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3D PRINTING IN PHARMACEUTICALS: TECHNOLOGIES, MATERIALS, CASE STUDIES, AND FUTURE PROSPECTS

Yogapriya G.*[1], Chandru B. S.[2], Nirmal Kumar R.[3], Anusha R.[4], Yalisai Arasu S.[5]

[1]B. Pharm Student, G.P.Pharmacy College, Mandalavadi, Tirupattur, Tamil Nadu, India.

[2]Assistant Professor, Department of Pharmaceutics, G.P.Pharmacy College, Mandalavadi, Tirupattur, Tamil Nadu, India.

[3,4,5]B. Pharm Student, G. P. Pharmacy College, Mandalavadi, Tirupattur, Tamil Nadu, India.

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***Corresponding Author**
Yogapriya G.
B. Pharm Student, G.P.Pharmacy College, Mandalavadi, Tirupattur, Tamil Nadu, India.

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ABSTRACT

Three-dimensional (3D) printing, often known as additive manufacturing, is a fast-developing technology in the pharmaceutical industry. It permits the creation of tailored medicines with precise drug dosages, bespoke forms, and controlled drug release profiles based on patient requirements. Tablets, capsules, implants, and sophisticated drug delivery systems are manufactured using a variety of 3D printing techniques, including fused deposition modeling (FDM), inkjet printing, binder jetting, stereolithography (SLA), and selective laser sintering. SPRITAM®'s FDA approval was a significant step forward in pharmaceutical 3D printing, demonstrating its clinical promise. The production method employs a variety of materials, including polymers, hydrogels, ceramics, resins, and nanoparticles, to improve medication stability, biocompatibility, and therapeutic effectiveness. 3D printing also enables the creation of polypills that include numerous medications in a single dosage form, increasing patient compliance and reducing dosing complexity. In addition, the technology provides benefits such as quick prototyping, decreased material waste, flexible manufacturing, and on-demand drug manufacture. Despite barriers such as regulatory approval, quality control, and production costs, advances in artificial intelligence, biomaterials, and pharmaceutical engineering are likely to expand the future reach of 3D printing in healthcare. Overall, 3D printing has the potential to transform pharmaceutical manufacturing by allowing for tailored therapy, enhanced drug delivery methods, and more efficient healthcare solutions.

KEYWORDS: 3D printing, additive manufacturing, pharmaceuticals, industry 4.0, personalized medicine, inkjet printing, binder jetting, fused deposition modelling (FDM), selective laser sintering (SLS), stereolithography (SLA), semi-solid extrusion (SSE), drug delivery systems, polypill, controlled drug release, hydrogels, nanoparticles, rapid prototyping, on-demand drug production, patient compliance, SPRITAM®.

1. INTRODUCTION

The fourth industrial revolution has brought about a technological revolution in creating finished items. The fourth industrial revolution, or Industry 4.0, aims to overcome constraints in human-machine interactions. Automation-promoting digital technologies, such as artificial intelligence (AI) and the Internet of Things (IoT), will be used in various public and private spheres to provide individualized methods for each individual, building on present manufacturing tactics.

Three-dimensional (3D) printing is projected to play a crucial role in manufacturing and mass customization of sophisticated, bespoke products as part of Industry 4.0.[1] 3D-printing is a new additive manufacturing (AM) technology that creates items by layer- by -layer deposition.[2]

In the 1990s, 3D printing was considered a potential platform for individualized treatment. The FDA's Center for Devices and Radiological Health (CDRH) has approved 3D printed medical devices, marking significant progress. The first 3D printing technology utilized in pharmaceuticals was inkjet printing a binder solution onto a powder bed, which bound the particles together. The technique was repeated until the final desired structure was achieved. Sachs et al. devised and patented this technology at the Massachusetts Institute of Technology in the early 1990s. In 1989, Scott Crump patented fused deposition modelling, which involves extruding polymer filaments into a semi-liquid state and depositing them onto a build platform layer by layer to solidify.[3]

Aprecia Pharmaceuticals developed the first 3D printed orodispersible tablet, SPRITAM® (Levetiracetam), which received FDA approval in 2015. This medicine is recommended for treating myoclonic, primary generalized tonic-clonic, and partial onset seizures in both adults and children with epilepsy.[4] This regulatory method is intended to make it easier to approve new technologies and complex items, such as pharmaceuticals made with 3D printing technology. Unfortunately, there is still uncertainty about the regulatory criteria for quality testing and approval of 3D-printed medicinal products. From rapid prototyping to large-scale manufacturing, this technology has helped to provide many novel solutions in a variety of industries, including automotive, aerospace, and biomedicine.[5]

Therapeutic Drug Monitoring focuses on maintaining drug plasma concentrations within the therapeutic index window. Factors such as age, gender, weight, pharmacogenetics, medication clearance, metabolism, and illness severity lead to varying drug concentrations amongst patients.[6] Additive Manufacturing Technologies (ATMs) have been successfully used to create several dose forms, including pills, patches, and microneedles.[7] This approach is effective for a variety of pharmacological components, including peptides, proteins, and water-insoluble medicines.[8]

In pharmaceutical manufacture, 3D printing technology has permitted the fabrication of complicated dosage forms with various geometries, rough surfaces, and hollow structures, which are normally difficult to make using traditional manufacturing procedures. Novel 3D printed pharmaceutical products include multilayer tablets, caplet-in-caplet, and floating capsules.[9]

3D printing has numerous medical applications, including anatomical models for training, patient organs created from ultrasound scans, implants, and surgical equipment. Polish specialists, surgeons, and cardiologists are already utilizing 3D printing to prepare for surgeries. Hospitals and laboratories have invested in 3D printing technologies, including hardware, software, and services. About 3% of large hospitals and medical and research institutions already have on-site printing facilities. They print replicas of the heart to help cardiac surgeons prepare for surgery, as well as joint components based on natural prototypes.

In the next three years, one out of four surgeons will prepare for surgery using entire 3D-printed patient model.[10] Pharmaceutical researchers are increasingly exploring three-dimensional printing and tailored formulations. Recent years have been an increase in published articles on 3D -printed pharmaceutical preparations, including original studies and reviews that serve as valuable references for further research.[11]

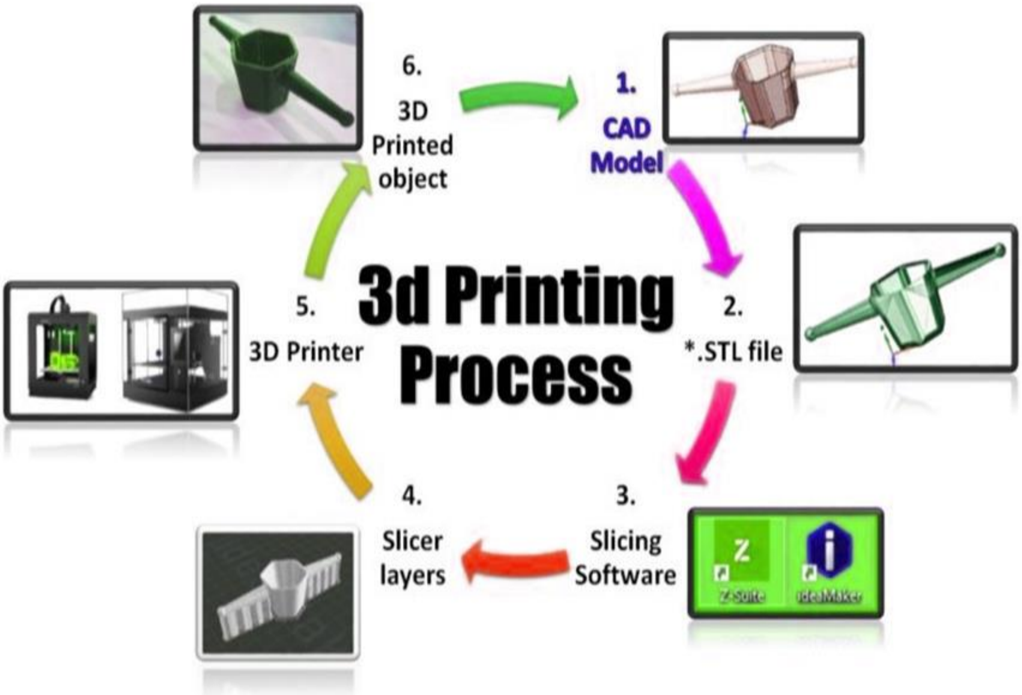

Figure 1: General process of 3D printing in pharmaceuticals.

2. CLASSIFICATION OF 3D PRINTING

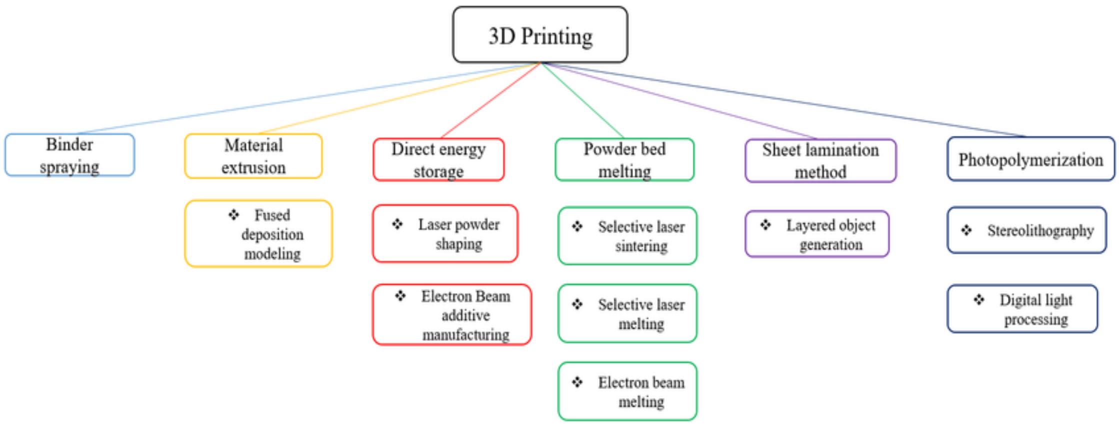

Figure 2: Classification of 3d Printing Technologies.

2.1 TYPES OF 3D PRINTING TECHNOLOGIES

Various 3D Printing systems have been created using different energy sources, materials, and mechanical characteristics.[12] The pharmaceutical industry mostly uses 3D printing processes such as inkjet-based printing, extrusion-based printing, and laser-based printing. The techniques employed include.

- Inkjet printing

- binder jetting (BJ),
- fused deposition modelling (FDM)
- Semi Solid Extrusion (SSE)
- Stereolithography (SLA)
- Selective laser sintering (SLS).[13]

INKJET- BASED PRINTING.

INKJET PRINTING

Inkjet printing is a 3D printing process that deposits microscopic droplets of medication solutions on substrates to create dosage forms. This technology is used in pharmaceuticals to provide customized dosages and multi-drug combinations in a single dosage form. Inkjet printing enables individualized pharmaceutical manufacture, with drug doses tailored to each patient's needs. It also allows for the design of dosage forms with complex release characteristics, such as combining immediate and controlled-release layers in one tablet.[14]

Binder jetting

The method of selectively depositing liquid droplets over a bed of powder, which is then layer-solidified to create a three-dimensional object, is known as binder jetting (BJ). This technology has mostly been utilized to create a variety of pharmaceutical goods with distinctive qualities, such as multilayered tablets tailored to patients' needs including oral pills that dissolve quickly.[15,16] This method, which Emanuel Sachs patented in 1993, has also drawn interest in the creation of drug-eluting devices. There are three crucial phases in the printing process: powder contact, droplet deposition, and solution drying.[16] To achieve uniform droplet deposition, Critical process parameter (CPPs) optimization which includes nozzle diameter, roller speed, and droplet-specific parameters is crucial. Droplet volume is directly impacted by the diameter of the binder jetting nozzle, and appropriate management is required to prevent clogging and/or flaws in pharmaceutical products like splashing or coffee staining.[17,18] Additionally, Critical material attributes (CMAs) have a significant impact on the resolution and layer thickness of pharmaceutical products, especially when an exact API dosage is required. There are two ways to include APIs into pharmaceutical products: powder mixtures or binder solutions, based on their stability and compatibility with printing processes. Evaluate powder flowability, particle size, binder viscosity, and surface tension to avoid faults in the final product.[19,20,21] Research implies that organic solvent-based binding droplet solutions should have a surface tension of 35-40mJ N−1.[22] Binder jetting eliminates the need for high temperatures or lasers during fabrication, making it a viable 3D printing approach for manufacturing thermolabile APIs.[23]

EXTRUSION BASED PRINTING

Fused deposition modelling (FDM)

To create three-dimensional prints using additive manufacturing, import an STL (Standard Tessellation Language) file from a stereolithography CAD program, such as 3D Systems, into preprocessing software. This technique is widely used in various industries. Controlling the four fundamental parameters of the FDM process is crucial for improving the quality of created products.

- Contour count
- Layer Thickness
- Raster angle
- Road width[24]

Fused deposition modeling uses a heated extrusion nozzle.[25] In FDM, thermoplastic polymers are extruded via the printer head at a precise temperature and direction. The semi-molten material is then placed on the build plate to form layers.[26,27] FDM can be separated into three stages: The process involves molten material extrusion, layer deposition, and layer solidification.[28] During printing, the outside layer is created first, followed by the layer-by-layer construction of the inside components. Extruded polymer known as "infill" is used to fill internal spaces to the desired amount.[29,30]

Semi-Solid Extrusion (SSE)

Semi-Solid Extrusion (SSE) is a 3D printing process that produces semi-solid, paste-like materials. SSE uses a syringe to extrude a semi-solid material. Semi-Solid Extrusion (SSE) materials have a thicker, non-flowing consistency. Customized drug forms can improve therapeutic outcomes for patients. SSE may require multiple post-processing steps to get the desired surface quality. This new technology holds great potential for personalised medicine and customised drug delivery systems.[31]

LASER BASED PRINTING

Selective laser sintering (SLS)

Selective laser sintering is similar to binder jetting, however instead of a binder, a laser is used to fuse powder particles together.[32] A SLS system consists of three key components:

the spreading platform, powder bed, and laser system.[33] This method is advantageous since it is a one-step, quick production process that does not require the use of any solvent. The application of laser precision yields high-resolution objects.[34]

Stereolithography (SLA)

Stereolithography (SLA) is a 3D printing technology that utilizes a laser to solidify layers of photosensitive resin, resulting in precise three-dimensional structures. SLA is used in pharmaceuticals to create complicated drug delivery devices including implants and microcapsules with intricate geometries and exact release rates. SLA's great resolution and accuracy make it ideal for creating personalized drug delivery devices that distribute medications at specified rates and places within the body, improving therapeutic efficacy and reducing side effects.[35]

3. MATERIALS USED IN 3D PRINTING

Choosing the right materials for 3D printing in pharmaceutical manufacturing is essential for product quality, stability, and utility. Materials are selected based on application and desired attributes.[36] The materials are widely used in pharmaceutical industry 3D printing.

Polymers[37]

PLA, a biodegradable and biocompatible polymer, is commonly used to create drug-loaded filaments in Fused Deposition Modelling (FDM) 3D printers. It’s appropriate for creating oral medicine dosage formulations.

PLGA (Polylactic-co-glycolic Acid) is commonly utilized for drug encapsulation and controlled release due to its biocompatibility and slow degradation in the body.

PVA (Polyvinyl Alcohol): PVA's aqueous solubility makes it ideal for drug delivery systems with fast disintegration.

Polycaprolactone (PCL): A biodegradable polymer utilized in tissue engineering and drug-loaded implants.

PEEK (Polyether ether ketone) is a high-performance thermoplastic used for medical and dental implants.

CERAMICS

Ceramics such as hydroxyapatite and tricalcium phosphate are utilized in 3D printing to create bone implants and scaffolds for tissue engineering.[38]

METALS

Metal 3D printing utilizes materials such as titanium and stainless steel to make orthopedic implants and medical devices.[39]

HYDROGELS

Hydrogels, with high water content, are used in 3D bioprinting to create soft tissues and organoids for pharmaceutical research and regenerative medicine applications.[40]

NANOPARTICLES

Controlled drug release can be achieved by incorporating nanoparticles into 3D-printed objects.[41]

RESINS

Resins are utilized in technologies such as Stereolithography (SLA) and Digital Light Processing (DLP) for developing prototypes and dental implants. Dental resin materials can include photopolymerizable resins with biocompatible additives.[42]

4. CASE STUDIES OF 3D-PRINTED PHARMACEUTICALS

Spritam® is the first FDA-approved 3D-printed pill

SPRITAM utilizes Aprecia's Zip Dose® Technology platform, which uses three-dimensional printing to create a porous formulation that dissolves quickly with a sip of liquid. This technology allows for a high drug load of up to 1,000 mg per dose. SPRITAM improves patient experience by allowing for the administration of high-potency levetiracetam with a single sip of drink. Aprecia built its ZipDose Technology platform on 3DP technology created at Massachusetts Institute of Technology.[43] ZipDose uses a layer-by-layer powder bed fusion technology. The first layer includes the active medicinal ingredient and necessary excipients for the matrix tablet. Next, a binder liquid is applied to ensure seamless integration and aggregation of all succeeding layers.[44,45]

POLYPILL CONCEPT

The term "polypill" refers to a single tablet containing multiple medications. This concept is especially advantageous for the geriatric population, who often suffer from several illnesses and require multiple therapies.[46] Five active medicinal compounds with varied release characteristics were combined in a single 3D dosage form. Pravastatin, atenolol, and ramipril were printed in the extended-release section. A permeable barrier made of hydrophobic cellulose acetate separated the medicines. A quick-release compartment containing aspirin and hydrochlorothiazide was placed on top of the extended-release compartment.

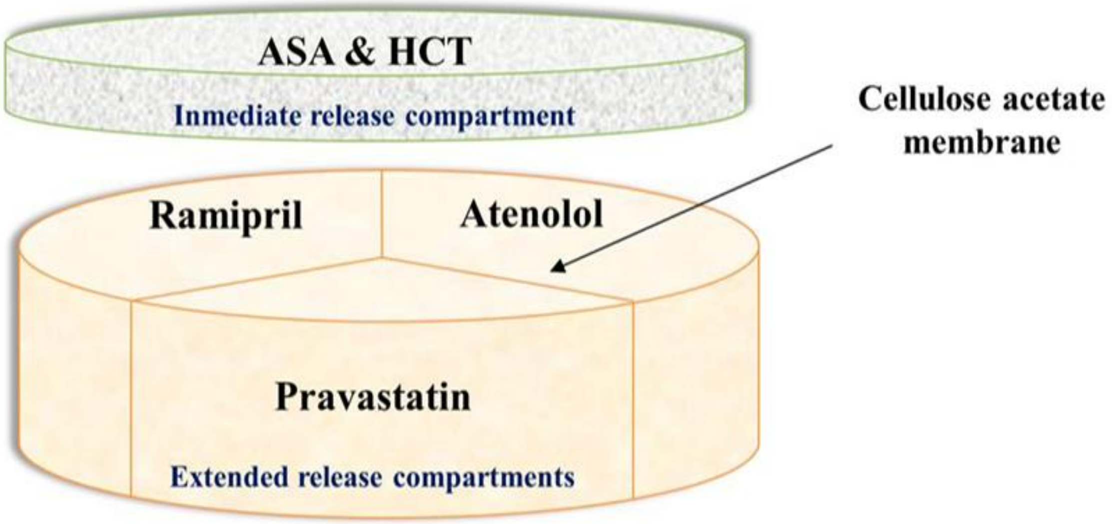

Figure 3: Additive manufacturing technology.

Three-dimensional (3D) extrusion-based printing was used to create the 'polypill', demonstrating that complex pharmaceutical regimens can be bundled in a single tablet and can be modified to an individual's needs. The pills demonstrating this concept have an osmotic pump for captopril and sustained release compartments for nifedipine and glipizide. This drug combination may help diabetics with hypertension. The pharmaceutical sector often uses a room temperature extrusion technique to print compositions containing excipients.[47]

5. APPLICATION USED IN 3D PRINTING

Here are some essential applications of 3D Printing in the pharmaceutical industry.

Personalized Medicine

3D printing technology helps in preparing patient-specific medicines with customized doses and drug release patterns according to individual therapeutic needs.[48]

Polypill Technology

Polypharmacy refers to a patient's regular use of at least five drugs. This is often observed in elderly or young people with specific illnesses.[49] Patients may experience bewilderment, noncompliance issues, and bad medical consequences. Studies have combined multiple active pharmaceutical ingredients into a single tablet to address polypharmacy.[50] 3D printing technology allows for the combination of many medications, doses, and drug-release characteristics in a single "polypill" dosage unit.[51]

Drug Delivery System

3D printing is widely used in the development of advanced drug delivery systems such as tablets, capsules, implants, and transdermal patches with controlled drug release properties.[52]

Fast-Disintegrating Tablets

The technology supports the manufacture of rapidly disintegrating tablets that improve drug absorption and provide convenience to patients who have difficulty swallowing.[53]

Pharmaceutical Research and Development

Researchers use 3D printing for rapid prototyping and formulation development during preclinical studies and drug testing.[54]

ON-demand drug production

3D printing enables the production of medicines on demand, thereby reducing material wastage and improving supply chain management in the pharmaceutical industry.[55]

6. ADVANTAGES

There are various 3D printing methods available, including pen-based, moulding, powder bed fusion, inkjet printing, material jetting, fused deposition modelling (FDM), binder deposition, and photopolymerization. Research has recently focused on 3D printing as a means of producing personalised solid oral formulations. However, the types of thermoplastic polymers that can be created by commercially accessible FDM printers are limited.[56]

Rapid Prototyping

3D printing enables designers and engineers to rapidly develop prototypes and evaluate concepts before mass production. This significantly reduces product development time.[57]

Cost-Effective for Small Production

Traditional manufacturing methods require expensive moulds and specialised tools. In contrast, 3D printing minimises these expenses, making it suitable for low-volume production.[58]

Design Flexibility

Complex and customised structures that are difficult or impossible to produce using conventional manufacturing techniques can be easily fabricated using 3D printing technology.

Reduced Material Waste

Since material is deposited layer by layer, only the required amount of material is used. This reduces waste generation compared to subtractive manufacturing processes.[59]

Customization

3D printing allows products to be tailored according to user requirements, particularly in medical implants, prosthetics, dental devices, and fashion accessories.[60]

Faster Manufacturing

Components can be directly manufactured from digital models without multiple processing stages, thereby reducing production time.[61]

Lightweight and Strong Parts

3D printing facilitates the production of lightweight yet mechanically strong structures, which are especially valuable in aerospace and automotive applications.[62]

Easy Accessibility

Desktop 3D printers are becoming increasingly affordable and accessible to schools, students, hobbyists, and small-scale industries.[63]

7. FUTURE OUTLOOK SECTION

3DP technology has potential for manufacturing pharmaceuticals and medical equipment in the healthcare industry, providing numerous benefits. Scientists are continually creating new 3D printed medication delivery systems to enhance and speed up drug administration due to its numerous benefits. 3DP will continue to play a significant part in the drug delivery sector, and is not a passing fad.[64] The 3DP technology uses modified nano carriers like liposomes and cyclodextrins with specific pharmacological characteristics. The FDA prioritizes innovation in healthcare by employing digital health technology and developing advanced analytical procedures. In the near future, a retail pharmacy may install a 3D printer powered by AI. In the future, individualized pharmaceuticals will be promptly created based on individual medical information. AI-controlled 3D printing technology accelerates and reduces the cost of personalized medicines. It also eliminates human error. According to futurologist Jeremy Rifkin, 3D printing could usher in a new industrial era by replacing traditional assembly line production from the late 1800s.[65] Here are some key future trends in pharmaceutical 3D printing.

Personalized Medication

3D printing allows for personalized drug compositions based on genetic profiles and individual demands, leading to a rise in personalized medicine.[66]

Drug Combinations and Polypills

3D printing can help create complicated polypills with many medications to optimize treatment regimens for different illnesses.[67]

Advanced Drug Delivery System

Further research will result in novel drug delivery systems with precise control over release profiles, enhancing therapeutic efficacy.[68]

Pharmaceutical prototypes

Pharmaceutical businesses will embrace 3D printing for faster prototyping and iterative design of drug delivery systems, decreasing development time and costs.[69]

Material innovation

The research aims to create new materials with enhanced drug release qualities, biocompatibility, and stability for 3D printing.[70]

Drug tests and screenings

3D-printed tissue models are useful for drug testing, toxicity studies, and disease modeling, minimizing the requirement for animal testing.[71]

Sustainability Initiatives

To minimize environmental impact, pharmaceutical 3D printing will prioritize eco-friendly materials and sustainable manufacturing techniques.[72]

Collaborative research

Collaborations between pharmaceutical businesses, academic institutions, and 3D printing technology providers promote innovation and knowledge sharing.[73]

Clinical Applications

More clinical trials will investigate the safety and efficacy of 3D-printed medications, resulting in more usage in clinical practice. As 3D printing technology advances, it has the potential to revolutionize the pharmaceutical sector by improving drug development, patient care, and production efficiency. To fully utilize 3D printing in medicines, it is crucial to address regulatory constraints, ensure quality and safety, and improve accessibility.[74]

8. CONCLUSION

3D printing has emerged as an innovative and disruptive technology in the pharmaceutical business, opening up new avenues for the creation of tailored medications and enhanced drug delivery methods. The technology allows for the production of complicated dosage forms with customizable drug release profiles, exact doses, and patient-specific formulations, which are difficult to obtain using traditional manufacturing methods. Several 3D printing processes, including inkjet printing, binder jetting, fused deposition modelling (FDM), stereolithography (SLA), selective laser sintering (SLS), and semi-solid extrusion (SSE), have shown great promise in pharmaceutical applications.

The utilization of various materials, such as polymers, hydrogels, ceramics, metals, nanoparticles, and resins, has increased the scope of pharmaceutical 3D printing. Furthermore, the successful creation of products like SPRITAM® and advancements in polypill technology demonstrate the practical and clinical importance of this strategy. 3D printing also helps with rapid prototyping, decreased material waste, flexible manufacturing, and on-demand drug production, which improves healthcare system efficiency.

Although various challenges relating to regulatory approval, quality assurance, manufacturing costs, and large-scale production, ongoing advances in artificial intelligence, biomaterials, and pharmaceutical engineering are projected to overcome these constraints in the future. Overall, 3D printing is predicted to play an important role in the evolution of pharmaceutical production by improving treatment outcomes, increasing patient compliance, and fostering future growth in personalized healthcare and precision medicine.

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