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3D Printing in Medicine: A New Era for Pharmaceuticals

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Abstract: The introduction of three-dimensional (3D) printing technology in the pharmaceutical industry is poised to revolutionize the field, enabling personalized treatments tailored to individual patients' specific needs, including age, weight, and genetic characteristics. This innovative technology allows for the creation of complex dosage forms, such as microcapsules and multilayered drug delivery devices, using various printing methods like inkjet, fused deposition modeling, and hot melt extrusion. With its widespread applications in pharmaceuticals, from lab-grown organs to personalized medicines, 3D printing is emerging as a valuable, efficient, and economical tool that has the potential to transform the future of pharmacy practice and pharmaceutical care.

Keywords: 3D Printing, Pharmaceutical formulation, pharmaceutical market.

1. Introduction:

3D printing, or additive manufacturing, has become a transformative force across industries, particularly in pharmaceuticals, by allowing the rapid creation of intricate and tailored products. Its reliance on technologies like CAD, CAM, and CNC enables the quick transition from digital design to physical object, significantly shortening product development cycles and enhancing prototyping capabilities. Originating from Charles W. Hull's stereolithography in 1983, 3D printing employs a process where fine powders are layered and bound to build objects, showcasing unparalleled potential in innovation and manufacturing efficiency. This versatility in producing complex geometries has opened new avenues for drug development and delivery while impacting fields such as engineering, design, and education.

This passage describes the step-by-step process of 3D printing, where a design created in CAD software is translated into physical form through layering and binding of fine powders. After completion, the finished part is carefully removed and cleaned, highlighting the technology's ability to produce complex and customized products that showcase their versatility in modern manufacturing.

The 3D printing process begins with creating a virtual design of a product using Computer-Aided Design (CAD) software or by scanning an existing object to generate a digital 3D model. This model is then sliced into hundreds or thousands of horizontal layers, which the 3D printer reads as 2D images. The printer builds the object layer by layer by solidifying or binding liquid or powder at specified locations within each slice, seamlessly blending the layers together to produce a final three-dimensional object with no visible layering.

This technology is widely utilized for creating prototypes of new parts using materials such as metals, plastics, and ceramics, with fine plastic or metal powders being the most common. Particle sizes can be as small as 20 micrometers, and these powders are stored in cartridges or beds, dispensed in thin layers that match the thickness of the particles. A binding agent is then sprayed in a pattern defined by the CAD design, followed by the spreading of a fresh layer of powder. This process is repeated with the build platform lowered after each layer is applied. Once the build is complete, the part is extracted from the surrounding unconsolidated powder, cleaned, and possibly finished, showcasing the technology's ability to produce highly complex and customizable products.

2. Types of 3D Printing

A 3D printer is a type of industrial robot. It can be classified based on the form of materials used to make the model. The form of material can be solid, liquid, or powder (1). The classification is given below:

1. Stereolithography (SL)
2. Fused Deposition Modelling (FDM)
3. PolyJet or MultiJet Printing
4. Selective Laser Sintering (SLS)

Stereolithography (SL)

The Stereolithography (SL) process, also known as SLA, was developed by Chuck Hull of 3D Systems in 1986, not 3D System, Inc. (note the typo). SL is a widely used rapid prototyping method that involves the layer-by-layer solidification of photopolymer resin, typically using a UV laser, to create complex geometries and precise details. The process typically begins with the creation of an STL file from CAD software, and the SLA machine automatically generates a support structure before producing the final object, which is then removed from the support material and finished. SL is ideal for creating visual prototypes, showcasing fine details, and testing market demand.

Fused Deposition Modelling (FDM)

Fused Deposition Modelling (FDM) technology was developed by S. Scott Crump in the late 1980s and commercialized in 1990 by Stratasys. The process involves building objects layer by layer from the bottom up by heating and extruding thermoplastic filament. The first step is to create 2D slices of the object using CAD software, which also determines the path for extruding the thermoplastic material and support material, if needed. The thermoplastic material is then heated to its semi-liquid state and deposited in fine filaments, typically around 0.254 mm thick, to create the object layer by layer on a fixtureless base. Support material is added as needed to

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prevent sagging or warping. Once the process is complete, the support material is removed, and the object is finished. FDM is widely used in various industries, including aerospace, automotive, and medical, and is popular among professionals like engineers, designers, and educators for creating prototypes and products. Mainly polymeric materials such as ABS, PLA, PC, PA, and PS are used in FDM 3D printing.

PolyJet or MultiJet Printing

PolyJet 3D printing technology uses multiple inkjets to spray liquid photopolymers that are instantly cured with UV light. One jet is used for the build material, while another jet can be used for support material, which is not cured by UV light and is removed after printing. The PolyJet process is capable of producing highly detailed objects with thin layers (as low as 16 microns) and ultra-thin walls (down to 0.6 mm). While the process has its limitations, such as producing weaker objects compared to other technologies like SLA or SLS, it offers the ability to produce multi-colored objects. Companies like Materialise and Stratasys offer a range of materials with varying properties, including general-purpose resins, flexible rubber-like materials, and composite materials. For example, Materialise's VeroWhitePlus is a general-purpose resin with good mechanical properties, while TangoWhitePlus is a flexible resin with exceptional elongation at break. Stratasys also offers a range of materials, including PolyJet copolymers that simulate the functionality and appearance of polypropylene.

Selective Laser Sintering (SLS)

Selective Laser Sintering (SLS) technology was developed and patented by Dr. Carl Deckard and Dr. Joe Beaman at the University of Texas at Austin in the mid-1980s. In this additive manufacturing process, various materials—in powdered form, such as metals, polymers, or combinations thereof—are used, with particle sizes typically around 50 µm. A carbon dioxide laser selectively fuses these powders at specific locations according to the 3D design. After each layer is completed, the powder bed is lowered by one layer's thickness, and a new layer of material is applied on top. This is repeated until the object is fully formed. The SLS process is performed in an inert atmosphere to prevent oxidation, and it uniquely does not require support material since the unsintered powder surrounding the part provides necessary support. A diverse range of materials, including various polymers like nylon and metals such as steel and titanium, can be processed, achieving density levels up to 100% and material properties similar to those of conventional manufacturing. Other notable additive manufacturing techniques include 3DP, ProMetal, Electron Beam Melting (EBM), Laminated Object Manufacturing (LOM), and Laser Engineering Net Shaping.

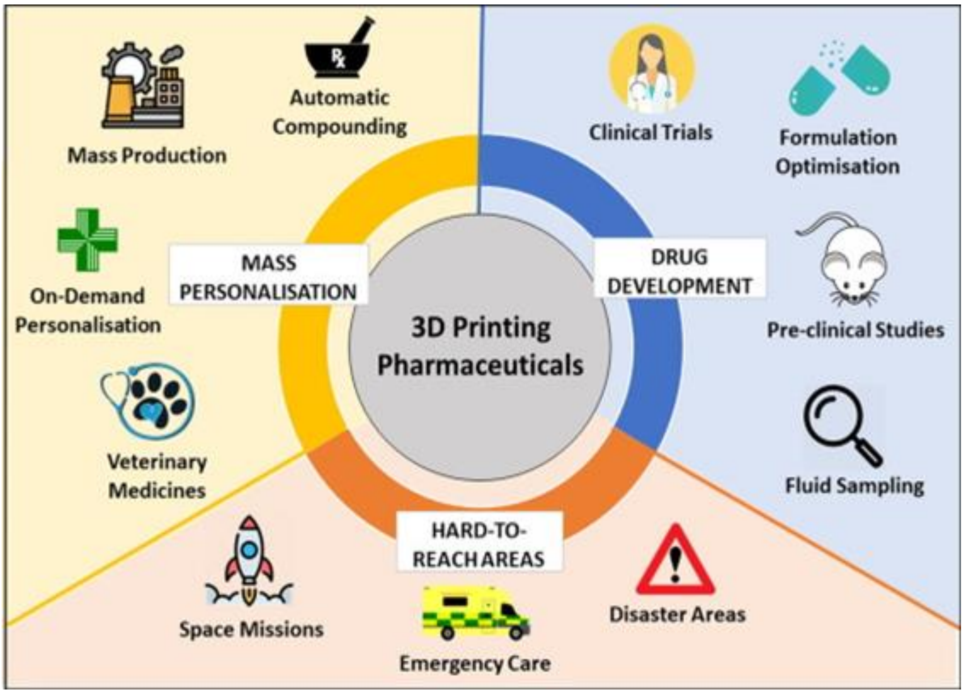

Figure-1 Applications of 3D Printing in the Pharmaceutical Industry

3. Printing

Before printing a 3D model from an STL file, it must first be examined for errors. Most CAD applications produce errors in output STL files, including the following types:

- Holes
- Face normals
- Self-intersections
- Noise shells
- Manifold errors
- Overhang issues

A step in the STL generation process known as "repair" fixes such problems in the original model. Generally, STLs produced from models obtained through 3D scanning often contain more of these errors, as 3D scanning is frequently achieved through point-to-point acquisition/mapping. 3D reconstruction often includes errors.

Once completed, the STL file needs to be processed by a piece of software called a *slicer*, which converts the model into a series of thin layers and produces a G-code file containing instructions tailored to a specific type of 3D printer (e.g., FDM printers). This G-code file can then be printed using 3D printing client software (which loads the G-code and uses it to instruct the 3D printer during the printing process).

Printer resolution describes layer thickness and X–Y resolution in dots per inch (DPI) or micrometers (µm). Typical layer thickness is around 100 µm (250 DPI), although some machines can print layers as thin as 16 µm (1,600 DPI). X–Y resolution is comparable to that of laser printers. The particles (3D dots) are around 0.01 to 0.1 µm (2,540,000 to 250,000 DPI) in diameter. For that printer resolution, specifying a mesh resolution of 0.01–0.03 mm and a chord length ≤ 0.016 mm generates an optimal STL output file for a given model input file. Specifying a higher resolution results in larger files without an increase in print quality.

3:30 Timelapse of an 80-minute video of an object being made out of PLA using molten polymer deposition.

Construction of a model with contemporary methods can take anywhere from several hours to several days, depending on the method used and the size and complexity of the model. Additive systems can typically reduce this time to a few hours, although it varies widely depending on the type of machine used and the size and number of models being produced simultaneously.

4. Finishing

Though the printer-produced resolution and surface finish are sufficient for some applications, post-processing and finishing methods allow for benefits such as greater dimensional accuracy, smoother surfaces, and other modifications such as coloration.

The surface finish of a 3D-printed part can be improved using subtractive methods such as sanding and bead blasting. When smoothing parts that require dimensional accuracy, it is important to consider the volume of the material being removed.

Some printable polymers, such as acrylonitrile butadiene styrene (ABS), allow the surface finish to be smoothed and improved using chemical vapor processes based on acetone or similar solvents.

Some additive manufacturing techniques can benefit from annealing as a post-processing step. Annealing a 3D-printed part allows for better internal layer bonding due to recrystallization of the part. It allows for an increase in mechanical properties, some of which include fracture toughness, flexural strength, impact resistance, and heat resistance. Annealing a component may not be suitable for applications where dimensional accuracy is required, as it can introduce warpage or shrinkage due to heating and cooling.

Additive or Subtractive Hybrid Manufacturing (ASHM) is a method that involves producing a 3D-printed part and using machining (subtractive manufacturing) to remove material. Machining operations can be completed after each layer, or after the entire 3D print has been completed, depending on the application requirements. These hybrid methods allow for 3D-printed parts to achieve better surface finishes and dimensional accuracy.

The layered structure of traditional additive manufacturing processes leads to a stair-stepping effect on part surfaces that are curved or tilted with respect to the building platform. This effect strongly depends on the layer height used, as well as the orientation of a part surface inside the building process. This effect can be minimized using variable layer heights or adaptive layer heights. These methods decrease the layer height in areas where higher quality is needed.

Painting a 3D-printed part offers a range of finishes and appearances that may not be achievable through most 3D printing techniques. The process typically involves several steps, such as surface preparation, priming, and painting. These steps help prepare the surface of the part and ensure the paint adheres properly.

Some additive manufacturing techniques are capable of using multiple materials simultaneously. These techniques are able to print in multiple colors and color combinations simultaneously and can produce parts that may not necessarily require painting.

Some printing techniques require internal supports to be built to support overhanging features during construction. These supports must be mechanically removed or dissolved (if using a water-soluble support material such as PVA) after completing a print.

Some commercial metal 3D printers involve cutting the metal component off the metal substrate after deposition. A new process for GMAW 3D printing allows for substrate surface modifications to remove aluminum or steel.

1. Plastics

a. ABS (Acrylonitrile Butadiene Styrene)

- Properties: Impact-resistant, heat-resistant, and affordable
- Advantages: Easy to print, good for prototypes and models
- Limitations: Can be brittle, prone to warping
- PLA (Polylactic Acid)
- Properties: Biodegradable, renewable, and non-toxic
- Advantages: Easy to print, good for beginners, and eco-friendly
- Limitations: Can be brittle, prone to degradation

b. PETG (Polyethylene Terephthalate Glycol)

- Properties: Strong, flexible, and resistant to chemicals
- Advantages: Good for mechanical parts, outdoor use, and food contact
- Limitations: Can be prone to stringing, more expensive than PLA
- Nylon
- Properties: Strong, flexible, and abrasion-resistant
- Advantages: Good for mechanical parts, outdoor use, and textiles
- Limitations: Can be prone to warping, moisture absorption

c. TPU (Thermoplastic Polyurethane)

- Properties: Flexible, elastic, and abrasion-resistant
- Advantages: Good for wearable products, seals, and gaskets
- Limitations: Can be prone to stringing, more expensive than PLA

2. Metals

a. Aluminum

- Properties: Lightweight, corrosion-resistant, and conductive
- Advantages: Good for aerospace, automotive, and industrial applications
- Limitations: Can be prone to oxidation, expensive

b. Copper

- Properties: Conductive, corrosion-resistant, and ductile
- Advantages: Good for electrical applications, heat sinks, and antennas
- Limitations: Can be prone to oxidation, expensive

c. Steel

- Properties: Strong, durable, and corrosion-resistant

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- Advantages: Good for industrial applications, machinery, and tools
- Limitations: Can be prone to rust, expensive

d. Titanium

- Properties: Lightweight, corrosion-resistant, and strong
- Advantages: Good for aerospace, medical, and industrial applications
- Limitations: Can be prone to oxidation, expensive

3. Ceramics

a. Silica

- Properties: Hard, brittle, and corrosion-resistant
- Advantages: Good for wear-resistant applications, ceramics, and glass
- Limitations: Can be prone to cracking, expensive

b. Alumina

- Properties: Hard, corrosion-resistant, and electrically insulating
- Advantages: Good for wear-resistant applications, electronics, and ceramics
- Limitations: Can be prone to cracking, expensive
- Zirconia
- Properties: Hard, corrosion-resistant, and biocompatible
- Advantages: Good for wear-resistant applications, medical implants, and ceramics
- Limitations: Can be prone to cracking, expensive

4. Glass

- Borosilicate Glass
- Properties: Transparent, corrosion-resistant, and thermal shock-resistant
- Advantages: Good for laboratory equipment, medical devices, and cookware
- Limitations: Can be prone to thermal stress, expensive

5. Carbon Fiber

- Carbon Fiber-Reinforced Polymers (CFRP)
- Properties: Lightweight, strong, and corrosion-resistant
- Advantages: Good for aerospace, automotive, and industrial applications
- Limitations: Can be prone to delamination, expensive

6. Wood

- Wood-Filled Filaments
- Properties: Renewable, biodegradable, and aesthetic
- Advantages: Good for furniture, decorations, and architectural models
- Limitations: Can be prone to warping, moisture absorption

7. Biomaterials

Bio plastics (e.g., PLA, PBAT)

- Properties: Biodegradable, renewable, and non-toxic
- Advantages: Good for packaging, disposable products, and medical devices
- Limitations: Can be prone to degradation, expensive
- Biocompatible Materials (e.g., PEEK, PSU)
- Properties: Biocompatible, corrosion-resistant, and strong
- Advantages: Good for medical implants, surgical instruments, and pharmaceutical applications
- Limitations: Can be prone to degradation, expensive

8. Conductive Materials

- Conductive Filaments (e.g., Carbon-Based, Metal-Filled)
- Properties: Conductive, corrosion-resistant, and flexible
- Advantages: Good for electrical applications, sensors, and wearable products
- Limitations: Can be prone to oxidation, expensive

5. Application Of 3d Printing

The application of 3D printing in the pharmaceutical industry offers numerous benefits, including the creation of personalized medicine, complex dosage forms, and customized implants and inserts. With 3D printing, pharmaceutical companies can produce tablets, capsules, and implants with specific drug-release profiles tailored to individual patients' needs, improving treatment outcomes and patient compliance. Additionally, 3D printing facilitates rapid prototyping, enabling the accelerated development of new drug formulations and delivery systems. Technology also allows for the creation of pharmaceutical products with complex geometries, customized packaging, and novel drug-delivery systems, such as microneedle arrays, which can enhance drug delivery and efficacy. Furthermore, 3D printing can aid in regulatory compliance, enabling the production of customized labels and packaging that meet track-and-trace requirements, ultimately transforming the pharmaceutical industry with its innovative and customized solutions.

5. Limitations

Despite the promising benefits of 3D printing in the pharmaceutical industry, several challenges need to be addressed. A clear and evolving regulatory framework is necessary to ensure the safe and effective use of 3D-printed pharmaceuticals. Maintaining quality control and consistency in production is also a crucial aspect, requiring robust measures to guarantee the quality of the final product. Currently, the scalability of 3D printing is a significant limitation, hindering its ability to meet commercial demands. Additionally, the limited range of materials compatible with 3D printing restricts the types of pharmaceutical products that can be produced. Furthermore, public perception of 3D-printed pharmaceuticals may be a concern, prompting the need for education and awareness efforts to address any potential safety or efficacy concerns.

5. Conclusion

3D printing is indeed revolutionizing the pharmaceutical industry by facilitating the production of customized, complex, and personalized drug products, offering significant advantages such as tailored dosages and improved patient compliance. While challenges like regulatory framework development, quality control, scalability, material limitations, and public perception remain, the transformative potential of this technology is clear. As advancements in 3D printing continue to progress, we can anticipate broader adoption and innovative applications within the pharmaceutical sector, ultimately enhancing drug delivery and patient outcomes.

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