*Review Article*

**ADVANCEMENTS AND APPLICATIONS OF 3DP PRINTING IN PHARMACEUTICAL DEVELOPMENT AND BIOMEDICAL SCIENCES**

**ABSTRACT:**

Three-dimensional printing (3DP) is revolutionizing pharmaceutical sciences and biomedical applications by offering unprecedented precision, efficiency, and personalization in drug formulation and medical device manufacturing. It enables the production of tailored drug dosage forms with controlled release profiles, making it highly suitable for treating complex diseases such as epilepsy, cancer, and cardiovascular disorders. 3DP also facilitates the creation of polypills, enhancing therapeutic compliance and reducing medication burden in polypharmacy cases.

In the biomedical field, 3DP supports the fabrication of patient-specific prosthetics, implantable devices, and bioprinted tissues and organs, thereby improving clinical outcomes. Innovations such as four-dimensional (4D) printing have introduced smart biomaterials that respond to physiological stimuli, significantly advancing drug delivery systems and tissue engineering applications.

Moreover, the integration of artificial intelligence (AI) and machine learning with 3DP is paving the way for precision medicine by enabling predictive modeling for drug formulation, streamlining clinical development, and optimizing production parameters.

However, the widespread adoption of 3DP in healthcare faces several challenges. Regulatory concerns remain a major hurdle, as existing frameworks are not fully equipped to assess the safety, reproducibility, and quality control of 3D-printed pharmaceuticals. Each formulation often requires individual validation, posing complexities in approval pathways. In addition, biocompatibility issues associated with printing materials—such as thermal degradation, residual solvents, and potential toxicity—demand thorough evaluation to ensure patient safety.

Despite these obstacles, ongoing research, regulatory advancements, and interdisciplinary collaboration continue to accelerate progress. Ultimately, 3DP holds immense promise in transforming personalized medicine, decentralized drug manufacturing, and regenerative therapies—ushering in a new era of effective, accessible, and patient-centric treatment strategies.

***Key words-*** *3D printing, Pharmaceutical Manufacturing, Drug Development, Automation, Personalized Medicine, Biocompatibility, Regulatory Compliance*

**1. INTRODUCTION**

The pharmaceutical industry has long been built on the mass production of drugs in predetermined dosage forms. For the benefit of both producers and consumers, this traditional manufacturing process guarantees the creation of pharmaceutical products of superior quality at a lower cost per unit (1) This approach's limited flexibility in dose customisation and combination therapies, which might not always match the unique needs of individual patients, is a significant disadvantage. The quick development of digital technologies has created new chances to transform the pharmaceutical industry (2). Among these, three-dimensional printing (3DP) has attracted a lot of interest as a cutting-edge way to get around some of the problems with conventional pharmaceutical manufacturing. 3DP is currently having a significant impact on the pharmaceutical and biomedical industries. It was first created more than thirty years ago for use in the robotics, automotive, chemical, and prototyping industries (3).

The additive manufacturing technique known as 3DP makes it possible to create intricate, personalised structures layer by layer. Digital models are created using computer-aided design (CAD) software and can be printed with extreme precision (4). The desired physical and chemical properties of the finished product can be obtained by adjusting important parameters like geometry, infill percentage, printing speed, layer thickness, and extrusion temperature. Because of its adaptability, 3DP is especially well-suited to creating customised drug formulations, medical equipment, and prosthetics that meet each patient's unique anatomical requirements (A. Pharmaceuticals. (2015). When the US Food and Drug Administration (FDA) authorised Spritam, the first 3D-printed tablet, in 2015, it was one of the most significant turning points in the history of pharmaceutical 3DP. Spritam, which was created to treat epilepsy, has a special porous structure that enables quick disintegration, which makes it particularly helpful for patients who have trouble swallowing, including young children, the elderly, and people with neurological conditions. However, instead of being customised for each patient, Spritam is still mass-produced in industrial facilities even by 3DP (A. Pharmaceuticals. (2015).

The potential of 3DP technology for pharmaceutical applications is being actively assessed by regulatory agencies like the European Medicines Agency (EMA) in the European Union and the Food and Drug Administration (FDA) in the United States. This involves evaluating its viability for on-demand drug production in pharmacies and hospitals, where drugs could be customised to meet patients’, precise dosage needs (5). 3D printing has the potential to greatly improve treatment outcomes, reduce side effects, and increase patient adherence to recommended therapies by enabling personalised medicine. However, there are obstacles to the broad use of 3DP in the pharmaceutical industry. Concerns regarding the stability, effectiveness, and safety of 3D-printed medication formulations are among them, as are regulatory challenges and the requirement for strict quality control. Large-scale adoption may also be hampered by the high upfront costs of 3DP supplies and equipment. In the pharmaceutical industry, 3DP is a revolutionary development in spite of these obstacles (5). A new era of personalised medicine, in which treatments are customised for each patient as per their specific medical needs, may be ushered in by its ability to enable precise and customisable drug manufacturing. 3DP is anticipated to become more and more important in the future of healthcare as research and regulatory frameworks change, improving patient-centred, efficient, and accessible medication. Pharmaceutical products customised for each patient are becoming possible thanks to developments in 3DP technology. In contrast to conventional subtractive manufacturing, which involves removing material from solid blocks, 3DP creates objects layer by layer, hence the term "additive manufacturing (6)." With 40–70% of prescription medications turning out to be ineffective and numerous hospitalisations caused by incorrect dosages, personalised medicine is becoming more and more popular. Drug formulation requires accuracy and flexibility due to the complexity of diseases and the variety of patients. A potential remedy that offers individualised treatments that improve therapeutic results is additive manufacturing (7)**.**

**2. CLASSIFICATION OF 3DP TECHNIQUES**

Additive manufacturing builds materials layer by layer using extruders, lasers, or binders. Liquid-based methods solidify resin, while powder-based techniques use lasers or binders. 3D bioprinting employs droplet, extrusion, and laser-based systems, each suited for medical and pharmaceutical applications. (8).

**2.1 Powder bed printing**

This method involves spraying a liquid binder over a thin powder layer to help particles adhere. Layers build upon each other, with excess powder removed afterward. Unlike fused deposition modeling, it does not create hollow structures. It was used to produce the first FDA-approved 3D-printed drug, Aprecia Pharmaceuticals’ Spritam® (levetiracetam), an oral dispersible tablet (9). In large-scale tablet production, the binding solution spreads over a powder bed via a conveyor belt, depositing layers while recycling unused powder. The Zip Dose® technology, also known as powder bed deposition, enables precise drug composition and dosage control while maintaining stability. Powder bed fusion 3D printing is widely used across industries, including electronics, automotive, aerospace, explosives, medical implants, surgical tools, tissue engineering, and dental prosthetics. In pharmacoprinting, drop-on-solid deposition—also called binder jetting or powder bed 3DP—allows for precise drug formulation by selectively spraying a liquid binder onto a powder bed, layer by layer, until the final product is formed (10). (11).

**2.2 Pharmaceutical inkjet printing**

Inkjet printing has gained prominence due to advancements in digital, non-contact manufacturing techniques. Increased research investment has enhanced its applications in pharmaceuticals, tissue engineering, regenerative medicine, rapid prototyping, and electronics (12). Known for its reliability and precision, inkjet printing deposits liquid droplets (1–100 picolitres) to create 2D and 3D structures. The technology operates through two main methods: drop-on-demand (DoD) and continuous inkjet (CIJ) printing. DoD ejects droplets only when needed, ensuring precise control and efficient material use. CIJ continuously ejects ink through a high-pressure nozzle (13), with a piezoelectric transducer directing charged droplets to the target while recycling unused ones. DoD printheads, containing 100–1000 nozzles, rely on either piezoelectric or thermal actuation. Piezoelectric printheads deform ceramics to generate pressure pulses, supporting a wider range of liquids, while thermal printheads heat the liquid to create vapor bubbles, expelling droplets in a simpler, cost-effective process (14). Inkjet printing’s adaptability and scalability make it a vital tool across industries. With ongoing advancements, it is set to become a standard fabrication method in materials science, pharmaceuticals, and electronics. (15).

**2.3 Stereolithography (SLA)**

Stereolithography (SLA), developed by Charles Hull in the 1980s, has evolved into a key technology in biomedicine and pharmaceuticals (16). Utilizing photopolymerization, SLA creates intricate 3D structures layer by layer, revolutionizing tissue engineering, drug delivery, and bioresorbable implants. Its high precision enables the fabrication of personalized tablets, microneedle patches, and multi-compartment drug carriers, improving controlled drug release, bioavailability, and patient adherence. SLA also supports bioresorbable implants that degrade over time, eliminating the need for surgical removal (17). Advancements like micro-stereolithography (MSL) and multiphoton polymerization (MPP)-based direct laser writing (DLW) allow ultra-thin and nanoscale printing, enhancing applications in bone and cartilage tissue engineering. SLA's porous structures and polymer-based hydrogels optimize drug dispersion and stability, further demonstrating its pharmaceutical versatility (18). Challenges include the need for FDA-approved biocompatible resins, extensive post-processing to remove toxic residues, high equipment costs, and scalability issues. However, ongoing research into novel materials, improved fabrication techniques, and streamlined post-processing methods is addressing these limitations. SLA is poised to transform personalized medicine by enabling precise, patient-specific drug formulations. As advancements continue, its role in pharmaceutical manufacturing and regenerative medicine will expand, offering customized, efficient, and effective therapeutic solutions. (19).

**2.4 Selective Laser Sintering (SLS)**

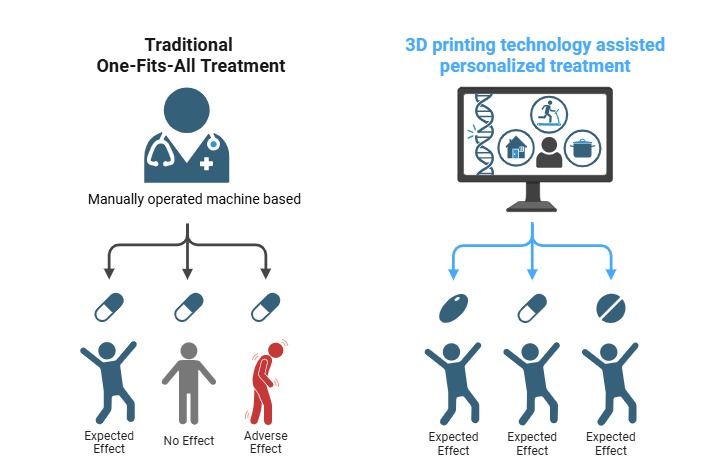
Selective Laser Sintering (SLS) is an advanced 3D printing (3DP) technique that sinters powdered drug-excipient mixtures using a high-powered laser, eliminating binders and enabling precise drug composition control (20). It produces immediate- and extended-release tablets with enhanced dissolution and bioavailability, particularly for poorly water-soluble drugs. SLS also enables multi-drug formulations by spatially distributing multiple compounds in a single dosage form (21). The process involves spreading thin powder layers, which are selectively sintered by a CO₂ or fiber laser (22). Adjusting laser parameters ensures controlled porosity and drug release while preventing heat-sensitive drug degradation (23). Post-processing includes depowdering, polishing, and coating to enhance stability and dissolution. Quality control measures like scanning electron microscopy (SEM) and X-ray diffraction (XRD) ensure uniformity and regulatory compliance (24). SLS plays a key role in personalized medicine, allowing on-demand drug printing tailored to individual needs, particularly for pediatric and geriatric patients requiring polypharmacy (25). Challenges remain in regulatory approval and scalability, but ongoing research aims to expand compatible formulations and optimize sintering efficiency (26). With further advancements, SLS could revolutionize pharmaceutical manufacturing, enabling customized, on-demand medications that improve therapeutic outcomes. (27).



***Fig1- Comparison of Traditional Tablet Manufacturing and 3D-Printed Pharmaceuticals***

**Table 1*- Comparison of 3DP Technologies in Pharmaceutical Applications***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Technology | Method | Advantages | Limitations | Examples |
| Powder Bed Printing (PBP) | Uses liquid binder to fuse powder particles | High drug load, rapid disintegration | Limited control over drug release | Spritam® (Levetiracetam) |
| Fused Deposition Modeling (FDM | Melts polymer-based filament and deposits it layer by layer | Customizable drug release, easy scalability | Requires high-temperature drug stability | FabRx Printlets® |
| Stereolithography (SLA) | Uses light to polymerize liquid resin into solid structures | High precision, adaptable for implants | Limited biocompatible materials | Sildenafil Orodispersible Films |
| Selective Laser Sintering (SLS) | Uses a laser to sinter powdered materials | No need for binders, high porosity for fast dissolution | High equipment cost | Caffeine Tablets |
| Inkjet Printing (IJ) | Deposits drug solution onto a substrate | High-precision dosage, complex polypills | Limited to low-viscosity formulations | Warfarin Tablets |

**  
 *Fig 2- Comparison of One-Size-Fits-All Treatment vs. 3D-Printed Personalized Medicine***

**3. APPLICATIONS OF 3DP**

Currently, 3DP technologies like IJ, FDM, and SLS can be used to produce sufficient pharmaceutical dosage forms (28). The biomedicals, oral solid dosage forms, and transdermal delivery systems that appear to be making comparatively more progress and are better suited for broad 3DP applications are the main focus of this review of the pharmaceutical applications of 3DP technology (29). Once 3DP was invented in the early 1980s, additive manufacturing's influence on the biomedical field grew quickly. This is because the technique makes it possible to create materials with unique architectures and functionalities.

**3.2 Bio-medical applications**

**3.2.1 Developments in Medical 3D-Printed Functionalised Materials**

Additive manufacturing advances to meet the demand for customized, functional materials. While nanotechnology addresses medical challenges, safety concerns remain. 3D printing (3DP) offers a safer alternative for intricate, personalized materials (30). Notable applications include antimicrobial wound dressings from polycaprolactone (PCL) infused with copper, silver, and zinc, providing bactericidal properties and prolonged metal release. These cost-effective, adaptable dressings outperform traditional ones. Another innovation is a 3D-printed hybrid scaffold combining a pericardium matrix with poly (ethylene glycol) (PEG), enhancing vascular grafts and congenital heart defect reconstruction by improving scaffold modulus and reducing inflammation (31).

**3.2.2 3D-Printed Medical Phantoms in Surgery and Training**

3D printing (3DP) has transformed medical phantoms, improving diagnosis, treatment planning, and surgical training by converting medical imaging into physical models. In liver transplantation, 3D-printed models aid in visualizing biliary and vascular structures, enhancing safety (32). Transparent, color-coded liver and kidney models assist in tumor resections and renal surgeries. In cardiology, 3DP supports congenital heart disease treatment and surgical planning for aortic disorders. Neurology benefits from MRI-based brain models for studying Alzheimer’s disease. While further validation is needed, 3D-printed phantoms are advancing preoperative planning, medical education, and personalized patient care (33).

**3.2.3Personalized Implants and Prosthetics: Advancements Through 3DP**

Additive manufacturing has transformed personalized medical devices, enabling custom-fitted prosthetics, implants, and supportive structures with precise mechanical properties and bioactive components (34). 3D printing (3DP) enhances mobility and comfort with low-cost prosthetics, breathable exoskeletal casts, and precise craniofacial reconstructions. It also advances implantable devices like customized ureteric stents and bioresorbable tracheal splints for pediatric care (35). Metal 3DP enables patient-specific titanium implants for bone tumor surgeries, improving post-operative stability. By integrating imaging and CAD modeling, 3DP offers cost-effective, functional solutions that enhance surgical outcomes, patient care, and rehabilitation across medical fields (36,37).

**3.2.4 Advancements in 4D Printing for Biomedical Applications**

3D printing (3DP) is transforming pharmaceuticals by enabling polypills, personalized dosages, and localized drug manufacturing, improving adherence and reducing waste. It allows precise drug delivery with tailored release mechanisms, enhancing therapeutic outcomes. Future advancements include multi-material printing and bio-printing for drug testing, making treatments more efficient, accessible, and personalized (38).

**3.2.5 Bioinspired Biorobots for Therapeutic Uses**

Bio robotics, particularly bio-inspired hybrid devices, replicates biological functions using soft robots with hydrogel or polymer scaffolds supporting living cells. Unlike rigid robots, they interact with their environment, mimicking biological motion (39). Examples include muscle cell-based actuators and 3D bioprinter flagellar swimmers seeded with cardiomyocytes (40). Microscale heart pumps using cardiomyocytes on PDMS membranes demonstrate biohybrid potential (41). These self-sustaining biorobots offer applications in drug delivery and tissue regeneration (42). Challenges remain in controlling viability and motility, but advancements in 3D bioprinting and stimulus-responsive cells drive progress toward specialized medical devices (43).

**3.2.6 Developments and Obstacles in Organ Regeneration Using 3D Bioprinting**

Organ failure often requires lifelong immunosuppression after transplantation. 3D bioprinting offers a promising alternative by creating biological constructs to restore tissue function (44). Using additive manufacturing, tissues like cartilage, bone, blood vessels, liver, and heart have been developed. Alginate-nanocellulose bioinks aid cartilage printing but face viability challenges, while liver-specific bioinks enhance cell function (45). Autologous cells reduce rejection risks, and hydrogels with stem cells show potential for heart repair. Microchannel hydrogels improve biomolecular exchange, and organ-on-chip models aid research (46). Despite progress, challenges in cell viability, proliferation, and scaffold design must be addressed to advance organ regeneration (47).

**3.3 Applications of oral dosage forms**

Oral dosage forms like tablets and capsules are the most common pharmaceuticals. 3D printing (3DP) has been widely explored for tablet manufacturing, including single- and multiple-API formulations, showcasing its potential in pharmaceutical production. The following sections outline specific examples of each category (48).

**3.3.1 Developments in Pharmaceutical Applications of 3D Printing**

3D printing (3DP) began with simple immediate-release (IR) tablets using fused deposition modelling (FDM), enabling efficient production of high drug-loaded formulations like paracetamol (80%) and thermoplastic polyurethane tablets (60%). Beyond IR tablets, FDM facilitates extended-release (ER) formulations with up to 24-hour drug release by modifying polymer blends. Inkjet (IJ) printing and stereolithography (SLA) further enhance precision and scalability, with SLA enabling diverse drug release profiles (49). While FDM has limited excipient options, polymer blending improves miscibility and solubility, making FDM and IJ printing the most promising methods for oral solid dosage forms. (50).

**3.3.2 Polypills for Complicated Drug Regimens 3D Printed**

3D printing (3DP) revolutionizes pharmaceutical manufacturing by enabling polypills—single tablets with multiple APIs—to simplify drug regimens and enhance adherence (51). It allows precise control over drug release through advanced designs like osmotic pumps and multi-layered tablets. Techniques such as multi-nozzle 3DP and stereolithography (SLA) enable customized dosing and modified-release formulations. Beyond pharmaceuticals, 3DP advances biomedical applications, including organ regeneration and personalized implants, with 4D printing further expanding possibilities. Despite challenges like scalability and regulatory hurdles, ongoing research will drive its role in personalized medicine, regenerative medicine, and advanced drug delivery. (52).

***Table 2*- Applications of 3D Printing in Biomedical Sciences**

|  |  |  |  |
| --- | --- | --- | --- |
| Application | 3D Printing Method used | Key Benefits | Example Use Cases |
| Prosthetics & Implants | FDM, SLS, SLA | Personalized fit, reduced costs | 3D-printed dental implants, titanium knee replacements |
| Tissue Engineering & Bioprinting | SLA, Inkjet, Extrusion-based | Scaffolds for tissue regeneration, biocompatible materials | 3D-printed heart tissue, bone graft scaffolds |
| |  | | --- | | **Medical Phantoms** |  |  | | --- | |  | | FDM, SLA | Enhanced surgical planning & training | 3D-printed liver/kidney models for preoperative assessment |
| Personalized Drug Delivery | Inkjet, SLA, SLS | Targeted drug release, multi-drug formulations | Polypills with different APIs, controlled-release tablets |
| Bio robotics | SLA, FDM | Smart drug delivery, biohybrid robotics | Microbiorobots for targeted therapy |

**FDM:** fused deposition modelling; **SLS:** selective laser sintering; **SLA:** Stereolithography;

**4. ADVANTAGES OF 3D PRINTING IN PHARMACEUTICAL DEVELOPMENT**

3D printing (3DP) transforms pharmaceuticals with polypills, personalized dosages, and on-demand production, improving adherence and reducing waste. Advances in multi-material printing and bio-printing drive personalized, accessible, and efficient treatments global (53).

**4.1 Personalized Medicine and On-Demand Drug Manufacturing with 3DP**

3D printing (3DP) is revolutionizing personalized medicine by enabling customized drug formulations, benefiting patients with complex diseases like cancer, Alzheimer’s, and epilepsy. It is especially useful for pediatric and geriatric patients who require tailored dosages based on metabolism, weight, and genetics (54). Unlike conventional medications, 3DP allows precise dosage titration, optimizing pharmacokinetics and pharmacodynamics for better outcomes. It also supports controlled-release drugs, ensuring consistent delivery while minimizing side effects. Additionally, 3DP enables on-demand, localized drug manufacturing, reducing supply chain reliance and waste. As the technology advances, it is set to transform pharmaceutical manufacturing, enhancing treatment precision and accessibility (55).

**4.2 3D Printing's Function in Developing Polypills and Complex Drug Therapies**

3D printing (3DP) is transforming pharmaceuticals by enabling polypills, improving adherence, reducing side effects, and allowing precise dosing (56). It supports on-demand drug production, cutting waste and costs while promoting sustainability. Future advancements include multi-material printing for complex drug release and bio-printing for preclinical testing. As 3DP evolves, it shifts pharmaceuticals from mass production to personalized medicine, enhancing accessibility and outcomes (57).

**4.3 3D Printing Developments for Innovative Drug Delivery Systems**

3D printing (3DP) is revolutionizing pharmaceutical manufacturing by offering flexibility, precision, and efficiency in developing solid dosage forms. Unlike traditional methods with multiple steps and batch variability, 3DP enables rapid design, optimization, and customization of drugs with improved uniformity (58). It has been applied to oral dosages, implants, stents, and various drug delivery systems. Since the approval of the first 3D-printed epilepsy drug, interest in 3DP has grown due to its ability to streamline production, lower costs, and enhance patient satisfaction. Key applications include modified-release tablets, transdermal patches, microneedles, and personalized suppositories. By improving bioavailability and solubility, 3DP supports personalized medicine and enhances drug regimens, making it a cornerstone of modern pharmaceutical development (59).

**4.4 3D Printing in Biomedicine**

3D printing is revolutionizing biomedical sciences by enabling precise, personalized solutions for tissue engineering, prosthetics, implants, and organ creation. Its ability to produce detailed structures from medical imaging allows for patient-specific medical devices (60).

4.4.1 Organ and tissue bioprinting

Bioprinting offers a promising solution to organ shortages by using specialized bioinks with living cells, growth factors, and biomaterials to create functional tissues. Layer-by-layer printing enables complex vascular networks for nutrient exchange. Researchers have successfully printed miniature livers, kidneys, and hearts, advancing transplantation and regenerative medicine.

4.4.2 Ophthalmology and Otolaryngology 3D Printing

3D printing is revolutionizing otic medicine and ophthalmology by enabling the creation of artificial corneas, retinas, and eyes for vision restoration. Its precision allows replication of optic nerve structures and retina layers. In otolaryngology, 3D-printed ears, cochlear implants, and airway splints aid hearing impairments and airway obstructions. (61)

4.4.3 Orthopaedics and Dentistry

3D printing is transforming orthopaedics by enabling personalized implants, prosthetics, and bone grafts. Surgeons can pre-plan complex procedures using precise 3D-printed bone models. Custom implants benefit patients with skeletal abnormalities, fractures, or spinal disorders. In dentistry, 3D printing enhances accuracy in creating crowns, bridges, aligners, and endodontic scaffolds for tissue regeneration. (62).

**4.5 3D Printing's Function in Early-Phase Drug Development**

Early-stage drug development ensures an API's stability, effectiveness, and safety before clinical trials. Traditional methods are costly and time-consuming, but 3D printing enables small, customized batches with minimal waste. It allows flexibility in drug concentration, shape, and release, supporting personalized medicine. Rapid prototyping refines formulations, improving bioavailability and accelerating trials. (63)

4.5.1 Personalisation and Tailored Medication Administration

3D printing enables personalized drug development by adjusting formulation composition, release kinetics, and dosage. This benefits children, the elderly, and chronically ill patients requiring specific dosages or drug combinations. Additionally, on-demand printing at clinical trial sites improves accessibility to experimental medications and reduces logistical challenges in global trials.

***Table 3*- Advantages and Challenges of 3D Printing in Pharmaceuticals**

|  |  |  |
| --- | --- | --- |
| Category | Advantages | Challenges |
| Tablets & Oral Dosage Forms | ***- Personalized medicine:*** Customized dosages for individual patients.  **- *Polypills****:* Combines multiple drugs in a single tablet for better adherence.  ***- Controlled drug release:*** Enables immediate, extended, and modified-release formulations.  - ***Complex geometries:*** Enhances dissolution, bioavailability, and therapeutic effects. | ***- Regulatory uncertainties:*** Lack of standardized guidelines for 3D-printed drugs.  ***- Material limitations*:** Some drugs degrade under high temperatures (FDM printing).  ***- Scalability issues***: Large-scale production remains a challenge. |
| Transdermal Drug Delivery | ***- Microneedles for painless drug delivery***: Enhances drug absorption without injections.  ***- Custom-fit patches:*** Conforms to body contours for better adhesion.  ***- Sustained drug release:*** Provides controlled and extended drug diffusion.  - ***Reduced systemic side*** effects: Minimizes toxicity and improves patient comfort. | ***- Drug permeability*** limitations: Not all drugs can effectively penetrate the skin.  - ***Microneedle fragility:*** Requires strong yet dissolvable structures.  - ***Manufacturing complexity***: Requires precise material selection and layer control. |
| Implants & Prosthetics | - ***Patient-specific implants:*** Custom-designed for better fit and function.  - ***Faster production:*** Reduces lead time compared to traditional methods.  ***- Bioactive materials:*** Supports tissue integration and healing. | - ***Biocompatibility concerns:*** Requires extensive testing for long-term safety.  - ***Post-processing requirements:*** Sterilization and surface finishing add complexity. |
| Tissue Engineering & Bioprinting | - ***3D-printed scaffolds:*** Supports tissue regeneration and organ repair.  - ***Biocompatible hydrogels:*** Enhances cell attachment and growth.  - ***Potential for organ printing***: A future solution to organ transplant shortages. | ***- Limited vascularization***: Difficulty in creating fully functional blood vessels.  ***- Cell viability challenges***: Maintaining live cells during the printing process. |
| On-Demand Drug Manufacturing | ***- Decentralized production:*** Enables drug manufacturing in pharmacies and hospitals.  ***- Reduces drug waste:*** Produces medicines as needed, minimizing overproduction.  - *Rapid prototyping:* Accelerates drug formulation and testing. | - ***Regulatory approval:*** Requires new quality control and standardization measures.  ***- Equipment costs***: High initial investment in 3D printing infrastructure. |

**5. Regulatory Challenges and Biocompatibility Concerns**

Regulatory Issues and Biocompatibility Issues (Conclusion)

The incorporation of 3D printing into pharmaceutical and biomedical uses is confronted with considerable regulatory and biocompatibility challenges that need to be overcome in order to facilitate extensive clinical adoption. Existing drug regulations are mainly geared to traditional batch production and do not completely support the singular features of 3D printing, including individualized dosing and on-demand manufacturing (65). The gap in regulation creates ambiguity in process validation, product consistency, quality assurance, and scalability. While the FDA's clearance of Spritam® was a milestone in 3D-printed pharmaceutical development, clearance continues to be a complicated process requiring extensive safety, efficacy, and stability data for each product (66).

Just as important are issues of biocompatibility of the materials employed in 3D-printed pharmaceuticals. Numerous traditional excipients and polymers can experience physical or chemical degradation during the printing process, possibly leading to toxicity or compromised therapeutic efficacy. Thermal degradation, residual solvents, and non-uniform drug release are some of the issues that need to be thoroughly assessed. When applied in medical implants or tissue engineering, the printed materials need to interact with biological tissues in a safe manner, necessitating extensive testing for immunogenicity, cytotoxicity, and degradation behaviour (68).

Resolution of these issues will involve multidisciplinary cooperation among regulatory authorities, industry, and academia. Standardized guidelines for 3D-printed drug products must be developed, and more stringent material screening and testing paradigms must be developed. Achieving a scalable 3D printing process without compromising product safety and performance is also needed. Substitution of these regulatory and biocompatibility hurdles will be responsible for unlocking the full potential of 3D printing in providing novel, patient-specific treatments (69).

**6. FUTURE SCOPE**

3D printing is transforming healthcare with personalized medicine, advanced drug manufacturing, and regenerative therapies. It enables precise dosage customization, optimizing treatment while minimizing side effects. AI enhances drug formulation and adherence. 4D printing introduces smart drug delivery systems that respond to stimuli like pH or temperature, benefiting cancer therapy and chronic disease management. Decentralized, on-demand drug manufacturing improves accessibility and reduces supply chain dependence. Bioprinting creates tissues and organs using stem cell-based bioinks, addressing donor shortages. Regulatory approval will drive large-scale adoption, ensuring drug stability and biocompatibility. Multi-drug polypills with controlled release simplify chronic disease treatment. Additionally, 3D printing enhances sustainability by reducing waste and using biodegradable polymers. As technology advances, it will revolutionize pharmaceuticals and patient care.

**7. CONCLUSION**

3D printing is revolutionizing the biomedical and pharmaceutical industries by offering unmatched flexibility, efficiency, and precision in drug formulation, production, and delivery. Unlike traditional large-scale manufacturing, 3D printing enables rapid prototyping, on-demand production, and patient-specific medicines, fostering a more personalized approach to treatment. From polypills and controlled-release formulations to complex therapies, this technology enhances drug development and expands into biomedical fields like tissue engineering, implants, prosthetics, and organ bioprinting. By improving accessibility, reducing waste, and boosting treatment efficacy, 3D printing is shaping the future of personalized medicine. As it advances alongside AI and machine learning, its impact on precision medicine and decentralized drug manufacturing will continue to grow, redefining global healthcare with more effective, accessible, and affordable treatments.

**COMPETING INTERESTS DISCLAIMER:**

Authors have declared that they have no known competing financial interests OR non-financial interests OR personal relationships that could have appeared to influence the work reported in this paper.

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Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

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