

3D Printing in Pharmaceuticals: A Mini Review of Materials, Techniques and Challenges

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Abstract

The production procedures for pharmaceuticals and medical equipment have advanced significantly in recent years, especially considering the current pandemic and supply chain disruptions. Actually, 3D printers are a cutting-edge technology that enables its fabrication, such as custom-fit materials, equipment, and body parts, as well as meeting private patient requirements for certain conferences. As it gives a novel idea for delivery systems and technologies, 3DP is a sophisticated tool for creating straightforward, precise, affordable, organized, and customized DDSs. Recent examples of 3DP in the pharmaceutical industry include MNs, personalized ear treatment implants, oral dosage forms, contact lenses, drug-eluting implants for cancer purposes, and customized medical equipment (such cardiac implants and catheters). Using online computer-aided design (CAD) software to create a 3D model is the first step in 3DP. A 3D object is subsequently generated utilizing layer-by-layer (LBL) printing and a range of free software tools that can be found online. These techniques make the ongoing demand of manufacturing system potential. The 3D printing technology which is also referred as additive manufacturing, has adapted and transformed into a revolutionary tool in the field of pharmaceutical sciences, by providing earlier hidden potential for device development, personalized treatment and formulation of medication. This article covers how 3D printing technology can be used in pharmaceutical utility, focusing on how technology could modify dosage forms, drug delivery systems, and the ability to modify medications as per the need of an individual patients. The technology is discussed, along with different techniques such as fluid deposition modelling, binder jetting, stereolithography, selective laser sintering. The challenges faced while manufacturing are also discussed below. The article also highlights the emerging role of 3D printing in improving therapeutic outcomes, optimizing drug release profiles, and facilitating cost-effective manufacturing of personalized treatments.

Keywords

3D printing, Pharmaceutical sciences, Computer aided design(CAD), fused deposition modeling, stereo lithography, ink jet printing

1. Introduction

The idea of personalized medicine, which entails adjusting medical care for each patient specifically,

has gained popularity in recent years. Traditionally, medications are produced in vast quantities in a few distinct strengths, mostly with processes developed over 200 years ago. Importantly, the chosen dosage

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schedules correspond to the amount needed for the "average" patient to get a safe and effective outcome.[1] However, in the UK, 90% of pharmaceuticals only work in 30 to 50% of people, 7% of hospital admissions are due to adverse drug reactions, and up to 70% of patients do not benefit from standard mass manufacturing processes, demonstrating that one dose does not work for everyone.[2,3] The US Precision Medicine Initiative was created in 2015 to better understand how a patient's genetics, environment, and lifestyle might help determine the best way to prevent or treat disease.[4] Additionally, the UK healthcare policy has made personalized treatment a top priority. The NHS released a paper titled "Improving outcomes through personalised medicine" in 2016. The "UK Genome Strategy 2020" along with the "Life Sciences Vision 2021," which were recently announced by the UK government, set a high priority on the delivery of healthcare services via personalized medicine.[5,6]

When it comes to production, 3D printing is a "additive manufacturing" technology, as opposed to "subtractive manufacturing." A model is made with computer-aided design software, then it is cut out and printed. The layered manufacturing methodology is then used to construct the 3D product layer by layer.[7,8] One of the most active firms in 3D printed medications is FabRx, a UK company that was created in 2014. They have investigated and tested a variety of 3D printing methods, including as FDM (Fused deposition modelling), SLS (Selective laser sintering), SLA (Stereo lithography appearance), SSE (Selective laser sintering), and DPE (Direct powder extrusion). The company's innovative 3D printer, the M3DIMAKERTM, was launched in 2020 with a distinct commercial emphasis on individualized drug delivery.[9] By combining three technologies FDM, SSE, and DPE users may choose the print head that best meets their requirements and create 3D printed drugs quickly and easily utilizing a variety of materials and concepts that are better suited for certain pharmaceutical situations. The company will collaborate with the Gustave Roussy Cancer Center in France in 2021 to develop personalized drugs for the early detection and treatment of breast cancer.[10] Development of technologies that facilitate the shift from the traditional large-scale manufacturing of medications with fixed strengths to the creation of customized and adaptable dosage forms and dose combinations on demand is essential as the vision for personalized medicines comes to fruition.[11,12] 3D printing creates customized printlets, adjusting dosage, drug release, and even shape, size, texture, or flavor to match patient needs and preferences.[13-17]

A variety of pharmaceuticals, such as flexible multi-drug combinations (i.e., polyprintlets), controlled release preparations, gastro-retentive tablets, suppositories, minitables, medical devices, and rapidly dissolving orodispersible formulations, can be produced using 3D printing, according to numerous studies.[18-20] 3D printing provides a unique platform that can swiftly, digitally, and decentrally produce medications in response to evolving conditions and patient needs, especially since non-invasive drug and disease-monitoring techniques (like smart wearable devices with artificial intelligence [AI]) and electronic prescriptions have recently been developed and adopted.[21]

The first clinical study in history, conducted in 2019, explored the use of 3D printing in hospital pharmacies to deliver personalized treatments.[22,23] This technology was integrated into the Clinic Hospital at University De Santiago de Compostela in Spain to develop customized drugs for children aged 3 to 16 who suffer from maple syrup-induced urine disease, a severe metabolic disorder that stops the body from breaking down certain amino acids, resulting in a hazardous build-up of chemicals in the blood and urine. Chewable isoleucine printlets in four different dosages and six different flavors and colors were produced by researchers using SSE. They then evaluated the blood levels of isoleucine and the acceptability of each formulation. Compared to conventional isoleucine therapy, the 3D printed formulations showed better medication tolerance among the patients and more desired isoleucine pharmacokinetic profiles after six months of treatment. Patients responded favorably to all of the printlet compositions with varying flavors and colors, however individual preferences varied in terms of flavor.[24] 3D printing may be advantageous for elderly patients or those with complex dosing regimens where polypharmacy is common and leads to a high tablet load. Polypharmacy raises the risk of dosing mistakes by making patients confused and noncompliant, according to research.[25]

This article will provide an overview of the main 3D printing methods used in the pharmaceutical sector, with a focus on the motivations behind and cutting-edge applications of the technology in this domain. It will cover the remaining integration difficulties and highlight the critical role that healthcare professionals play as creators in developing and integrating 3D printing into the pharmaceutical business.

2. Materials used in 3D printing

2.1 Polymers Used in 3D printing

There are variety of polymers used in this technique based on the unique properties. It may be due to their biodegradability, biocompatibility, solubility and also as a support material. For example, For example, because of its good safety profile, polylactic acid (PLA), which comes from renewable resources, has been effectively utilized in drug delivery and biodegradable implants.[26] In contrast, polyethylene glycol (PEG) is highly biocompatible and water soluble, which makes it perfect for medication stabilization and tissue engineering.[27] Because it produces homogeneous filament formation, hydroxypropyl methylcellulose (HPMC) has been used in fused deposition modeling (FDM) for tablet production.[27] Because it improves disintegration and patient compliance, polyvinyl alcohol (PVA) has drawn interest in oral quickly dissolving tablets.[27] Furthermore, because ethylcellulose (EC) is water-insoluble and thermoplastic, it has been utilized for controlled medication release.[29] Organ and tissue printing is now possible because to the incorporation

of natural polymers like gelatin and alginate into bioinks for scaffolds, which go beyond these synthetic ones.[30] The polymeric material along with its biological characteristics, effect or application and representative result are mentioned in Table 1.

2.2 Bioinks used in 3D printing

Bioinks are specifically made to support cell viability both during and after printing by simulating the extracellular matrix (ECM). In order to create constructions that closely resemble live tissues, cellular mixes combine cultivated cells with natural biopolymer hydrogels like gelatin or alginate.[30] Because of their adjustable mechanical strength, porosity, and biocompatibility, hydrogels—cross-linked networks of water-soluble polymers—are used extensively and are appropriate for both drug delivery and tissue engineering.[33] The bioinks along with its biological characteristics, effect or application and representative result are mentioned in Table 2.

2.3 Inorganic and compost]ite materials used in

Table 1. Polymers in 3D printing

Material	Biological characteristics	Effect/ Application	Results	References
PLA	Biodegradable, renewable source	Drug delivery, biodegradable scaffolds	Demonstrated safety and controlled degradation in implants	[26]
PEG	Water-soluble, biocompatible	Tissue engineering, drug stabilization	Enhanced protein stability and reduced immunogenicity	[27]
HPMC	Cellulose derivative, forms uniform filaments	FDM printing of tablets	Achieved reproducible drug release in oral formulations	[27]
PVA	Hydrophilic, soluble excipient	Oral rapidly dissolving tablets	Improved disintegration and patient compliance	[27]
EC	Thermoplastic, insoluble in water	Controlled release	Enabled sustained release in 3D-printed tablets	[29]
Gelatin/Alginate	Natural, biocompatible polymers	Bioink scaffolds	Supported viable tissue constructs	[30]

Table 2. Bioinks in 3D printing

Material	Biological characteristics	Effect/ Application	Results	References
Cellular mixtures	Cell-laden hydrogels	Tissue/organ printing	Maintained cell viability and ECM deposition	[30]
Hydrogels	Cross-linked polymer networks	Drug delivery, tissue scaffolds	Provided tunable porosity and mechanical support	[33]

3D printing

For applications needing strength, heat resistance, and bioactivity, a variety of inorganic and composite materials have been used in 3D printing in addition to polymers and bioinks. Ceramics that replicate the mineral makeup of natural tissues, such as tricalcium phosphate (TCP) and hydroxyapatite (HA), are widely used in bone and dental restoration.[32] Bioglasses are appealing for pharmacological and regenerative applications because of their bioactivity and controlled rates of degradation.[32] By mixing polymers with metals or ceramics, composite systems further improve mechanical and functional qualities, increasing their suitability for use in specialized biomedical devices.[31] The inorganic and composite material along with its biological characteristics, effect or application and representative result are mentioned in Table 3.

3. Techniques used in 3D printing

Multiple additive manufacturing techniques have been researched for application in biomedicine and pharmaceuticals. binder jetting, stereolithography (SLA), fused deposition modeling (FDM), and selective laser sintering (SLS) are the most widely studied researched platforms are. Different material requirements, processing conditions, and implications for drug formulation are characteristics of each approach. A summary of these techniques is given in the ensuing subsections, which also emphasize their processes, pharmacological uses, and pertinent research findings.

3.1 Binder jetting

One of the main 3D printing techniques used in the production of pharmaceuticals is binder jetting (BJ-3DP).[34] In this method liquid binder is particularly used to link powder particles to create three-dimensional dosage form. Because of its versatility,

binder jetting can be used with a wide variety of excipients and active pharmaceutical ingredients (APIs), making it suitable for the production of tablets and other solid dosage forms.[35]

The printing process operates layer-by-layer: a thin layer of powder is spread over the build platform, after which a printhead dispenses binder droplets at predefined locations. Repetition of this cycle builds the final structure, after which unbound powder is removed and post-processing steps are completed.[36] APIs can be incorporated either within the powder bed—often as solutions or suspensions of nanoparticles—or within the binder formulation itself.[37] Pretreatment strategies, such as particle size reduction or the use of amorphous solid dispersions, have been employed to improve the solubility of poorly water-soluble drugs, demonstrating that BJ-3DP is not limited to APIs with high aqueous solubility.[38]

Although the BJ-3DP technology's mechanism is complex, the printing process may be broadly divided into three steps: (1) the production of droplets, (2) the droplets' selective binding to the powder, and (3) the end product's drying or curing.[39] The complex process of droplet creation involves filament production and elongation, primary and satellite droplet formation and fusion, and filament necking, breaking, and rebounding. Surface tension, density, and viscosity are significant physical factors that impact the droplet generation mechanism as well as droplet volume and velocity in printing inks. The droplets produced by the printer should ideally be monodisperse, meaning that just one droplet is produced every pulse cycle, in order to get the optimum droplet ejection quality.[40] Droplet diffusion is primarily determined by the droplet volume and equilibrium contact angle when drops strike a smooth, nonporous surface.[41,42] According to Yarin's research, kinematic behavior, mostly from inertial forces, governed the initial impact phase. The diffusion process was later controlled by capillary forces, which were followed by impact-driven oscillation, droplet

Table 3. inorganic and composite materials in 3D printing

Material	Biological characteristics	Effect/Application	Results	References
Ceramics (TCP, HA)	Bioactive, bone-like mineral composition	Bone/dental restoration	Enhanced osteointegration in vivo	[32]
Glasses	Bioactive, customizable degradation	Drug delivery, regenerative therapy	Controlled degradation with therapeutic ion release	[32]
Composites	Hybrid systems	Customized biomedical devices	Improved strength and functionality	[31]

diffusion, and recoil.[43,44] the impact of droplets on powder beds has been studied, and researchers are constantly investigating the relationship between the dimensionless quantity of ejected droplets and the impact of droplets on a powder bed.[45](Figure 1).

Finally, the drying or curing procedure may also affect the final product's quality. The evaporation rate is a crucial factor in solvent selection since drying typically occurs by solvent evaporation. For instance, creating amorphous solid dispersions employing polymer-API-solvent mixtures as printing inks once the droplets have dried, provides an effective means of preparing low-dose drugs from insoluble APIs.[46-48] Furthermore, Print speed, nozzle diameter, droplet spacing, binder concentration, and the frequency and speed of droplet creation are all factors that should be considered during the printing process.[49]

Summary of Binder Jetting

Overall, binder jetting provides flexibility in formulation design and is particularly advantageous for low-dose drugs and customized dosage forms. However, challenges remain in controlling droplet dynamics, achieving uniform drug distribution, and ensuring scalability for industrial applications.

3.2 Selective laser sintering (SLS)

SLS uses a laser to selectively sinter powdered materials layer by layer to produce solid structures.[50] It removes the need for solvents and is especially well-suited for use with pharmaceutical excipients that have

been approved.[51] In order to bind powder particles together, this procedure uses a laser that is directed to draw a particular pattern on the powder bed, resulting in selective partial or complete melting. After the layer is sintered, a new layer of powder is applied on top of the sintered material using a roller. To create a 3D printed medication, this procedure is performed layer by layer.[52]

The first step is selecting the correct material for the desired application. Metals such as titanium, ceramics and polymers such as polyamide are often used materials for this technique. Excipients and powdered active pharmaceutical ingredients (APIs) are examples of materials used in medications. A roller or blade evenly distributes the powdered material throughout the build surface.[53]

The primary step comprise of selecting the right material for the particular application. As per the 3D model, the laser selectively melts the powdered material in specific areas that leads to join the particles for creating a solid layer. This method is repeated layer after layer. After each layer is sintered, the platform gradually descends to create space for the next layer of powder to be spread out and sintered. To match the design in the computer-aided design (CAD) file, the laser precisely scans and fuses the powder.[54]

Once each layer has been sintered, the laser is switched off and the bed is allowed to cool. The structure solidifies as the temperature drops because sintering partially melts the powder. Cooling is

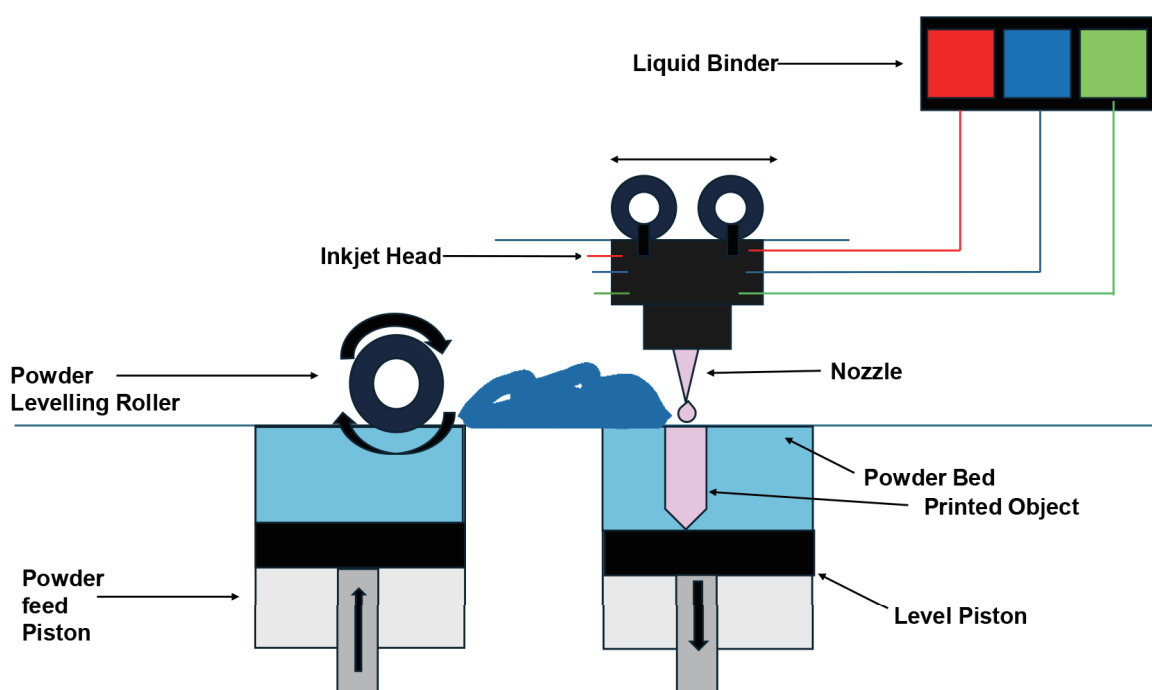


Figure 1. Schematic diagram of BJ 3DP technology.

important to prevent warping or deformations of the object.[55]

The solidified part is taken out of the powder bed after the 3D printing process is finished. Powder that is not needed is taken out and, in certain situations, recycled for use in subsequent prints(Figure 2). To enhance the printed object's appearance or functionality, surface finishing techniques like polishing, coating, or cleaning may be necessary.[56]

Summary of SLS

All things considered, SLS has a number of benefits for pharmaceutical applications, such as solvent-free processing, quick prototyping, and the capacity to create intricate, customized dosage forms. The selection of APIs and excipients may be restricted by the high processing temperatures, though, and maintaining uniform drug distribution and consistent mechanical strength continues to be a significant difficulty.

3.3 Stereolithography (SLA)

A process that produces 3D objects by layering liquid resins and curing them with light. SLA is renowned for its quick and incredibly precise printing method.[57,58]

Using CAD (Computer-Aided Design) software to create the 3D item is the first stage in the SLA process. The model needs to be made with exact measurements and information. The most popular file format for 3D printing, STL (Stereolithography), is then used to save the design.[59]

The STL file is loaded by the SLA machine's software. The software separates the 3D model into thin layers, typically 0.05 to 0.2 mm thick. In addition, the software calculates the laser's print route, optimizes alignment, and creates support structures for overhanging portions of the model.[60]

A build platform, a resin tank, and a UV laser or projector make up a SLA printer. The printer's resin tank is filled with photopolymer resin. Layer by layer, the resin will be cured by the laser to produce the model. Before printing the first layer, the construction platform is lowered into the resin tank.[61]

Based on the sliced model, the UV laser (or projector) follows the object's first layer. Where the laser shines, the resin is solidified into a thin layer. The resin layer is applied on top of the solidified coat when the first layer is finished, and the build platform is lowered a little. The process is repeated layer by layer until the desired outcome is obtained.[62] The object is taken off the construction platform once printing is finished (Figure 3). It may contain large amount of resin which should be removed by solvents such as isopropyl alcohol. To improve the object's strength and quality, UV light is frequently used to further cure it. The support structures that were created during the printing process are eliminated. Depending on the kind of support material employed, these can either dissolve in a chemical bath or break off.[63]

The model can undergo additional processing to improve its mechanical qualities and surface polish after cleaning and curing. To get the intended final look and quality, the object may need to be painted,

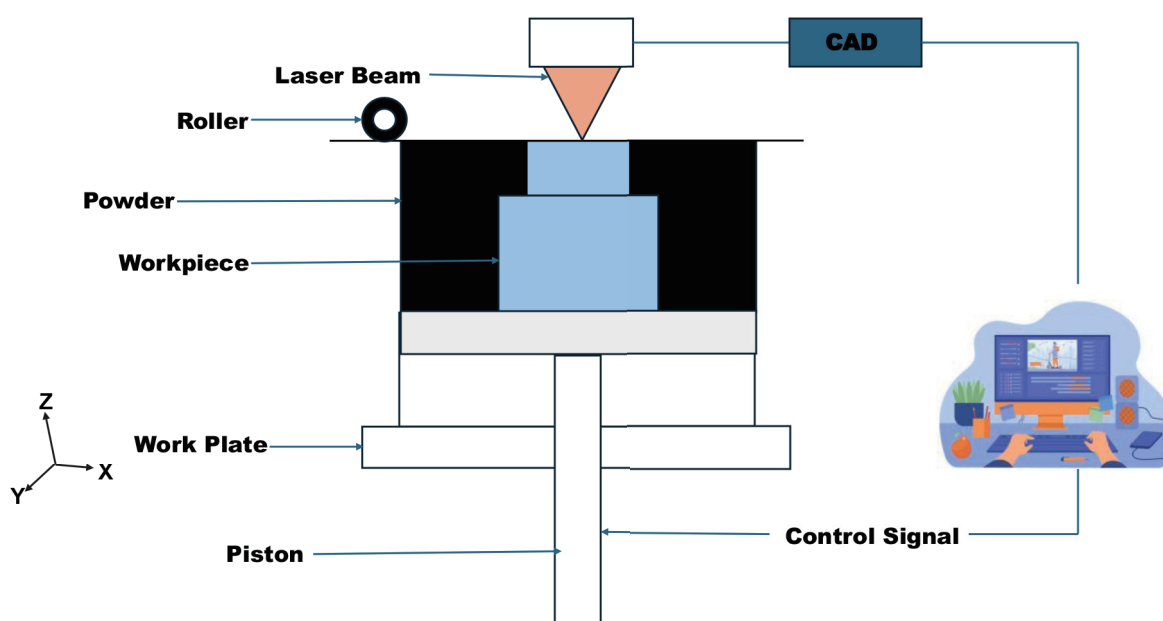


Figure 2. Schematic diagram of SLS Technology in 3D Printing.

polished, or sanded.[64,65]

Summary of SLA

SLA is especially well-suited for use in tissue engineering, microfluidics, and drug delivery devices because of its exceptional accuracy, smooth surface quality, and design freedom. The limited supply of biocompatible and biodegradable photopolymer resins, the possible cytotoxicity of unreacted monomers, and the comparatively high expense of supplies and equipment are some drawbacks.

3.4 Fused deposition modelling(FDM)

A common technique for producing three-dimensional objects involves extruding a molten polymer from a heated tube, stacking it, and then cooling it. FDM is preferred because it is easy to use, inexpensive, and produces tablets with great strength.[52]

Firstly, the required pharmaceutical product such as tablet, capsules or any customized drug delivery system should be designed using computer aided design (CAD) software. The model of personalized medicine can be modified or adjusted as per unique requirement of the patient, including its combinations or dose to be given. Features like multi-drug delivery or controlled release mechanisms can also be incorporated into the design.[66]

Biocompatible materials that dissolve safely in

the human body include polyvinyl alcohol (PVA), polyethylene glycol (PEG), and polycaprolactone (PCL). To construct the dosage form, APIs can be combined with polymers. This combination aids in the controlled release of the medication. The printing filaments can be modified to include other components including stabilizers, fillers, and binders.[67]

The polymeric substance and the APIs are blended to make filaments suitable for FDM. The process needs to ensure that the API is dispersed uniformly throughout the filament. To preserve the integrity of the API and guarantee appropriate filament creation, the extrusion temperature and speed may be changed.[68]

The CAD-designed 3D model is fed into the 3D printer after being transformed into a machine-readable format, typically STL or G-code. The prepared filament is expelled from the FDM 3D printer using a heated nozzle. The material is put in layers to produce the final product (Figure 4). To guarantee quality and uniformity in the printed product, parameters including printing speed, layer thickness, and extrusion temperature are meticulously managed.[69]

The product is given time to cool and solidify after printing. This is crucial for the proper stabilization of the dosage form. The printed product may occasionally have its surface altered to improve appearance, flavor masking, or disintegration. To guarantee consistency and precision of the dosage form, the product is

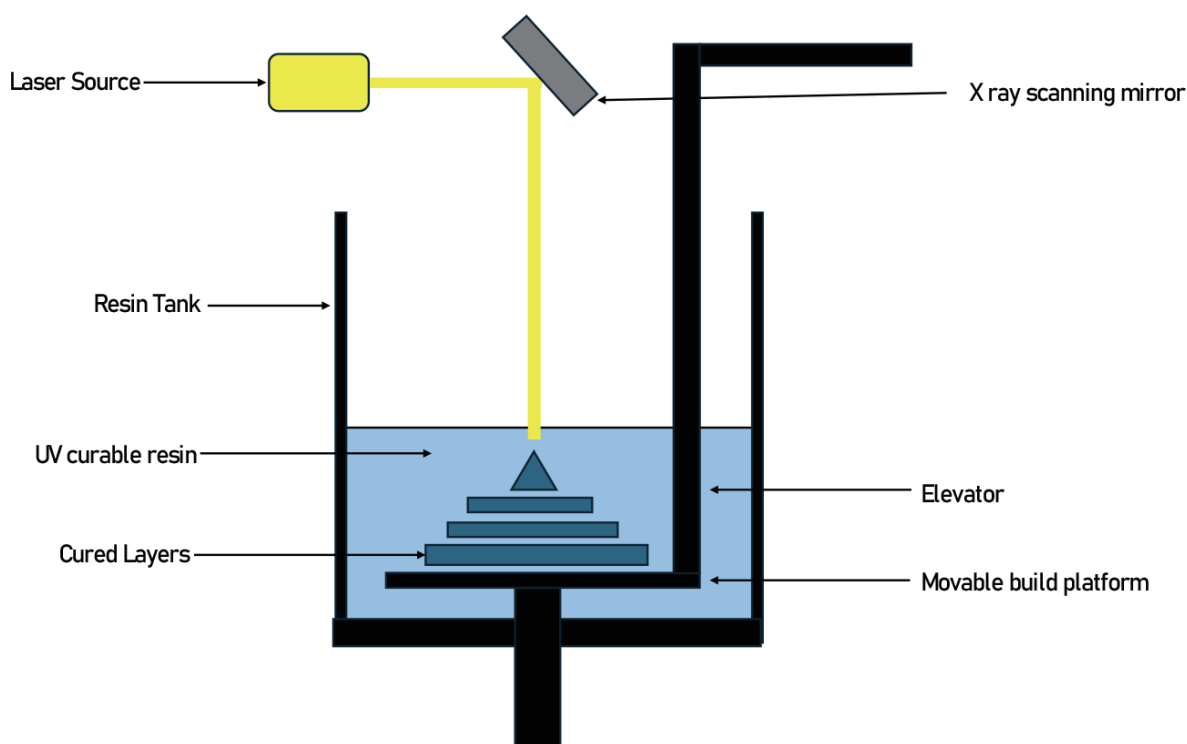


Figure 3. Schematic diagram of Stereolithography (SLA) Technology in 3D Printing.

subjected to quality checks after printing, including weight uniformity, drug content uniformity, and dissolving tests.[70]

The printed dosage form is exposed to dissolving and release testing to assure that the medication is delivered in a desired way that may be controlled release, instant release, or delayed release. To ensure the stability throughout its shelf life, its physical stability is examined in a variety of conditions, including fluctuating temperatures and humidity levels. Bioavailability studies can be carried out to examine therapeutic effectiveness and make sure the medication is efficiently absorbed and dispersed throughout the body.[71]

Before commercialization of the product it needs to meet various standards set by regulatory bodies such as EMA and FDA. This means ensuring that the product is consistently produced in a safe and efficient manner.[71] The production process, material composition, and test results must all be thoroughly documented for regulatory evaluation and approval.[72]

Summary of FDM

FDM presents a cost-effective, scalable, and adjustable way to create personalized medicines with exact control over drug release parameters. The ability to combine several APIs, create complex geometries, and modify formulations to meet the needs of specific

patients are some of its key benefits. The temperature sensitivity of APIs, the demand for filament pre-processing, and stringent regulatory requirements for product validation are some of the drawbacks, though.

4. Challenges

This demonstrated promising ends up in drug carriers. That also faces numerous difficulties including optimization techniques, increasing the effectiveness of sensors regarding powerful and flexible utilization, selection of the appropriate leakages, comment processes, and the like, to boost the effectiveness of 3D markets and increase the appliance spectrum along new drug delivery structures.[73]

4.1 Regulatory and Quality Control Issues

Absence of Standardization: The regulations concerning drugs produced through 3D printing are still evolving. Manufacturers face unpredictability or doubt as regulatory agencies such as the FDA and EMA do not provide clearly outlined criteria for the creation and evaluation of 3D printed pharmaceutical items.[74]

Consistency and Reproducibility: Guaranteeing that every batch of medication generated by 3D technology is dependable and complies with strict standards for

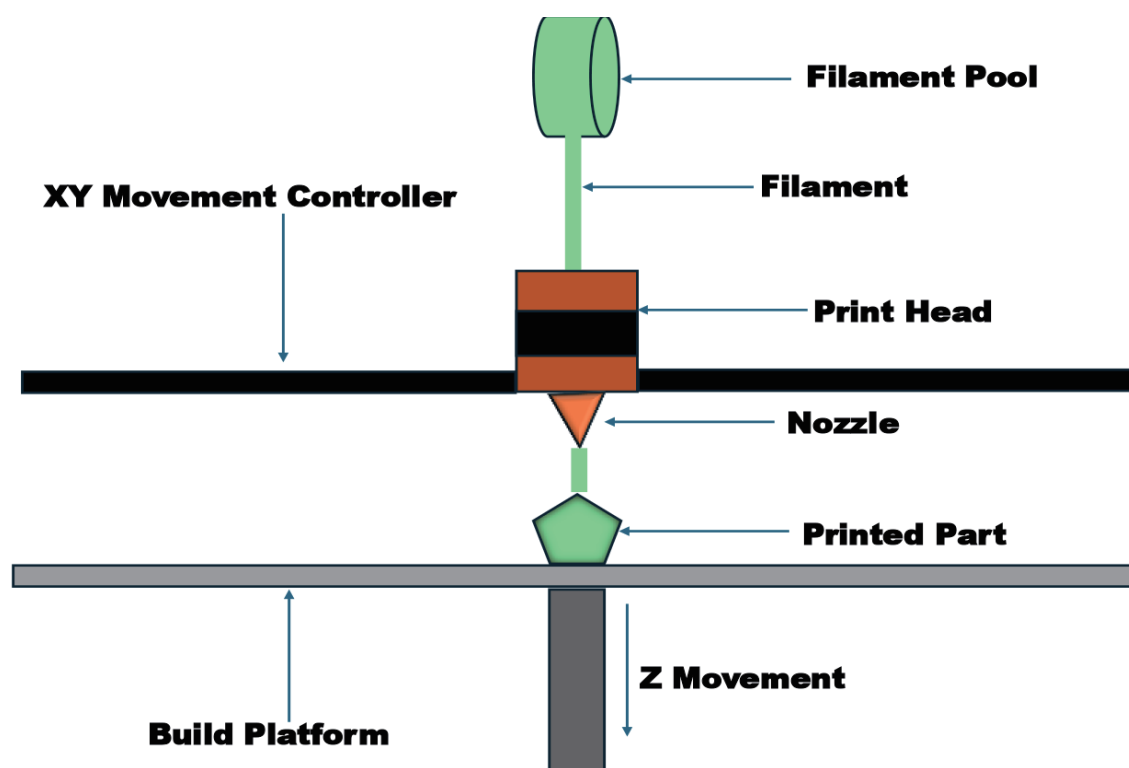


Figure 4. Schematic diagram of FDM Technology in 3D Printing.

safety, dosage, and purity can pose challenges.[74]

4.2 Material Challenges

Limited Suitable Materials: The pharmaceutical industry needs 3D printing materials that can be both biocompatible and capable of delivering drugs effectively. Currently, not all materials used in 3D printing are ideal for pharmaceutical applications.[75]

Complexity of Drug Formulations: Active pharmaceutical ingredients (APIs) can be challenging to include into 3D printed structures. It's possible that the material's solubility and stability don't quite match the drug's needs.[75]

4.3 Scalability and Production Costs

Cost-Effectiveness: 3D printing can be costly, particularly when premium, specialist materials are used. This calls into question whether 3D printed medications are affordable, especially when produced in large quantities.[76]

Scalability: Although 3D printing is excellent for prototype and small-batch production, scaling up to large-scale manufacturing with consistent quality can be challenging. For large-scale production, traditional manufacturing techniques (such as tablet pressing) are still far more economical and efficient.[76]

4.4 Technical and Equipment Limitations

Printer Resolution and Accuracy: To produce the appropriate release profile and dose forms, pharmaceutical applications frequently call for incredibly exact printing. For some medicine compositions, the present resolution of many 3D printers might not be sufficient.[77]

Printing Speed: 3D printing might be somewhat slow when compared to conventional manufacturing techniques, despite its benefits for custom, on-demand production.[77]

4.5 Intellectual Property (IP) Concerns

Patent Issues: As 3D printing technology advances, the manufacturing of pharmaceutical items may give rise to intricate intellectual property (IP) issues. Businesses might have to deal with a complex web of patents pertaining to particular medicine formulations, printing techniques, and materials.[78]

5. Role of AI in 3D Printing of Pharmaceuticals

AI (artificial intelligence) has proven to be a game

changing tool in Pharmaceutical and it also enhances additive manufacturing techniques such as 3D printing. Artificial Intelligence (AI) improves data-driven optimization of medicine formulation, process parameters, and quality control by combining predictive analytics, machine learning (ML), and deep learning algorithms. Its use in 3D printing has the potential to significantly boost customized medicine and produce complicated dose forms in an effective and repeatable manner.[79]

5.1 Material and formulation design

AI makes easier for researchers to choose and optimize the active pharmaceutical ingredients (APIs), excipients, and polymers used in 3D printing. Choosing of appropriate candidates for binder jetting, FDM, SLS, or SLA is supported by the ability of machine learning algorithms to forecast crucial material attributes like solubility, tensile strength, and thermal stability. Predictive algorithms, for instance, have been used to design filaments with the best drug loading for FDM applications and to estimate drug-polymer miscibility.[79]

5.2 Process Optimization

In 3D printing, multiple variables—such as nozzle temperature, print speed, laser power, or droplet spacing—directly affect product quality. AI-driven models can process large experimental datasets to identify optimal parameter windows, reducing the need for extensive trial-and-error experiments. Neural networks and reinforcement learning have also been used to anticipate printability and reduce printing errors, improving reproducibility.[80]

5.3 Quality Control and In-line Monitoring

Real-time printing process monitoring is made possible by sensor integration and AI-based computer vision systems. High-resolution cameras and machine learning algorithms may detect surface imperfections, layer misalignment, and structural defects during printing. Similarly, medication content uniformity and dissolving behavior can be predicted using AI-analyzed spectroscopic and imaging data without the need for damaging testing.[81]

5.4 Personalized Medicine

The creation of dosage forms specifically for each patient is one of the most exciting applications of AI in 3D printing. Age, weight, pharmacogenomic profile, and illness condition are just a few examples of the

patient-specific data that AI may use to create the best possible drug combinations, release kinetics, and dosage strengths. Personalized 3D models of tablets, capsules, or implants that satisfy certain therapeutic requirements can be quickly produced by AI-guided automated CAD design tools.[82]

5.5 Predictive modeling of drug release and bioavailability

AI algorithms are used to estimate the bioavailability, absorption kinetics and dissolution profiles of 3D printed dosage forms. By gaining knowledge experimental datasets, Machine learning models can predict how changes in geometry, material composition, or process settings enhance drug release. This eliminates the need for time-consuming in vitro studies and accelerates the development of formulation.[83]

5.6 Implications for Industry and Regulation

By producing traceable digital records of design parameters, material properties, and process conditions, artificial intelligence (AI) can be included into 3D printing workflows to enhance regulatory compliance. This data-driven strategy supports Quality by Design (QbD) and digital manufacturing objectives from the FDA and EMA. AI may also help expand 3D printing technologies from lab prototypes to pharmaceutical manufacturing on an industrial scale.[84]

6. Conclusion

An advancing edge has been launched by the development of 3D printing, which introduces the previously uncharted path for innovation in medication modification and delivery. This prioritizes the basic characteristics of 3D printing technique, such as conceptual frameworks, range or variety of materials used and the span of methods used in the accuracy, expandability and the procedure of the techniques. Every methods such as binder jetting, fused deposition modeling, stereolithography, selective laser sintering ensure distinctive benefits. However, the mechanical strength, drug release profiles and biocompatibility of the final product are mostly influenced by the materials chosen, including polymers, hydrogels and composites used.

Although there are advantages, still there are lots of challenges to resolve so that 3D printing technique can be widely used in the standard pharmaceutical manufacturing. To ensure continuous improvement

it is important to eliminate the challenges in order to maintain consistency in quality, reproducibility and regulatory compliance. To move forward from laboratory scale models to commercially feasible products, concerns of reproducibility, cost effective and affordable and patient safety must also be rectified with the aim to assure patient safety and product dependability, which are crucial for broader clinical acceptance, by the regulatory bodies. There are a lot of potential advantages like the ability to create drug combinations and customized dosages as per the patients' need such as configurable tastes, forms, and release profiles, it also has potential to enhance patient compliance. By enabling quick prototyping the time taken for development and marketing can be made faster within short duration. Even though there are challenges still 3D printing is a revolutionary technology in the latest pharmaceuticals. It has the ability to completely change the development, production, and distribution of medications with more study, material innovation, and regulatory support, eventually proving it more efficient and patient-centered healthcare.

Looking ahead, the future of pharmaceutical 3D printing will be strengthened by the combination of advanced supplies, AI-assisted design, and real-time quality monitoring. This would probably accelerate pharmaceutical 3D printing in the future. It might be possible to create the next generation of responsive medication delivery systems by creating new bioinks and intelligent polymers that react to physiological stimuli. Furthermore, by combining 3D printing with patient data, and digital health platforms may enable completely customized medications that adjust to each patient's unique requirement. Regulatory bodies are likely to create clearer approval rules, which will help industry growth and commercialization. With continued technological progress and supportive policies, 3D printing could move from limited lab use to a mainstream method for making medicines.

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