delivery solutions.<sup>[35]</sup>

3D printing is advancing personalized medicine, with FabRx leading the development of the **M3DIMAKER™** and **Mark II M3DIMAKER** printers for point-of-care pharmaceutical manufacturing. These extrusion-based printers, suitable for clinics or pharmacies, feature real-time quality control, security measures, and rapid tablet production [~7–17 seconds].

FabRx also innovated a smartphone-powered SLA printer for custom tablet designs. Other developments include DiHeSys' **FlexDosePrinter**, capable of printing medications with APIs in filaments or inks. Clinical trials highlight the technology's promise, such as FabRx's success treating Maple Syrup Urine Disease and collaborations for cancer therapies and pediatric medicines. These advancements showcase the growing potential of 3D printing in personalized healthcare.<sup>[34]</sup>

3D printing is making a significant impact in medical education, surgical practice, and neurosurgery. It has already shown promise in creating realistic models for teaching and training, as well as providing valuable assistance during surgeries. As technology advances, we can expect even more durable and lifelike materials to be used, improving the overall effectiveness of these models. Enhancements in the layering process and material fusion are necessary to match the strength and accuracy of traditional manufacturing methods. Additionally, future improvements in the cost and speed of 3D printers will likely expand their accessibility, leading to greater adoption in the medical field. Ultimately, these innovations hold great potential to revolutionize the way medical professionals learn, practice, and treat patients.<sup>[38]</sup>

### **Ethical Considerations**

Patient safety refers to the proactive measures and practices implemented within healthcare systems to prevent harm and minimize the risk of adverse events during the course of patient care. It is an essential aspect of healthcare delivery that focuses on identifying, analyzing, and mitigating potential hazards and errors that could compromise the wellbeing of patients. Quality assurance in healthcare involves systematic activities and processes aimed at ensuring that the care provided to patients meets established standards and guidelines. It focuses on evaluating and continuously improving the quality and safety of healthcare services to enhance patient outcomes and satisfaction.<sup>[24]</sup>

The ethical considerations surrounding 3D printing in anatomy and medical education focus on informed consent, distribution, and commodification of donor-derived models. Issues include ensuring donors understand how their remains or replicas will be used, regulating access to digital and physical 3D content, and addressing commercialization of these models. Public attitudes suggest sensitivity around treating 3D prints similarly to actual human remains, emphasizing consent and ethical use. Scholars like Jones highlight the risk of "dehumanizing" anatomy by commodifying models and stress the importance of preserving

donor-donor family-learner connections. Updated donor agreements, acknowledgment of contributions, and strict distribution controls are vital for maintaining ethical integrity in this advancing field.<sup>[36]</sup>

**Ethical Considerations in 3D Scanning Human Remains** The advent of 3D scanning has revolutionized the study of human remains, offering new possibilities for research, education, and outreach. However, this technological innovation also brings ethical challenges that require careful navigation. A collaborative effort by researchers from the U.S., U.K., and Italy has resulted in a set of ethical guidelines to ensure respect and accountability in 3D scanning practices. These principles emphasize the importance of treating human remains with dignity, consulting descendant communities, and ensuring the legal acquisition of materials. They also advocate for responsible data sharing, safeguarding against misuse, and prioritizing access for educational and research purposes over commercialization. By integrating these ethical considerations, 3D scanning can remain a valuable tool for advancing science while upholding respect for humanity.<sup>[37]</sup>

The use of 3D imaging, particularly CBCT, for bracket placement in orthodontics presents several ethical and technical challenges. While 3D imaging can improve accuracy, the reliability of CBCT images for detailed bracket modeling may be affected by slice thickness and segmentation thresholds. These factors can lead to inaccuracies in tooth contours and volume measurements. Additionally, larger voxel sizes can reduce image sharpness, making it harder to ensure a precise fit for brackets and trays. Superimposing plaster cast scans on CBCT images can provide better detail, especially for tooth surfaces. Overall, while 3D imaging has potential, its limitations must be carefully addressed in clinical practice.<sup>[39]</sup>

**Table 1.1**

<b>Table 2. Components of Patient Safety and Quality Assurance</b>	
<b>Patient Safety</b>	Quality Assurance
<b>Error Reporting and Analysis</b> [18]	Performance Monitoring and Measurement
<b>Patient-Centered Care</b>	Clinical Guidelines and Protocols [19]
<b>Medication Safety</b>	Peer Review and Clinical Audits
<b>Infection Control</b>	Patient Satisfaction Surveys
<b>Communication and Teamwork</b>	Risk Management
<b>Technology and Equipment Safety</b>	Continuing Education and Training
<b>Staff Training and Education</b>	Accreditation and Certification
	Benchmarking



3D printing is transforming intellectual property challenges across industries-from household goods to pharmaceuticals. Patented drug formulations or designs replicated through unauthorized printing create piracy and unauthorized use issues. Indeed, the custom drug formulation is patented, and patent protection must be strictly enforced to preserve innovation and balance fair market activities.<sup>[3]</sup>

3D-printed organs or human tissues raise certain ethical debate about the medical research boundaries and possible abuse of such technology. Giving consumers the ability to print products, including customized drugs, poses liability problems if the products happen to harm the person. Indeed, holding responsibility becomes a tough issue, especially when it happens to be self-printed drugs or a product.<sup>[3]</sup>

Given the increased automation in manufacturing and healthcare through 3D printing, the risk of displacement increases. Traditional jobs will continue to decline in such sectors as manufacturing or pharmaceutical production, thus raising socioeconomic issues and requiring workers to learn new skills in this evolving job market.

Personalized medicine, particularly through 3D-printed drug delivery systems, is significantly based on patient-specific data, such as genetic information. This could be considered a risk in terms of data privacy and the security of sensitive health information, requiring adequate safeguards against breach and misuse of personal health data.<sup>[3][24]</sup>

## CONCLUSION

In conclusion, 3D printing represents a transformative advancement in drug design and manufacturing, enabling the creation of personalized medication tailored to individual patient needs. This innovative technology enhances cost efficiency and accelerates production processes, significantly reducing lead times and tooling costs associated with traditional manufacturing methods. Despite being in its early stages, 3D printing offers remarkable flexibility in drug delivery systems, paving the way for customized dosing and improved therapeutic outcomes.

Recent technological advancements and ongoing research are poised to enhance the safety and efficacy of treatments, further promoting individualized medicine. The potential of 3D printing in developing diverse drug delivery systems capable of administering multiple medications at varying rates illustrates its versatility and broad applications. Various

techniques, including stereolithography, inkjet printing, and extrusion-based methods, underscore the innovative capabilities within this field.

While it is unlikely that 3D printing will completely replace existing drug delivery systems, its integration into pharmaceutical practices is expected to significantly reshape how medications are produced and delivered, ultimately improving patient care and treatment precision.

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