Int. J. Pharm. Sci. Rev. Res., ISSN: 0976 – 044X, 86(7) – July 2026; Article No. 28, Pages: 183-190 **DOI:** 10.47583/ijpsrr.2026.v86i07.028

Review Article

3D Printing Technology in Pharmaceutical Formulation

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Received: 12-04-2026; **Revised:** 26-06-2026; **Accepted:** 03-07-2026; **Published online:** 20-07-2026.

ABSTRACT

Three-dimensional (3D) printing is an interesting technology that can be utilized to prepare personalized, complex dosage forms and thus it has eventually turned out to be a potential option in pharmaceutical formulation development. It enables precise control over drug dose, shape, size and release characteristics, thereby addressing the concept of personalized medicine. Various 3D printing technologies are popularly investigated for controlled release, implant, capsule and tablet formulation development. There are multiple benefits that the technology offers, including precise dosing, convenient administration for patient compliance, rapid prototyping and decreased material waste. However, there remain challenges to large-scale application through regulatory approval, materials selection, manufacturing cost and production scalability. Recent technological advances in printable biomaterials and automated manufacturing systems have also enhanced pharmaceutical 3D printing. Therefore, 3D printing was considered as a promising future innovation for the production of sophisticated and personalized drug delivery platforms.

Keywords: 3D Printing, Additive Manufacturing, Pharmaceutical Formulation, Personalized Medicines, Controlled Drug Release, Pharmaceutical Technology.

INTRODUCTION

3D printing, also known as additive manufacturing (AM), is an emerging technology in pharmaceutical sciences for the development of personalized product delivery systems. This specific technology that allows to create drug products (pharmaceutical formulations) build-up by layers following a digital design, and precisely controlled for drugs dose, shape and release.[1] The application of 3D printing in the production of tablets, capsules, implants, and controlled-release formulations has been considerably aided by the increased focus on customized medicine.[2] Because they can create complicated dosage forms that give excellent patient compliance, dose precision, etc., techniques including fused deposition modeling (FDM), stereolithography (SLA), and inkjet printing have been investigated for pharmaceutical usage.[3] Pharmaceutical 3D printing (P3) and its uses in modern medication manufacture were made possible by the US FDA's 2015 approval of a pill called Spritam®.[4] In the upcoming years, 3D printing is considered a possible technology for developing pharmaceutical formulations, despite a number of regulatory and material selection problems.[5]

Types of 3D Printing Technologies in Pharmaceutical:

Pharmaceutical formulations are developed using a variety of 3D printing procedures, depending on the kind of material and required drug release properties. Fused deposition modeling (FDM), which loads the medication into filaments that are fused and deposited in layers to create tablets and implants, is the most popular method.[6] Inkjet printing, which sprays tiny droplets of the drug solution onto a substance and is mainly used for accurate dosing and quickly disintegrating formulation, is another significant technological advancement.[7]

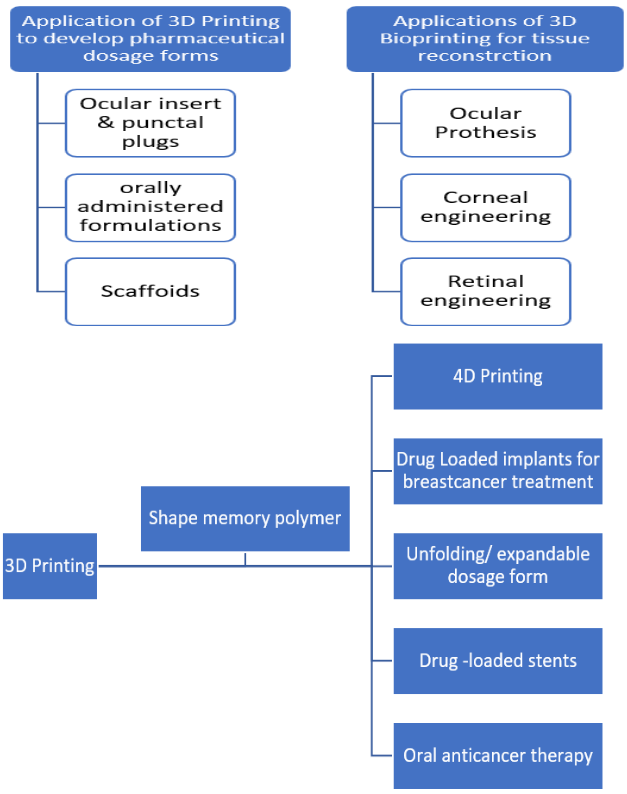


Figure 1: Application of 3D Printing[22]

Stereolithography (SLA) is said to produce extremely precise dosage forms by solidifying photopolymer resins under UV light to generate specified shapes.[8] A method called selective laser sintering (SLS) was developed to generate porous pharmaceutical structures with controlled drug release qualities by fusing powdered materials with laser light.[9] Binder jet printing is another intriguing technique that creates tablets with quick disintegration characteristics by depositing a liquid binder onto powder beds.[10]

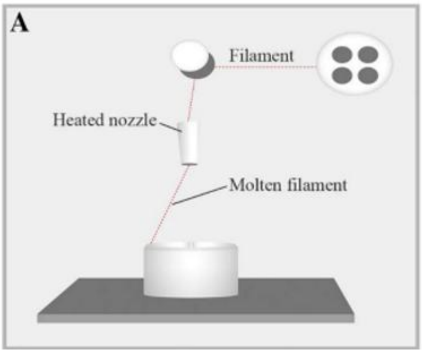
These technologies contribute significantly to the development of sophisticated drug delivery systems and customized medicine by providing flexibility in formulation design.

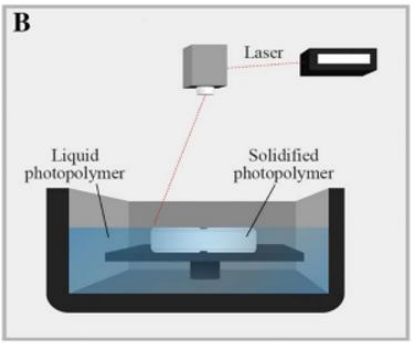
Material used in 3D printing:

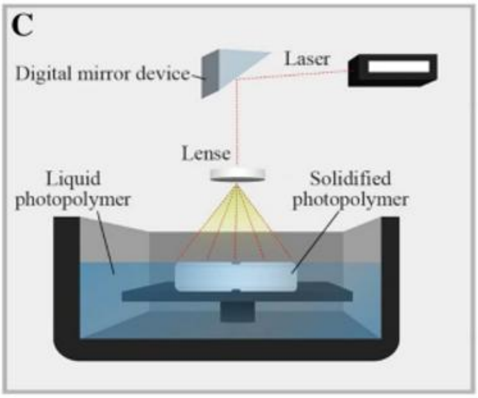
Depending on the printing method and required formulation features, different materials are utilized in pharmaceutical 3D printing. Polymers are the most widely used materials because they can be engineered to release medications and are biocompatible. Among the most widely utilized materials for tablets and implants are polyvinyl alcohol (PVA), polylactic acid (PLA), hydroxypropyl methylcellulose (HPMC), polyethylene glycol (PEG), and Eudragit polymers.[11] In addition to polymers, pharmaceutical excipients such as binders, plasticizers, lubricants, and disintegrants are added to improve dosage forms' mechanical strength and printability.[12] To create a printable filament, powder, or resin that can be utilized in a variety of 3D printing techniques, these materials are combined with medications.[15] In order to achieve stability, optimal drug delivery, and safety in 3D-printed pharmaceutical formulations, selecting the appropriate materials is essential.

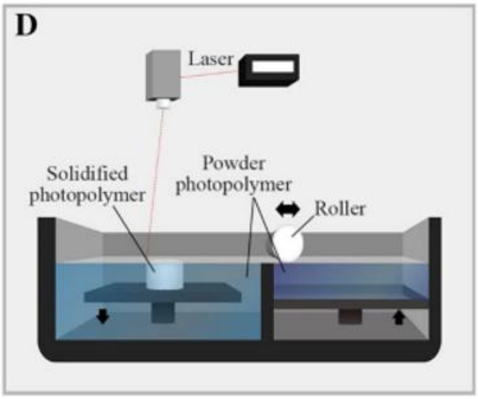
Graphical illustration of 3D Printing technology[20]

A. FDM Printer
B. SLA Printer
C. DLP Printer
D. SLS Printer









Type of 3D Printer

Inkjet-based 3D printers, selective laser sintering, stereolithography, pressure-assisted microsyringes, and fused-deposition modeling are among the 3D printers utilized in the pharmaceutical industry.

Inkjet-based 3D printers

The liquid is sprayed as droplets using inkjet-based 3D printers. These are categorized as continuous jet printers and drop-on-demand printers. Because it is more affordable, the former type generates the precise amount of ink required for printing. Either a thermal nozzle induces vapor bubbles or a piezoelectric nozzle vibrates to control the droplet stream. In contrast, a pressure pump creates a constant stream of ink droplets in continuous jet printers.[23]

Selective laser sintering 3D printers

With selective laser sintering 3D printers, a laser beam is directed onto a powder bed surface that contains a drug and polymer mixture. The laser beam boosts the temperature of the powder bed, causing abrupt powder sintering. Using a roller, this procedure repeatedly applies fresh powder layers on top of the sintered ones until the desired three-dimensional object is constructed.[24]

Fused-deposition modeling 3D printers

In contrast, a hot-melt extruder is utilized in the widely used fused-deposition modeling printers to create filaments from the drug and polymer, which are then coiled into a spool in preparation for printing. The intended 3D item is then deposited on the printing platform by the printer pulling the filament from the spool and passing it over a heated nozzle.

Although fused-deposition modeling printers are widely used because they print quickly and affordably, their usage with thermosensitive medications is restricted due to the high temperature exposure.[26]

Pressure-assisted microsyringe 3D printers

Pressure-assisted microsyringe 3D printers are one kind of nozzle-based printer. The pressure force of the syringe's nozzle piston deposits a paste made of the medicine and excipients to create the intended three-dimensional entity. This method works well for thermolabile medications, however during the post-printing drying stage, the products may shrink or be destroyed.[25]

Stereolithography 3D printers

Stereolithography (SLA) 3D printers work on the basis of exposing a liquid that contains a drug and a photosensitive polymer mixture to ultraviolet light, a powerful source of energy, until the mixture solidifies. While digital light is the source of ultraviolet light in digital light processing printers, the laser beam is the source of SLA printers. In short, photosensitive polymers function as a crosslinker when exposed to intense light energy, starting liquid solidification into the desired three-dimensional shapes. High-resolution 3D designs with smooth surfaces can be produced with SLA 3D printers. On the other hand, the photosensitive cross-linkers' high toxicity is the primary drawback.[22]

Applications in Pharmaceutical Formulation:

Pharmaceutical formulations can benefit from the use of 3D printing technology in a number of ways, particularly for complicated and personalized dosage forms. It is a typical excipient utilized for precise medication dose in immediate-release, extended-release, and controlled-release tablets.[23] This technology can also be used to create polypills, which combine multiple medications into a single dosage form to improve patient compliance, especially in chronic conditions.[14]

Additionally, 3D printing for customized medications is taken into consideration based on the patient's unique requirements, such as age, weight, and health state.[11] Pharmaceutical items such tablets, capsules, implants, transdermal patches, and drug-loaded scaffolds have been successfully produced using a variety of 3D printing processes.[15] The technology can also be used for on-demand manufacturing and rapid prototyping, which could be helpful in modern pharmaceutical research and development.

3D printing for fabricating drug-loaded ocular inserts and punctal plugs

Fused-deposition modeling and hot-melt extrusion 3D printing were utilized to create a patient-centered, customized, and intricately sculpted ciprofloxacin HCl-loaded ocular insert. Using an experimental design approach to achieve the desired customized drug release profile, the polymer of choice for the 3D printing method was the biodegradable, biocompatible, and bioadhesive KlucelTM hydroxypropyl cellulose. Drug-excipient compatibility, thermal properties, drug content, topography, in vitro drug release, antibacterial activity, ex vivo transcorneal penetration, and a stability analysis for the manufactured ocular inserts were all thoroughly investigated by the authors. The ideal design achieved an extended drug release profile for 24 hours and demonstrated the drug's existence in an amorphous state. Additionally, the ideal formulation had strong mucoadhesive strength, smooth surfaces, and no physical or chemical incompatibilities.[27]

Application of 3D printing to develop formulations intended for the oral administration Formulation of immediate-release tablets

Lopez-Vidal was the first to disclose using the melting solidification printing process to incorporate nanocrystals onto 3D-printed tablets (printlets). This method allowed for the successful incorporation of albendazole nanocrystals at a high concentration (50% w/w), which was never possible in traditional tablets. Albendazole nanocrystals were incorporated into a carrier ink made of polyethylene glycol 1500/propylene glycol. Following this inclusion, no loss of crystallinity or physicochemical interactions were observed. When compared to the free form, the drug's solubility in HCl 0.1 N was enhanced by the addition of albendazole nanocrystals to the printlets. Additionally, during the course of six months of storage, the intended formulation preserved the nanocrystals' crystallinity, particle size, and chemical stability. The results show the pharmacological potential of combining nanocrystals and 3D printing methods to create fast-release, stable, solid dosage forms for hydrophobic medicines. Additionally, this method works well for printing items that contain nanocrystals in polymers with low melting temperatures.[24]

Applications of 3D bioprinting for tissue reconstruction

These include 3D bioprinting for constructing ocular prosthesis, corneal, and retinal engineering.

3D bioprinting for constructing ocular prosthesis

In order to provide patients who have lost their eyes a normal appearance, a polymeric implant in the shape of an ocular prosthesis was created using 3D printing and sublimation. Following the necessary cytotoxic activities, intradermal response, systemic toxicity, and topical sensitization studies, three patients who had the 3D-printed prosthesis applied at least eight hours a day for a month were used in a case study. Using a slit-lamp assessment, safety evaluations were completed for the patients to document any allergic reaction or conjunctival irritation. The 3D bioprinted ocular prostheses were found to be free of cytotoxic effects, systemic toxicity, and transcutaneous sensitivity by physical, chemical, and pharmacological safety inspections. Additionally, the proposed ocular prosthesis showed the same results for iris color, sclera, and vascular patterns and produced no negative consequences in the conjunctival sac. The designed prostheses were physiochemically and physiologically safe, and their appearance and functionality were satisfactory.[29]

3D bioprinting for retinal engineering

Retinal pigment epithelium and photoreceptor dysfunction may cause retinal degeneration and irreversible vision loss. The current medications do not fully restore function; they simply slow the disease's progression. Additionally, it is challenging to diagnose retinal illnesses in older adults during their early stages since they are asymptomatic. Therefore, using 3D bioprinting technology could have a significant physiological impact on retinal restoration.[30]

Advantages of 3D Printing in Pharmaceutical Formulation:

Benefits: The development of pharmaceutical formulations benefits greatly from the use of 3D printing technology. It makes it possible to produce personalized medicine, which enables the prescription of medications at the appropriate dosage for each patient [5]. Additionally, the technology can be utilized to create controlled medication release systems and sophisticated dosage forms that are difficult to produce through traditional production processes.[12]

The ability to provide many medications in a single dosage form, which improves patient compliance and reduces pill load, is one significant advantage.[4] In the contemporary environment of pharmaceutical research and development, 3D printing is a useful technology since it facilitates quick prototyping, reduces material waste, and offers manufacturing process flexibility.[1]

3D Printing technologies in pharmaceutical Sciences

Nozzle-based deposition systems

The efficient mixing of medications with polymers for further 3DP is made possible by the nozzle-based deposition technology. Pressure-Assisted Microsyringes (PAM) do not require component melting, while Fused Deposition Modeling (FDM) must.

Pressure-assisted micro syringes technology (PAM)

The technique depends on applying pressure to the piston in order to form the proper shape. Semi-liquid and viscous materials are dispensed by the syringe extruder. The method's reproducibility depends on viscosity, elastic limit, and viscoelasticity. The technology advances by continuously flowing at room temperature, which is not possible with other techniques.

Laser-based writing system

Charles Hull invented "Stereolithography" (SLA), a device that uses a laser to photopolymerize resin using ultraviolet (UV) light. The procedure starts with a laser projecting onto photopolymerizable resin, which causes the first layer to solidify. Then, further layers are created until the 3D printed product is finished. The energy of the UV light employed determines how thick the layers are. For human safety, resin selection is crucial and needs regulatory approval. A tank pours resin that solidifies to create a secure basis while the laser aligns successive layers.[43]

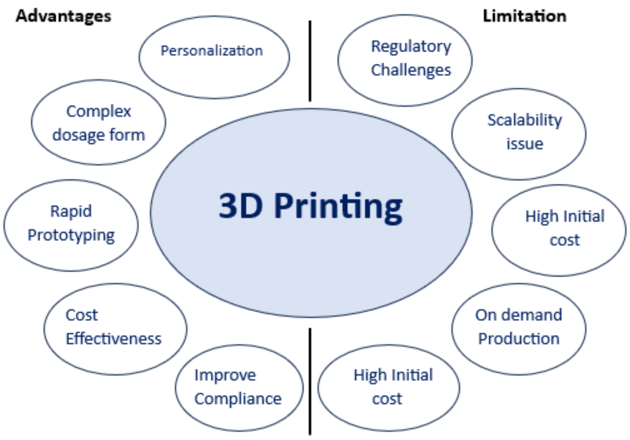


Figure 2: Advantages and limitation of 3D pharmaceutical printing[21]

Limitations and Challenges

There are certain restrictions on the use of 3D printing technology in the pharmaceutical industry. The scarcity of pharmaceutical-grade printable materials appropriate for various printing methods is one of the main obstacles.[12] Its use in large-scale industrial production is further hampered by its expensive equipment cost, limited production rate, and manufacturing scale restriction.[15]

The commercialization of 3D-printed dosage forms is still hampered by significant issues with quality control, repeatability, and safety.[15] Additionally, the formulation performance and product uniformity may be impacted by worries about the drug's stability under high temperature printing circumstances and the absence of standards in production procedures.[10] Therefore, further research and the development of regulations are required to successfully incorporate 3D printing technology into standard pharmaceutical manufacturing.

Regulatory Considerations for 3D printing

When developing and commercializing 3D-printed pharmaceutical products, regulatory considerations are crucial. The significance of quality control, safety, efficacy, and repeatability of 3D-printed dosage forms has been emphasized by regulatory bodies such as the US Food and Drug Administration (FDA).[10] It is necessary to closely monitor factors such as printing accuracy, material consistency, medication stability, and batch homogeneity during manufacture.[11]

Although Spritam® was approved in 2015, indicating that 3D-printed medications could be used for regulatory purposes, pharmaceutical 3D printing is still not standardized.[12] The development of the regulatory frameworks necessary for the safe and efficient application of this technology in the pharmaceutical industry is currently ongoing, with an emphasis on issues pertaining to validation, process optimization, and large-scale manufacture.[5]

Recent Advances in 3D Printing in Pharmaceuticals

In recent years, pharmaceutical 3D printing has advanced significantly, which has aided in the creation of intricate and customized drug delivery systems. Researchers are currently investigating cutting-edge technologies including multi-material printing, bioprinting, and AI-driven formulation optimization to improve dose accuracy and therapeutic efficacy.[16] These days, selective laser sintering (SLS) and fused deposition modeling (FDM) are widely utilized techniques to create polypills and controlled-release formulations with extreme precision.[17]

The expanding importance of additive manufacturing in healthcare has been highlighted by recent studies that have looked into 3D bioprinting in the fields of tissue engineering and drug screening [18]. Additionally, the development of bioinks, printable polymers, and automated quality control has helped to remove earlier restrictions related to medication stability and repeatable manufacture.[19]

The use of polymeric nanoparticles, such as those derived from chitosan and polylactic co-glycolic acid (PLGA), in targeted and regulated drug delivery systems has drawn a lot of interest.[24,26] These biodegradable polymers are perfect for developing sustained-release formulations that reduce adverse effects and increase medication efficacy. By allowing for precise spatial control of medication distribution, their incorporation into 3D-printed pharmaceutical forms has created new avenues for personalized treatment.[31]

This method guarantees localized distribution and long-lasting therapeutic effects by creating intricate structures suited to certain anatomical requirements. In order to embed polymeric nanoparticles into 3D-printed scaffolds, materials that are compatible with the intended drug release profile must be chosen. For example, chitosan nanoparticles can be used to provide localized and sustained medication release in 3D-printed implants due to their superior biocompatibility and mucoadhesive qualities.[32]

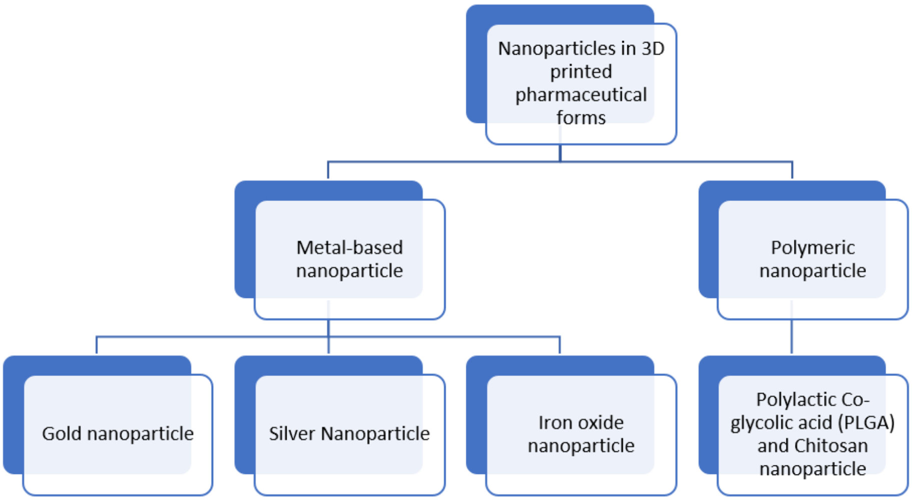


Figure 3: Integration of nanoparticle in 3D printed pharmaceutical in 3D Printed pharmaceutical formulation types and application [42]

Future Prospects in 3D Printing in Pharmaceutical Formulation

3D printing technology is expected to have a major impact on pharmaceutical manufacturing in the future since it can produce complex drug delivery systems and customized medications. Future advancements could be utilized to instantly manufacture medications at pharmacies and hospitals according to a patient's requirements.[11] It is also expected that the application of advanced printable biomaterials, automation, and artificial intelligence will improve product quality, production efficiency, and product formulation accuracy.[5]

Furthermore, the development of complicated dosage forms that are distributed in targeted and regulated ways may be made easier by novel polymer and multi-drug printing technologies.[3] Ongoing research and technology developments are anticipated to boost the potential use of pharmaceutical 3D printing for commercial applications in the future, even though there are still certain production and regulatory issues to resolve.[1]

Adaptive Neural Interfaces

Adaptive neural interfaces that may respond dynamically based on real-time neural activity may be made possible by the combination of 3D-printed scaffolds with nanoelectronic components. Developing 3D-printed neural meshes with nanoscale sensors and actuators to track local neurotransmitter levels is a promising application.[33]

Quantum Dot-Enhanced Theragnostics

Neurological condition theragnostics could be revolutionized by incorporating quantum dots into 3D-printed medicine delivery systems.[34] These nanostructures enable real-time monitoring of drug distribution and effectiveness in the brain by serving as both imaging agents and drug transporters. By permitting accurate viewing and tailored therapy, this method could greatly enhance therapies for brain malignancies. Because of their ultrafine size, adaptable surface functional groups, and remarkable sensitivity to pH, temperature, and light, carbon quantum dots have recently become attractive candidates for targeted drug delivery. This allows them to successfully cross difficult barriers like the blood–tumor and blood–brain barriers.[35]

AI-Driven Personalized Formulations

In the future, 3D-printed formulations could be optimized using artificial intelligence (AI) algorithms based on patient-specific data, such as genetic profiles, neuroimaging findings, and biosensor feedback. Treatment plans that adjust to the patient's changing neurological status and maximize efficacy while reducing negative effects could result from this technology. However, a thorough grasp of the ethical and legal issues pertaining to the use of AI in patient care is necessary for the actual implementation of AI-driven formulations.[36,37]

Nanorobot-Assisted Neurosurgery

The creation of personalized nanorobots for minimally invasive neurosurgery treatments may be made easier by 3D printing. These nanodevices can be used for precision tumor ablation while protecting healthy tissue, targeted drug delivery, or plaque removal in Alzheimer's disease when guided by external magnetic fields or self-navigating systems.[38,39]

Neuroplasticity-Enhancing Hybrid Systems

Patients with traumatic brain injuries or stroke may benefit greatly from the combination of 3D-printed hybrid systems, electrical stimulation, and controlled release of medications that promote neuroplasticity. These technologies, which are designed to target particular neuronal circuits, may maximize the brain's inherent repair processes. Nonetheless, there are still unanswered questions about the best design and stimulation parameters for reaching the intended therapeutic results in various patient populations.[40,41]

CONCLUSION

The development of pharmaceuticals is rapidly changing due to 3D printing. Rather than adhering to "one-size-fits-all" mass production, this technology enables the development of customized medications and intricate medical devices that are precisely fitted to a patient's requirements. Precision techniques, such as layering materials or shaping a dosage form with lasers, can improve outcomes and make it much simpler for patients to adhere to their treatment plans.

Naturally, the system is still not flawless. Government laws, locating suitable materials, and figuring out how to manufacture things on a large scale are still obstacles to overcome.

Based on their operating principles, several 3DP techniques have been created and divided into subgroups. 3DP technology has increased the freedom to modify the shape and microstructures of dosage forms and enables the creation of extremely complex and sophisticated medication dosage forms.

Additionally, 3DP is a novel and extremely promising method for on-demand manufacturing and dosage form customization, which may enhance patient compliance and drug efficacy, lessen side effects, fix stability problems with medications with short shelf lives, and ultimately result in patient-specific healthcare with on-demand customized medications.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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