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A REVIEW ON EXPLORING 3D PRINTING TECHNIQUES FOR SOLID DOSAGE FORMS

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Abstract:

Digital fabrication technology, also referred to as 3D printing or additive manufacturing, creates physical objects from a geometrical representation by successive addition of materials. 3D printing technology is a fast-emerging technology. Nowadays, 3D Printing is widely used in the world. 3D printing technology increasingly used for the mass customization, production of any types of open source designs in the field of agriculture, in healthcare, automotive industry, locomotive industry and aviation industries. 3D printing technology can print an object layer by layer deposition of material directly from a computer aided design (CAD) model. This paper presents the overview of the types of 3D printing technologies, the application of
3D printing technology and lastly, the materials used for 3D printing technology in manufacturing industry. As the pharmaceutical industry continues to embrace the potential of 3D printing, this review offers valuable insights into the current state and future prospects of these innovative manufacturing approaches for solid dosage forms.

Keywords: *3D Printing Technologies, Solid dosage forms like tablets, Capsules*

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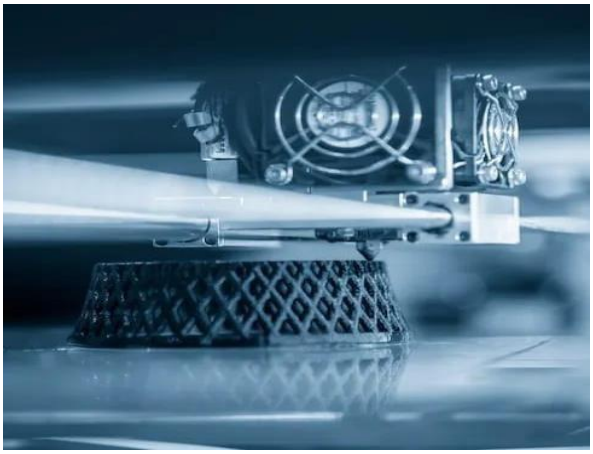
INTRODUCTION:

3D Printing, also Referred to as rapid prototyping and additive manufacturing technology is a cutting-edge technology constructs three-dimensional Models layer by layer using specialized materials. In the last three decades, it has undergone significant advancements, enabling cost-effective production of complex objects with the need for assembly. this technology offers unlimited design possibilities, rapid delivery, and utilizes cost-efficient materials .it has found diverse applications across industries, including aerospace, automotive, medical, and even food production. Within the medical field, 3D printing is used for creating medical models, biological tissues, organs and pharmaceuticals solid medicines. From 2000, they used powder delivery 3D printing technology to prepare chlorpheniramine maleate tablets, Notably, it has made significant strides in drug production, including the approval of "levetiracetam instant tablets" by the US FDA in 2015, which marked a pivotal moment in pharmaceutical manufacturing. This progress has sparked extensive global research, who leveraged 3D to develop and assess the quality of rapid -acting gastric floating oral disintegrating tablets.



Polymers are commonly employed in 3D Printing due to their versatility, affordability, and ease of use. They consist of materials that can be melted and extruded into various shapes, such as plastics, resins, and rubber- like substance. Among the 3D Printing methods, Fused Deposition modelling (FDM) stands out as the most popular technique for polymer-based printing. There is a variety of polymers used in 3D Printing, each with its distinct characteristics and applications. One of the widely used polymer materials is polylactic acid (PLA), dominating the world of desktop 3D Printing. PLA finds applications in prototyping, DIY Projects, artistic creations, household items, and even biomedical uses.

History:

The origins of 3D Printing research can be traced back to the late 1970s when several patents were filed for compute raided additive manufacture using different approaches. Charles (chuck)Hull, known as the inventor of stereo lithography (SLA), patented 'this key 3D Printing technology in the mid-1980s. SLA employed UV light to polymerize resins, and Hull went on to establish 3D Systems to commercialize these SLA printers. In 1986, Texas university student Carl Deckard introduced another groundbreaking technology called Selective Laser Sintering (SLS), which utilized a laser to fuse powder material in 1989, Scott and Lisa Crump from the company Stratasys registered a patent for Fused Deposition Modelling (FDM), a method that involved heating 1989, plastic or metal through a nozzle. Around the same time in Emanuel Sachs and colleagues at MIT developed technique called "3D printing" by extruding a binding solution onto a powder bed using an altered inkjet printer. This approach later became as ''Binder jetting''. Additionally, in 1989, Hans Langer pioneered Direct Metal Laser Sintering (DLMS), which used lasers to create 3d objects based on computer models.

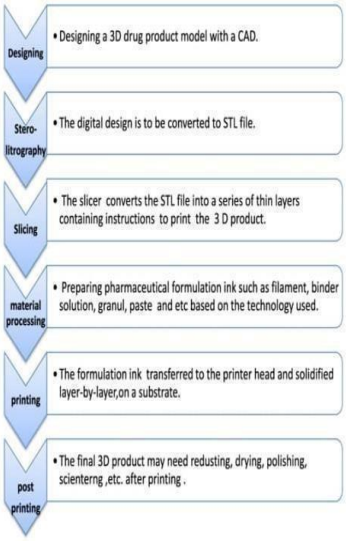
Efforts were also made to make 3d Printing accessible to consumers at lower costs. Andrew Bowyer's Rep Rap project, based at the University of Bath, focused on producing 3D printers capable of manufacture most of their own components, leading to various collaborations. Since its inception,3D printing technology has found applications in numerous fields. Its early applications in healthcare included surgical planning, guidance, and implant production.

Moreover, 3D Printing allowed for the creation of implants containing active pharmacological ingredients, offering customization potential. The technology also found its way into clinical education. Notably, in 2015, the FDA approved (Levetiracetam), a prescription epilepsy medication developed by Pharmaceuticals, as the first 3D printed drug.

How to print:

Depending on the specific print you are planning to do there could be more or few steps in your process. But in
general, 3D printing involves the following actions:

Step 1: Create or find a Design.
Step 2: Export the STL File.
Step 3: Choose your Materials.
Step 4: Choose your Parameter.
Step 5: Create the G code
Step 6: Print



"In the realm of 3D printing, a variety of items such as medicines, components, medical implants, and devices are created through the layer-by-layer accumulation of materials until the desired three - dimensional model, based on a computer-Aided Design (CAD) file, is physically produced. Presently numerous 3D Printing techniques are available, but they all share a common sequence of steps.

1.Conversion of a three- dimensional model using CAD software.

2. Conversion of the model from step 1 into "STL" Format.

3.Slicing the file using specialized slicing software.

4.Utilization of computer Numerical control (CNC) codes to manufacture the 3D Print.

Types of 3D Printing:

Extrusion Material
Vat Polymerization
Powder Bed Fusion
Material Jetting
Binder Jetting
Direct Energy Deposition
Sheet Lamination

Material Extrusion:

In this technique the material is extruded from the automated nozzle on to the substrate and it does not require any higher support material. The materials that can be extruded are molten polymers, suspensions, semi solids, pastes.

Vat polymerization:

Photo polymerization is also known as vat polymerization is a 3D printing process that involves selectively curing a photo polymer resin in a vat using a light source. Two well-known variations of vat polymerization are SLA (Stereo lithography) and DLP (Digital Light Processing). The key difference between 3D printing technologies lies in the type of light source used to solidify the resin. They can be compared as follows: `SLA Printers employ a point laser.

Powder Bed fusion:

Powder bed fusion is an additive manufacturing approach that employs thermal energy to meld powders together, as it names implies. Within this category, various techniques exist, including Selective Laser Sintering (SLS), Electron Beam Melting (EBM), Direct Metal Laser Sintering (DMLS), and Selective Heat Sintering (SHS). This 3d printing method can employ solid particles such as metals, polymers, and ceramics as additive materials. To accelerate the process, recent innovations have focused on using high- speed lasers

Material Jetting:

Material jetting (MJ) Is a 3D Printing technique that shares similarities with traditional inkjet printers. In MJ a printer head ejects a wide range of photo polymer droplets, which are subsequently cured or solidified using infrared (UV) light within a controlled environment, once one layer has been processed and deposited, the build platform is lowered by one layer's thickness, and this layer by -layer approach continues to construct three dimensional objects. What sets MJ apart from other 3D Printing methods is its ability to deposit `and build material without being constrained to a predefined path. Offering great flexibility in the fabrication 'process.

Binder Jetting:

Binder jetting is a 3D Printing method that uses inkjet technology to create objects. It starts with a layer of loose powder. A printer nozzle sprays a liquid binder onto the powder, making it stick together. This Process is repeated layer by layer until the object is done. Spritam was made using a similar method called zip dose technology and Their Form, a way to create medicine doses layer by layer using binder jetting.

Direct Energy Deposition (DED):

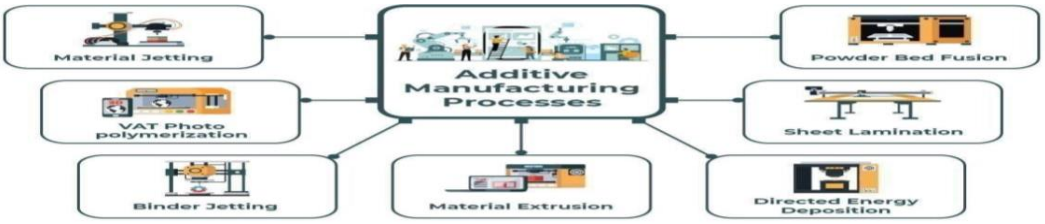
It is a distinctive 3D printing method primarily geared towards the maintenance and repair of components, rather than their initial production. DED relies on the controlled melting and depositing of material to form new objects or restore existing ones. Central to the DED 'Process are the deposition head, sophisticated equipment units that combine an energy source with two power feed nozzles. In addition to metal powder, DED can incorporate thin wires, providing flexibility in material choice some setups include a platform for

material deposition and inert gas tubing to maintain the desired atmosphere.

Sheet Lamination:

It is also known as laminated object manufacturing (LOM) is a process where sheets of material are bonded together to create an object. This technology was firstly developed by HELISYS in 1991 and later improved upon by MCOR technologies in 2012. In LOM, a sheet of building material, often with a glue backing or adhesive, is fed onto a building stage. A laser is then used to cut a pre designed structure into the sheet while the platform moves, and this process is repeated until the object is complete. Besides metals, polymers, and ceramics can also be used in this process.

Ultrasound consolidation/Ultrasound Additive Manufacturing.



3D Printed Dosage Forms:

Oral Tablets

Using this multidisciplinary technology result in a range of various dosage forms each having specific effects that are influenced by the materials and techniques used. These feedstock materials (some listed in Table 1) come in different forms such as powder, sheet, wire or liquid, and are pre-made to be compatible for use within the different printers. Related to of pharmaceutical uses, materials like polymer filaments, hydrogels or smart material polymers act as drug carriers (or excipients) and are mixed with the active pharmaceutical ingredients (APIs) to produce biocompatible dosage forms suitable for drug delivery. A similar technique can be used for four- dimensional printing (fourdimensional printing is a technology where researchers print 3D solid components but they are subject to change to other shapes once exposed to specific environmental conditions, such as temperature, light, or humidity). The applicable 3D-printing processes are subject to powder, liquid and extrusion based additive manufacturing (AM) methods, where the common techniques used are fused deposition modelling (FDM), ink-jet printing and stereo lithography (SLA). These techniques, amongst others, have been used to produce a variety of devices and print let for 3D printed solid oral dosage forms – that contain APIs and modifying agents. Primarily, medicine production begins with computer-aided design (CAD) technology; desired dosage forms are designed using freeform geometries and fabricated with Characteristics such as release Profiles that have Been set to suit clinical requirements.

Drug release profiles, in particular, are vital in supporting optimal drug absorption and distribution as this is related to drug efficacy and patient compliance and safety. Upon the completion of the 3D design, templates are transferred to a chosen 3D printer and APIs and excipients amongst other parameters are selected for the development of the print lets. An interest in such 3D printed products within drug development has emerged using various printing process.

Table 1. Table presents example of 3D printed dosage forms developed by different techniques.

Technique	Dosage form	API(s)	Excipient(s)	Effect
Powder-based Drop on solid (a type of Drop on Demand (DoD Technique)	Implant	Isoniazid	Polylactic acid (PLA), acetone, ethanol, water	Slow-release
Selective Laser Sintering (SLS)	Tablets	Paracetamol	Kolli coat IR or Eudragit L, candurin gold sheen	Oral drug loaded dosage forms
	Oro dispersible tablets	Paracetamol	Hydroxypropyl methylcellulose (HPMC) vinylpyrrolidone- Vinyl acetate copolymer	Fast dissolving release dosage form
	Drug delivery device	Progesterone	Polycaprolactone (PCL)	Zero-order Release dosage form
Semi-solid Extrusion (SSE) or pressure assisted micro syringe	Multicompartment tablet (polypill)	Nifedipine, captopril and glipizide	HPMC,microcrystalline cellulose, D Mannitol, etc.	Controlled release
	Multicompartment tablet (polypill)	Aspirin, Atenolol, Hydrochlorothiazide, Pravastatin and Ramipril	Polyethylene glycol (PEG) 600, D-mannitol, cellulose acetate.	Sustained- release of five in one dosage form for cardio vascular disease
Extrusion -based Fused Deposition Modelling (FDM)	Oro dispersible films	Aripiprazole	Polyvinyl alcohol (PVA)	Fast dissolution
	Caplets	Budesonide	PVA	Controlled-Release and Osmotic Dosage form
	Tablets	Theophylline	Hydroxypropyl Cellulose, triacetin, crospovidone, Sodium starch Glycolate,croscarmellose sodium	Fast/immediate release dosage form
Liquid- based Stereo lithography	Tablets	Paracetamol and 4- Amino salicylic acid	Polyethylene glycol diacrylate (PEGDA), PEG 300 and diphenyl-(2,4,6-trimethyl benzoyl) phosphine oxide (DPPO)	Controlled Release dosage form
	Drug- loaded Nose mask	Salicylic acid	PEGDA, PEG 300, DPPO	Personalized drug device with anti -acne drug release
	Micro needles	Insulin	Dental SG resin, Xylitol, Mannitol Trehalose	Rapid transdermal Release of insulin

The quality of the 3D printed dosage forms is dependent upon the formulations used and as shown in Table 1 each technique uses a range of materials, especially polymers. However, some of these materials are not economic available for pharmaceutical use, due to the novelty of 3D printing in this industry. This includes drug-loaded filaments that are necessary for FDM processes. Admitting this is a drawback, researchers are taking the initiative to prepare filaments containing thermo-stable APIs and pharmaceutical excipients by using hot melt extrusion (HME). This solution offers advantages when delivering high-quality filaments and these include vital dosage form attributes such as constant dimension, elasticity, homogenous dispersion of the drug, solubility and biocompatibility. In addition, the filaments carry greater drug content and better mechanical properties that are suitable for 3D printing. Adaptations of this technique were done to create filaments containing polyvinyl alcohol (PVA) and different concentrations of glipizide – a drug that stimulates insulin secretion. Li et al. employed HME to produce two filaments each containing a different drug concentration which were necessary to make the novel double chamber dosage form, called Duo Tablet, by using dual nozzle FDM printer.

The tablet-in-tablet structure of the Duo Tablet exhibited different drug release kinetics, with the outer-layer dissolving mostly in the first 2 hours. Although this mechanism showed that unique dosage forms can be created by using the 3D printing technique known as FDM, there are crucial parameters such as the infill density of the filaments which need to be considered. Infill density is given as a percentage; 0% density is a hollow object and 100% density is a thick and solid object. The percentage defines the volume of material used within the object and is related to the porosity level of that object. It also has an overall effect on the dissolution profiles of the printed dosage forms which is a highly beneficial feature for creating prolonged-release drugs use of CAD in 3D printing technology allows the manufacturing of drug formulation with the desired release rate and pattern. Apart from the type of polymer and the ratio of polymer to drug which can alter the release profiles of drug from 3D printed tablets, there are other parameters such as geometrical shape which could modulate the drug release pattern to reach the desired release profile. In addition, it has been shown that the drug loading in filaments can significantly have an impact on drug release. So, 3D printing provides possibilities to fine-tune drug release profiles. Miscibility of drug with polymer incorporated in the filament is another parameter that could change the drug release pattern as a drug with high miscibility with the polymer can reduce the viscosity of the complex remarkably. In addition, the use of polymer blends can provide an opportunity to modulate drug release from printed dispersions to achieve the desired release pattern. FDM is a low cost and efficient method to create oral drug dosage forms that are personalised to the individual and also for the production of formulations with modified-release pattern. This method allows the production of personalised tablets that are able to decrease the adverse effects caused by under/overdosing, increase ease of delivery and improve the patients' adherence to the therapy. FDM allows increased control of droplet size and drug release which increases reproducibility. It has been used to create tablets with varying infill percentages which suggest FDM is a feasible method to create tablets that are drug loaded. It was found that decreasing infill percentage gave a faster drug release and this can be used to modify and control release time. The concentration of polymer as well as drug/polymer ratios, and formulation compositions used in the tablet can also affect release rate, all of which can be taken into consideration when using 3D printing as a method to create tablets.3D printing can also be used to create tablets in shapes that would be too difficult to produce by other methods, such as powder compaction, and as shape determines surface area: volume ratio, it also modifies drug release This can be manipulated to produce low dose drugs for more sensitive patients The adaptability of 3D printing for producing different geometries can be exploited to increase patient adherence to their medication. Some shapes (and sizes) are preferable in terms of the patient's willingness/ability to swallow the tablet (Figure 2) This information can be used when designing medication in the future to ensure the fast release of the drug but without compromising on patient preference.

3D Printed: Oral Capsules

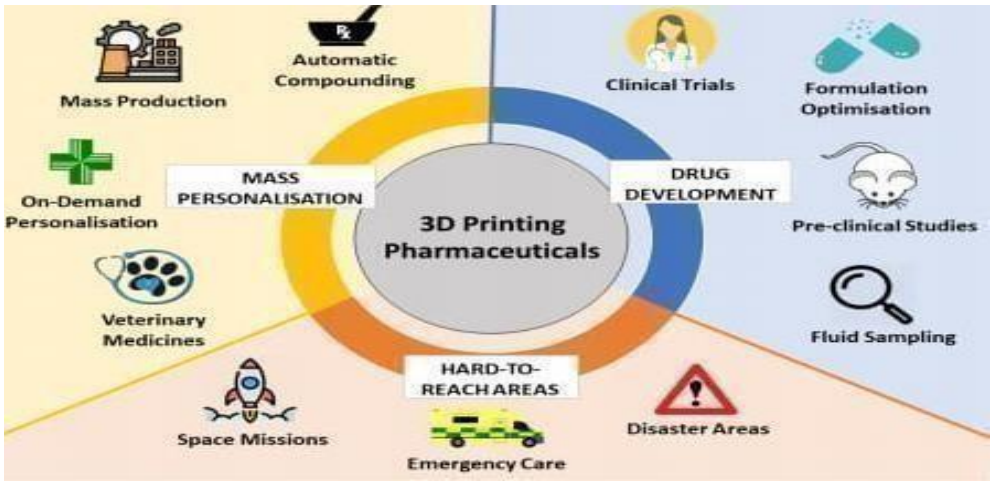
Capsules are often used to achieve gastro-resistant, immediate, enteric and pulsatile drug release in an oral drug delivery system. The gastro-resistance of a capsule is made possible by using the correct type of polymeric film. Hence, 3D printing would be an appropriate manufacturing technique for a capsular device as most polymeric materials are suitable to be used in 3D printing. FDM 3D printing has been used to produce a swellable capsular device for oral pulsatile drug release by using hydroxypropyl cellulose as the base polymer. The study by Melocchi et al. showed that the 3D printed capsules have comparable release performance with those of analogous systems fabricated by injection moulding.

The study was then extended to 3D printing a multi-compartment capsular device for two-pulse oral drug delivery, allowing the combination of a promptly soluble, swellable/erodible or enteric soluble device. This multi-compartment device allowed the release of two separate drugs at different times despite being in the similar capsule again increasing patient adherence. These multi-capsular tablets are shown in Such a device again showed the potential for Personalised medicine applications. Charoenying et al. have used 3D printing to fabricate a floating device that can be combined with commercial capsules to produce a gastroretentive drug delivery system The aim is to allow the device to float on the surface of the gastric fluid for a prolonged period to prolong drug release and achieve effective treatment of gastric ulcers. Apart from that, a study by Beck et al. has also shown the possibility of coupling nanotechnology and 3D printing to produce drug-loaded nano capsules. In other words, the drug delivery devices were first 3D printed, then soaked in the deflazacortloaded polymeric nano capsules to load drug onto the 3D printing devices. This method allows the conversion of a nano capsule suspension into a solid dosage form.

There are many pH-sensitive polymers on the market and some of them such as cellulose acetate phthalate (CAP), cellulose acetate trimelliate (CAT), hydroxypropyl methylcellulose phthalate (HPMCP), and Eudragit L and S were used in the preparation of drug/polymer matrix tablets. In addition, chitosan and alginate have also been employed to make pH sensitive formulations. Among these polymers, polymethacrylates such as Eudragit® L100-55 and Eudragit® S100 are polymers that can be used for the fabrication of filaments which are suitable for 3D printing and their solubility is pH-dependent. The study by Gioumouxouzis et al. produced pH-responsive chitosan-coated alginate beads loaded with 5-Fluorouracil. The beads were then placed in a 3D printed tablet that is made of PLA and Eudragit. The Eudragit layer of the 3D printed drug is only soluble when pH value corresponds to the colonic environment, ensuring a colon-specific drug delivery. Poly(2-vinylpyridine) (P2VP) is also a pHresponsive polymer which can be used for 3D printing. In addition, hydrogels such as Poloxamers and Pluronics exhibit pHresponsive properties and can also be used for the 3D printing of scaffolds.

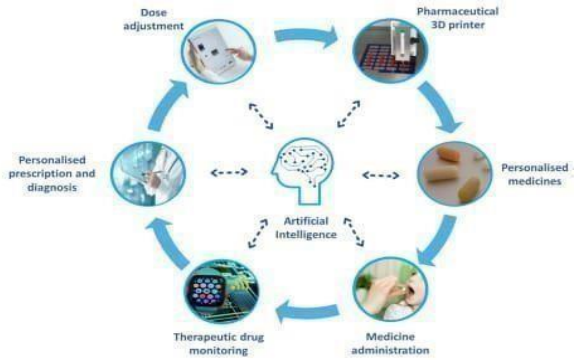
Applications:

- **Rapid prototyping**: Used to create a real scale model of an object in short lead time, using CAD software.
- **In the healthcare sector**: Tools can be prepared for surgery and are made to measure the patient's body.
- **Reconstituting bones and body parts in forensic pathology**: Fingerprint examination, accident reconstruction, structural, and industrial accidents.
- **Drug testing**: Ability to fabricate complex geometries to achieve various drugs releasing kinetics.
- **Personalized dosing**: It uses digitally controlled devices for formulating active pharmaceutical ingredient (API) and excipients.
- **Unique dosage forms**: Capable of producing various 3D drug products and various customized dosage forms.
- **Complex drug release profile**: To fabricate fully customizable tablets that can deliver drugs with any type of releasing profiles.
- **Low cost of production**: It can decrease production time, costs, and allow testing of new product designs.[18]



Challenges and Future Directions of 3D Printing in Pharmaceuticals:

Challenges and Future Directions of 3D Printing in Pharmaceuticals39The integration of 3D printing, alongside other innovative technologies, into pharmaceuticals has been forecast to give rise to a new digital pharmacy era. With the integration of non-invasive diagnostics or drug monitoring strategies (e.g., via artificial intelligence and point-of-care testing) and electronic prescriptions, 3D printing could provide a digital and decentralised platform for the production of tailored medicines in response to these monitored outputs Indeed, numerous researchers around the world hold this vision for 3D printing, with new research papers being published every day to further evidence the potential of 3D printing technologies in formulation development and patient care. However, as discussed in the previous sections, only a limited number of studies have been performed in pre-clinical and clinical settings. This hesitation around testing formulations in vivo is likely due to a combination of reasons, ranging from regulatory, quality and technical concerns through to a need for a shift in mindset and culture for the acceptance of digital technologies in Pharma.



CONCLUSION:

The exploration of 3D printing techniques for solid dosage forms presents a promising avenue for pharmaceutical advancements. The reviewed studies underscore the potential of this technology in providing personalized and precise drug delivery solutions. The ability to customize dosage forms based on patient-specific needs, coupled with the potential for complex drug formulations, signifies a transformative shift in pharmaceutical manufacturing. While challenges such as regulatory considerations and material optimization persist, the overall trajectory of 3D printing in pharmaceuticals is poised for significant growth and innovation. As researchers continue to refine techniques and address existing limitations, the future holds exciting possibilities for the integration of 3D printing in the production of pharmaceutical dosage forms.

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