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Review Article

3D Printing Technology in Pharmaceutical Formulation - An Overview

Soumyadip Saha, Soumallya Chakraborty*, Somenath Bhattacharya

Department of Pharmaceutical Technology, Global College of Pharmaceutical Technology, Nadia, West Bengal, India

Three-dimensional (3D) printing technology has emerged as a transformative tool in pharmaceutical sciences, offering innovative solutions for drug development, manufacturing, and personalized medicine. This technology enables the fabrication of complex dosage forms with precise control over drug composition, geometry, and release characteristics. Various 3D printing techniques, including fused deposition modelling, stereolithography, and selective laser sintering, have been explored to produce tablets, implants, and drug delivery systems. The ability to tailor drug dosage and release profiles according to individual patient needs represents a significant advancement toward patient-centric therapy. Moreover, 3D printing facilitates rapid prototyping, reduces material wastage, and enhances formulation flexibility compared to conventional manufacturing methods. Despite its promising potential, challenges such as regulatory constraints, scalability, material limitations, and quality assurance remain critical barriers to its widespread adoption. This review highlights the principles, techniques, applications, advantages, and limitations of 3D printing in pharmaceutical sciences, while also discussing future perspectives and its role in advancing precision medicine. Overall, 3D printing holds significant promise for revolutionizing pharmaceutical manufacturing and improving therapeutic outcomes.

Keywords: Three-dimensional printing technology, Patient-specific drug delivery systems, Novel drug delivery, Stereolithography-based drug fabrication, Selective laser sintering (SLS).

INTRODUCTION

The pharmaceutical industry is undergoing a significant transformation driven by the need for more efficient drug development processes and patient-centered therapeutic approaches. Conventional manufacturing methods, while reliable, often lack the flexibility required to produce individualized dosage forms and complex drug delivery systems. In this context, three-dimensional (3D) printing technology, also known as additive manufacturing, has gained considerable attention as an innovative platform capable of addressing these limitations. 3D printing involves the layer-by-layer fabrication of objects based on digital designs, allowing precise control over the composition, structure, and geometry of pharmaceutical products. This capability has opened new avenues in the design and production of dosage forms with tailored drug release profiles, improved bioavailability, and enhanced patient compliance. Various 3D printing techniques, such as fused deposition modelling, stereolithography, and selective laser sintering, have been adapted for pharmaceutical applications, each offering distinct advantages in terms of material compatibility and product characteristics.[1-10] One of the most promising aspects of 3D printing in pharmaceutical sciences is its potential to enable personalized medicine. By customizing drug dosage, shape, and release kinetics according to individual patient needs, this technology supports a shift from the traditional "one-size-fits-all" approach to more precise and effective treatment strategies. Additionally, 3D printing facilitates rapid prototyping and small-scale production, making it particularly valuable in clinical settings and for rare diseases where mass production is not always

feasible. Despite its numerous advantages, the integration of 3D printing into mainstream pharmaceutical manufacturing faces several challenges. Issues related to regulatory approval, standardization, material selection, and large-scale production must be carefully addressed to ensure safety, efficacy, and quality. Furthermore, the development of suitable printable excipients and drug-loaded materials remains an area of ongoing research. [11-12]

History and Evolution:

The development of 3D printing began in the 1980s with the invention of stereolithography, initially used for rapid prototyping in industrial applications. During the 1990s, additional techniques such as fused deposition modelling (FDM), selective laser sintering (SLS), and inkjet printing were introduced, expanding the technology's capabilities. [13-16] The early 2000s marked the entry of 3D printing into pharmaceutical research, where scientists explored its potential in drug delivery systems. Between 2010 and 2015, rapid advancements were made in formulation development and printing technologies, leading to practical pharmaceutical applications. A significant milestone was achieved in 2015 with the approval of the first 3D-printed drug, levetiracetam, which demonstrated the clinical feasibility of this technology. Since then, research has expanded rapidly, focusing on personalized medicine and complex dosage forms.[1, 17-19]

Principles Of 3D Printing in Pharmaceutical Sciences:

3D printing in pharmaceuticals is based on the principle of additive manufacturing, where materials are deposited layer by layer to create a final product. The process begins with the design of a digital model using CAD software, which is then converted into printable instructions.[20-22] Pharmaceutical-grade materials, including polymers and active pharmaceutical ingredients (APIs), are used to form dosage forms. The technique allows precise placement of drug molecules, enabling control over drug release kinetics and spatial distribution. This level of precision facilitates the development of innovative drug delivery systems with enhanced therapeutic effectiveness.[23-25]

Types and Techniques Of 3D Printing Technology:

Binder Jet Printing- Uses a liquid to join powder materials. Binder jetting is a powder-based technique in which a liquid binding agent is selectively deposited onto a powder bed to form solid layers. The process is repeated to build the final structure. This method is widely known for producing fast-dissolving tablets due to the high porosity of the printed structure. It allows rapid disintegration and improved patient compliance. However, mechanical strength of the final product can be relatively low.

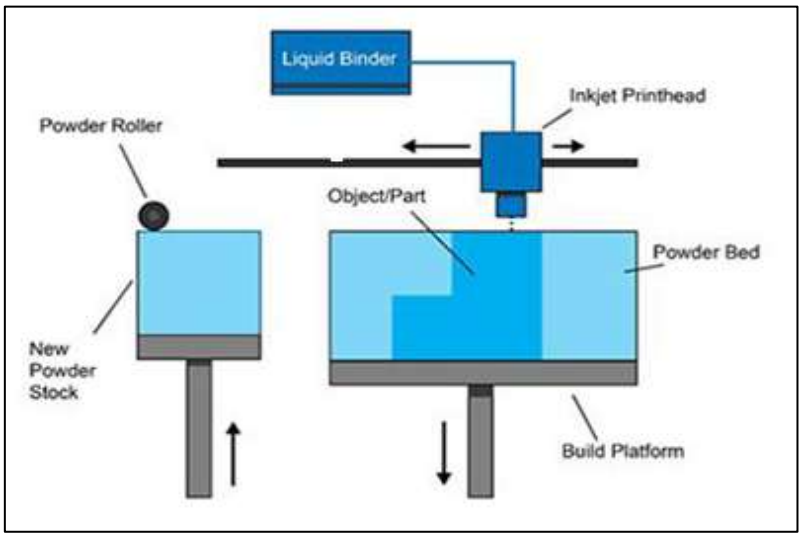

Figure 1: Binder Jet Printing Technique [26]

Inject Printing- Sprays tiny droplets of drug solution for accurate dosing. Inkjet printing operates by depositing small droplets of drug solution or suspension onto a substrate. It can be categorized into continuous inkjet and drop-on-demand systems. This technique allows highly accurate dosing and is especially useful for low-dose and potent drugs. It is widely applied in or dispersible films and personalized medicine. However, formulation stability and nozzle clogging can be potential challenges [26].

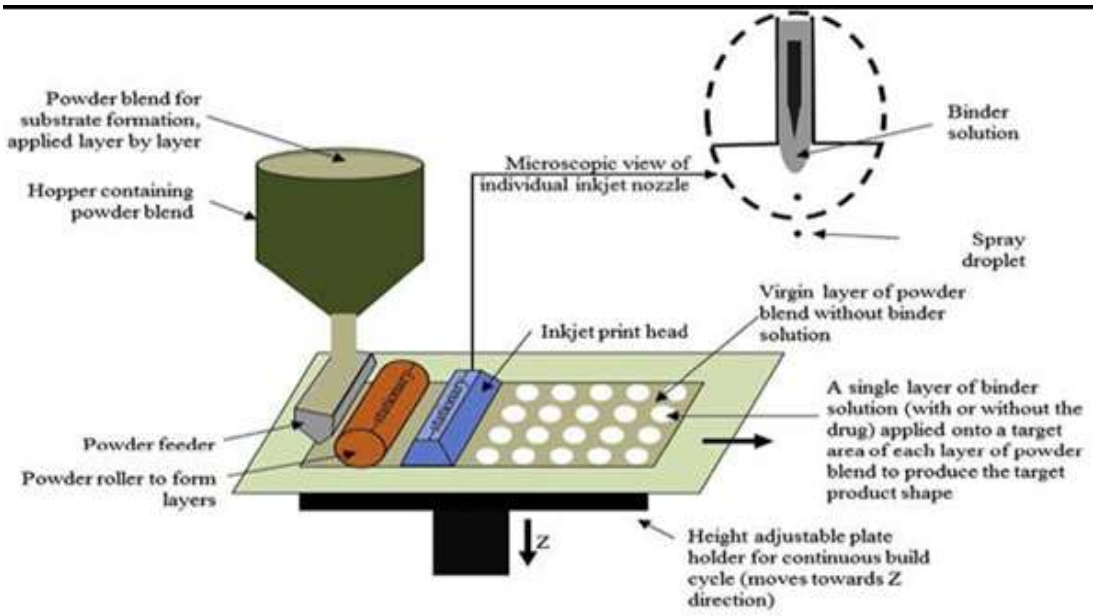

Figure 2: Thermal Inkjet Printing Technique [26]

Fused Deposition Modelling (FDM)- Uses heated drug to be loaded for filaments to prepare tablets layer by layer. Fused Deposition Modelling is one of the most used techniques in the pharmaceutical industries to produce several dosage forms. It involves the extrusion of thermoplastic filaments through a heated nozzle, where the material is deposited layer by layer to form a solid structure. In pharmaceutical sciences, drug-loaded filaments are prepared using hot-melt extrusion and then printed into dosage forms. This method is particularly suitable for producing sustained-release tablets due to the controlled diffusion of drugs through the polymer matrix. However, the high processing temperature may not be suitable for heat-sensitive drugs [26].

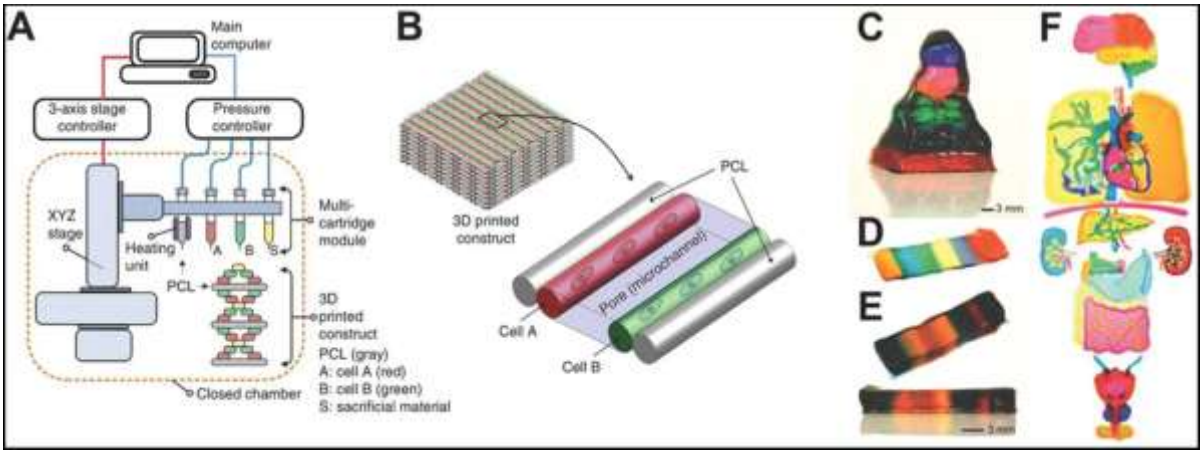

Figure 3: Fused Deposition Modelling Technique [26]

Stereolithography (SLA) – Uses light or laser to solidify liquid resin into dosage forms. Stereolithography uses a light source, typically ultraviolet (UV) light, to solidify a liquid photopolymer resin into a solid structure. The process occurs layer by layer, producing highly precise and smooth dosage forms. In pharmaceutical applications, SLA is used to create complex geometries and intricate drug delivery systems. Its high resolution makes it suitable for microstructures but concerns regarding the toxicity of photopolymer resins must be addressed [27,28].

Selective Laser Sintering (SLS)- Selective Laser Sintering involves the use of a laser to fuse powder particles into a solid structure without the need for solvents. The laser selectively sinters the material based on the digital design. This technique is advantageous for producing porous dosage forms that enhance drug dissolution and bioavailability. It is also suitable for heat-stable drugs, but the high energy input may degrade temperature-sensitive compounds [29,30].

Semi Solid Extrusion (SSE) – Semi-solid extrusion involves the extrusion of gels or pastes through a nozzle to create structures at relatively low temperatures. This technique is beneficial for printing heat-sensitive drugs and biopharmaceuticals. It is also used in the fabrication of topical formulations and chewable dosage forms. However, maintaining uniformity and structural stability can be challenging.[22]

Direct Powder Extrusion (DPE) – Direct powder extrusion eliminates the need for filament preparation by directly using powder blends for printing. This method simplifies the manufacturing process and reduces preparation steps. It is gaining attention for its efficiency, although optimization of powder flow and uniformity remains a challenge.[22,23]

Digital Light Processing (DLP) – This technique is used in fabrication of solid dosage form by using digital micromirror device which reflects UV lights on the upper surface of photoreactive solid dosage form [31].

Advantages Of 3D Printing Technology in Pharmaceutical Formulation: - [1,10,26]

- Enables personalized drug therapy
- Provides precise control over drug dosage and release
- Allows fabrication of complex structures
- Reduces material wastage
- Improves patient compliance
- Accelerates drug development and prototyping

Disadvantages Of 3D Printing Technology in Pharmaceutical Formulation: - [1,23,26]

- High capital investment
- Limited availability of suitable materials
- Slow production rate

Challenges Of 3D Printing in Pharmaceutical Sciences:

3D printing in pharmaceutical sciences offers exciting possibilities, but its practical use still faces several important challenges. These issues need to be addressed before the technology can be widely adopted in routine drug manufacturing. One of the biggest challenges is the high cost of implementation. Advanced 3D printers, along with the required software and compatible materials, are expensive. This makes it difficult for small pharmaceutical companies or research laboratories to adopt the technology easily. Another major concern is the limited range of printable materials. Not all pharmaceutical ingredients can be used in 3D printing processes. Many drugs are sensitive to heat, light, or pressure, which restricts the choice of techniques that can be applied. As a result, formulation flexibility remains limited. The issue of regulatory uncertainty also plays a significant role. Traditional pharmaceutical manufacturing follows well-established guidelines, but 3D printing introduces new variables such as digital design files, layer-by-layer fabrication, and personalized dosing. Regulatory bodies are still working on clear and standardized rules, which create delays in approval and commercialization[11, 19]. Scalability is another important challenge. While 3D printing is excellent for producing batches or customized medicines, it is efficient for large-scale production. The process is relatively easy compared to conventional manufacturing methods, making it difficult to meet high market demand. Maintaining consistent quality and reproducibility is also not Easy to Use. Small

variations in printing conditions - such as temperature, speed, or material flow - can affect the final product. Ensuring that every printed dosage form meets the same standards of quality and accuracy is a significant hurdle. There are also concerns related to drug stability. Some printing techniques involve heat or light, which can degrade sensitive drugs. Additionally, the long-term stability and shelf life of 3D-printed medicines are still under investigation. The technology requires skilled professionals who understand both pharmaceutical formulation and digital design. This combination of expertise is not yet widely available, which can slow down adoption and increase training costs. Another challenge is the need for post-processing steps, such as drying, curing, or finishing. These additional steps increase the overall production time and may introduce further variability if not properly controlled. Finally, there is a risk of cross-contamination if equipment is not thoroughly cleaned between different formulations. This is especially important when handling potent or multiple drugs in the Same way [21,32,33].

Application Of 3D Printing Technology In Pharmaceutical Sciences: -

- **Personalized Medicine:** [5,34,35]

Medicines can be customized according to individual patient needs (dose, shape, release).

- **Controlled Drug Delivery:** [3,36,37]

Tablets can be designed to release drugs slowly or at a specific site in the body.

- **Polypills:** [6,38]

Multiple drugs can be combined into a single tablet, reducing the number of medicines a patient takes.

- **Fast-Dissolving Tablets:** [39, 40]

Useful for patients who have difficulty swallowing, as they dissolve quickly in the mouth.

- **Drug Development:** [37]

Helps researchers quickly design and test new formulations.

- **Medical Implants:** [21,25]

Drug-loaded implants can provide long-term treatment at targeted locations.

- **Bioprinting:** [38,39]

Used to create tissues for drug testing and research.

- **On-Demand Manufacturing:** [14,39]

Medicines can be produced when needed, especially in hospitals or remote areas.

Risk Assessment During 3d Printing Technology:

- Assessing risk in 3D printing is essential to ensure that the final medicine is safe, effective, and consistent. Because this technology combines digital design with physical manufacturing, risks can arise at multiple stages - from formulation to final product use. A careful, step-by-step evaluation helps minimize errors and maintain quality.

- **Raw Material Risks** [11,16,22]

The quality of starting materials plays a major role in the final product. If polymers or active pharmaceutical ingredients (APIs) are not pure or compatible with the printing process, it can affect drug stability and performance. Moisture sensitivity and poor flow properties can also lead to uneven printing.

- **Formulation Risks** [39]

Designing a printable formulation is not simple. Some drugs may degrade when exposed to heat, light, or pressure during printing. There is also a risk of uneven drug distribution, which can lead to incorrect dosing.

- **Process and Equipment Risks** [13]

The printing process depends on precise control of parameters such as temperature, speed, and layer thickness. Any small variation can change the structure and drug release behaviour of the final product. Equipment malfunction or calibration errors can also lead to defective dosage forms.

❖ **Software and Design Risks [21]**

Since 3D printing relies on digital models, errors in design files or software can directly affect the product. A small mistake in the digital design may result in incorrect dosage, improper shape, or failure of the dosage form.

❖ **Environmental Risks [22]**

External conditions like temperature, humidity, and air quality can influence the printing process. For example, high humidity may affect powder flow or cause materials to clump, leading to poor print quality.

❖ **Cross-Contamination Risks [34,41]**

If the printer is used for multiple drugs without proper cleaning, residues from previous formulations can contaminate the next batch. This is especially critical with potent drugs when this 3D technology we used.

❖ **Post-Processing Risks [38]**

After printing, some products require additional steps such as drying or curing. Improper handling during these steps can affect the strength, stability, or drug release characteristics of the dosage form.

❖ **Dose Accuracy Risks [21,38,40]**

Ensuring that each printed unit contains the correct amount of drug is crucial. Variations in material flow or layer deposition can lead to underdosing or overdosing.

❖ **Stability and Storage Risks [9]**

3D-printed medicines may be sensitive to environmental conditions. Improper storage can lead to degradation, reduced effectiveness, or shorter shelf life.

❖ **Regulatory and Compliance Risks [11]**

Since 3D printing is still developing in the pharmaceutical field, regulatory guidelines are not fully standardized. This can create challenges in maintaining compliance with quality and safety requirements.

CONCLUSION

3D printing technology has introduced a new approach to pharmaceutical development and manufacturing by enabling precise control over drug formulation and dosage design. Its ability to produce customized medicines and complex drug delivery systems distinguishes it from conventional methods. This technology supports the shift toward patient-centred treatment, improving therapeutic outcomes and convenience. Despite its advantages, several challenges such as high cost, regulatory uncertainty. Ensuring consistent quality and long-term stability of printed dosage forms remains a critical requirement for wider adoption. Overall, 3D printing holds significant promise for the future of pharmaceutical sciences. With continuous advancements in technology, materials, and regulatory frameworks, it is likely to become an important tool in modern drug manufacturing and personalized healthcare.

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