

Review Article

A REVIEW ARTICLE OF 3D PRINTING DESIGN IN PHARMACEUTICALS SCIENCES AND ITS RESEARCH MANAGEMENT

¹Dr S C Marapur, ^{2,*} Dr K.S.Srilatha, ³Vinayraj ParamShetty, ⁴Susmitha K R, ⁵Chandana

¹Professor and HOD Department of Pharmaceutics BLDEA'S SSM college of Pharmacy and research center Vijayapur, Karnataka, India.

²Professor and HOD Department of Pharmaceutics, Shridevi Institute of Pharmaceutical Sciences Tumkur, Karnataka, India.

³Asst Professor Department of Pharmaceutics, SVET'S College of pharmacy Humnabad Karnataka, India.

⁴Asst Professor Department of Pharmaceutics, Shridevi Institute of Pharmaceutical Sciences Tumkur, Karnataka, India.

⁵Asst Professor Department of Pharmacy practice, Shridevi Institute of Pharmaceutical Sciences Tumkur, Karnataka, India.

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ABSTRACT

The advent of three-dimensional (3D) printing, or additive manufacturing, has revolutionized various industries, and its integration into pharmaceutical sciences is rapidly transforming drug development and manufacturing. This review provides a comprehensive overview of the current landscape of 3D printing technologies and their diverse applications within the pharmaceutical sector. We discuss various printing techniques, including fused deposition modelling (FDM), selective laser sintering (SLS), stereolithography (SLA), and inkjet printing, highlighting their unique advantages and limitations for drug formulation. Key applications explored include the fabrication of personalized medicines with tailored dosages and release profiles, multi-drug polypills, orally disintegrating films, and implants. Furthermore, the review delves into the potential of 3D printing for creating complex drug delivery systems, such as sustained-release matrices and targeted delivery devices. We also examine its utility in developing novel excipients, optimizing pre-clinical drug testing through organ-on-a-chip models, and accelerating pharmaceutical research and development. Challenges such as regulatory hurdles, material compatibility, and scalability are addressed, alongside future perspectives on the widespread adoption and transformative impact of 3D printing on precision medicine and pharmaceutical manufacturing.

Keywords: 3D Printing, Industries, Integration, Comprehensive, Multi drugs.

INTRODUCTION

There is a constant motivation towards new concepts in drug design, a better understanding of material properties, manufacturing technology and processes that assure high-quality dosage forms. The diversity of physicochemical and biopharmaceutical characteristics of active pharmaceutical ingredients (APIs) has to be considered and studied through each stage of product development. Auxiliary substances need to be examined as well to manufacture the desired dosage form.[1]

Active pharmaceutical ingredients (APIs) contain a variety of physicochemical and biopharmaceutical features that need to be taken into account and researched via each in the process of being developed. Additional materials must be Additionally studied to produce the optimal dosage form for the development of patient-centred drug products has received a lot of attention over the past ten years. It had direction. On cutting-edge technology methods and innovative dosage formulations. Increasing demand for customized gadgets along with an increase in the greatest advancements in personalized medicine is driven by technological innovation, as evidenced, for example, by the creation of a small series of tailored dosages and prosthetics created to satisfy the patient's anatomical requirements.

Three-dimensional printing (3DP), among the many breakthroughs introduced to the pharmaceutical and biomedical markets, is thought to be the most revolutionary and potent. This method is regarded as a flexible one. A tool for accurate gadget manufacture. It functions as a technology for creating novel dosage forms, engineering tissues and

organs, and simulating diseases. Three-dimensional printing is one of the fields of technology, art, and science that is now advancing the fastest. Increases the applications' scope.[2]

Three-dimensional printing (3DP) has become one of the most innovative technologies in the pharmaceutical field. Within the last decade, there has been a significant expansion in the manufacture of drug delivery and medical devices.[3]

3D printing is the ability to create 3D products, extracting their design from an instructed data process file. It is a procedure in which objects are produced by combining or placing materials, such as ceramics, liquids, powders, metal, plastic, as well as living cells, into layers to construct a 3D object. This technique is also referred to as rapid prototyping (RP), additive manufacturing, or solid free-form technology. The design of devices for 3DP was to initiate blueprints and advances in all fields of engineering.[4]

3D technology offers unique benefits to drug product manufacturing when compared to traditional methods—notably, the capacity to design personalized pharmaceutical forms with flexible dosage, different shapes, multiple active pharmaceutical ingredients (even incompatible ones), and modulated release kinetics. Moreover, the most diversified and sophisticated drug delivery devices for oral, dermal, and implantable administration can be produced with high accuracy using 3D printers.[5,6]

Since their implementation, devices have significantly decreased costs and time, to traditional methods used previously. Significant advances in the biomedical field have seen various printing of organs, dental devices, ophthalmological implants, as well as cell-cultured tissue implants, incorporated into scaffold-based polymeric systems.[4]

*Corresponding Author: Dr K.S.Srilatha,

¹Professor and HOD Department of Pharmaceutics, Shridevi Institute of Pharmaceutical Sciences Tumkur, Karnataka, India.

3D PRINTING PROCEDURE

First, a virtual 3D design of an object using digital design software like Onshape, Solidworks, Creo parametric, Autocad, Autodesk, etc. is created.



This digital model is then converted to (STL) digital file format which stands for standard tessellation language or stereo lithography.



Triangulated facets give information regarding the surface of the 3D model that is present in the (STL) file.



The (STL) file is converted into a G file by slicing the design into a series of 2D horizontal cross-sections with the help of specialized slicer software, which is installed in the 3D printer.



Now the print head is moved in the x-y axis to create the base of the 3D object.



The print head is now allowed to move in the z-axis, thereby depositing the layers sequentially of the desired material, hence creating a complete 3D object.

Maximum numbers of 3D printing technologies are compatible with (.STL) file format. Some errors might occur during the conversion of the 3D model.STL digital file; therefore, software like Magics (Materialise) can be employed to correct the errors during conversion. File formats other than.STL like additive manufacturing file format (AMF) and 3D manufacturing format (3MF) are used.STL does not have information regarding the type of material, its color, texture, properties, and other features.[7]

ADVANTAGES OF 3D PRINTING

1. Manufacturing oral dosage forms using 3D printing (3DP) techniques offers numerous benefits, particularly in the context of personalized medication delivery. This approach allows for the incorporation of the active ingredient into the dosage form based on the specific needs of each patient, enabling the attainment of a customized dose and release profile.
2. The utilization of 3D printing has been employed in the production of pharmaceutical combinations with intricate release profiles, encompassing multiple active substances. This innovative technology enables the fabrication of personalized products with distinctive geometries and designs, a feat that would prove challenging to accomplish through conventional tablet manufacturing techniques.
3. 3D printing technology has demonstrated superior efficiency compared to traditional manufacturing methods, particularly in the fabrication of implants and prosthetics. Moreover, it presents

advantages such as enhanced resolution, consistency, accuracy, and reliability.

4. One of the revolutionary benefits of this technology is the ability to produce specialized medical items and equipment. Tailored surgical instruments, implants, prosthetics, and fixtures can greatly assist both patients and doctors.
5. 3D printing allows for cost-effective production of objects, making it beneficial for small-scale manufacturing operations.
6. 3D printing technology enables the attainment of meticulous regulation over droplet dimensions, intricate drug release patterns, dosage potency, and the capacity to administer multiple doses.
7. Small-scale production is feasible, and the entire process can be accomplished in a single operation.
8. Three-dimensional (3D) printers are readily available and occupy a small footprint.
9. Prevents batch-to-batch variability found in traditional dosage form manufacture in bulk.
10. Because of the versatile design and production of this dosage form, it makes it easier to choose the appropriate treatment regimen for a particular patient because immediate and controlled release layers may be mixed.
11. Treatment can be tailored in cases of multiple medication therapies with multiple-dose regimens to increase patient adherence.
12. High medication filling capacity compared to dose forms with known composition.
13. Accurate and accurate administration of strong medications that are given in tiny amounts.
14. Reduces production costs by reducing material waste.
15. Appropriate drug delivery for active components that are difficult to manufacture, such as those with low water solubility and medications with a narrow therapeutic window.
16. Based on genetic variations, ethnic diversity, age, gender, and environmental factors, it is possible to tailor medical treatments to suit individual patients in specific circumstances.
17. The usage of 3D printing for low-stability pharmaceuticals, transportable military installations, and hospitals may be appropriate.
18. When creating dose forms for clinical studies, 3DP might be quite helpful.
19. Improved methods are used for poorly soluble API dissolution.
20. The contact surface area can be enhanced through the implementation of various techniques such as printing structures with hollowed or highly porous characteristics, which can lead to increased rates of disintegration and dissolution. Additionally, the utilization of 3DP extrusion techniques allows for the filling of internal holes with loose powders, further augmenting the contact surface area.[8]

DISADVANTAGES OF 3D PRINTING

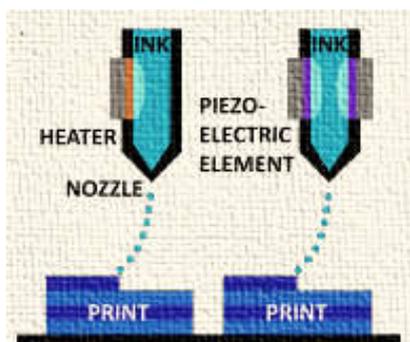
1. Some 3D printing methods can produce structures with many holes and inconsistent shapes for medication.
2. Using only stable medications and easily available excipients is a constraint when using the fused deposition modeling method.
3. UV light-induced polymerization in stereo lithography can potentially lead to drug degradation. Inkjet printing requires ink with a particular thickness to achieve the correct ink flow.
4. The ink's composition should allow it to adhere to itself but not to other parts of the printer. If the ink cannot bind to itself or if it binds to other printer components, the resulting formulation will not have the required level of hardness.
5. The rate at which medication is released may be affected by the way ink binds with other printer materials.

6. When choosing raw materials, it is crucial to conduct a comprehensive assessment of their printability, physicochemical properties, thermal conductivity, print fluid characteristics, and viscoelastic material. Furthermore, it is essential to evaluate the appropriateness of the raw materials for human consumption.
7. Powder-based 3D printing necessitates a more specific or exclusive area due to the potential danger of powder spillage, which can present occupational risks. The material utilized for creating the ink must possess the capability to adhere to itself while avoiding bonding with other parts of the printer.
8. If the ink in a specific formulation lacks sufficient self-binding capability or fails to bond with other printer components, it will create foam.
9. In 3D dosage forms, particularly those utilizing powder-based methods, there is an increased susceptibility to friability. The manufacturing technique employed plays a crucial role in determining the strength of the dosage form.
10. Compared to conventional tablet compression techniques, the range of materials, color choices, and surface finishes accessible for 3D printing is relatively restricted.
11. The dosage form's layers are formed through 3D printing with a nozzle mechanism. The printer head pauses and resumes to ensure a steady flow of printing material during the creation of each layer.
12. In certain situations, it may be necessary to use post-processing methods like hot air drying, microwaves, or infrared sources to remove any remaining solvents from the final product.
13. Boundaries become a significant consideration when considering polypills, particularly regarding the quantity of active pharmaceutical ingredients (APIs) employed and the overall dimensions of the end product.[8 ,9]

Applicable 3D Printing Method:

There are numerous 3D printing methods, many of which have previously been reported as adapted for bioprinting and drug manufacturing needs. In particular,

- **Inkjet Printing**



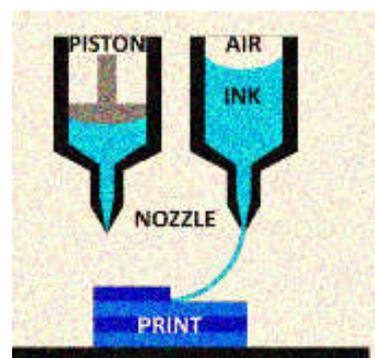
Inkjet-based printing follows the same principles as a commercial inkjet printer for paper ink is deposited onto a substrate by either a thermal-driven or piezoelectric-driven nozzle, offering high-resolution printing capabilities. With the introduction of z-axis motion, 3D patterns may be fabricated by this method.

For the thermal inkjet printing approach, a thermal element within the print head generates droplets of ink. This heating element is electrically controlled to cyclically produce brief spikes in thermal energy which is transferred to the ink. The increase in thermal energy causes the formation of a small bubble, which provides a pulse of pressure to force ink out of the nozzle, thereby producing a droplet.

An alternative to thermal inkjet printing is the piezoelectric approach, which implements a piezoelectric actuator to form droplets. A piezoelectric crystal within the print head is stimulated when voltage is applied, which induces a rapid, reversible deformation. This deformation propagates acoustic waves which supply the pulse of pressure needed to disrupt the flow of ink through the print head, thereby producing droplets.

The inkjet printing method can further be applied to microvalve-based 3D printing. Microvalve printing utilizes a motorized stage comprised of an array of microvalves that are capable of depositing droplets of material. Each microvalve is connected to its pressure regulator, allowing for individual control of each one. By controlling the stage and the pressure regulators in unison, various materials can be simultaneously deposited. This scheme has been previously applied to cell-laden bioprinting, whereby support material, growth media, and cell-laden material were printed together. Microvalve-based 3D printing can be applied to drug fabrication by depositing various drug-loaded materials along with binders, scaffolds, and other biodegradable materials.[10,11]

Extrusion 3D Printing



In this method, the material is extruded from the automated nozzle onto the substrate without any higher supportive material. The components that can be extruded are molten polymer, suspension, semisolids, and pastes.

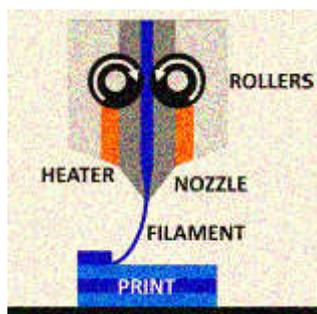
Zip dose: - Personalized 3D-printed medicine with a high drug load is produced using porous material. The procedure relies on high dissolution and disintegration levels. It is the world's initial and only FDA-approved commercial scale 3DP in current therapeutic areas for pharmaceutical manufacturing areas. It has distinctive digitally coded layering and zero compression practices, used for tablet formulation with large dosages and prompt disintegration. Hence, it helps in overcoming difficulty in swallowing.

SPRITAM-R (anti-epilepsy drug) is an oral dispersible tablet, marketed by APRECIA Pharmaceutical based on powder bed fusion by layer-by-layer production system which contains the active ingredient, excipients, and a binder liquid to produce a matrix tablet.

Hot Melt Extrusion: - Hot melt extrusion (HME) is the most popular technique in polymer processing and can be utilized to blend drugs with polymers and extrude the formulation through a circular orifice to form a rod-shaped filament for FDM 3D printing.

It is a continuous manufacturing technique that involves feeding, heating, mixing and shaping. In recent years, it has proved that hot melt extrusion capable of optimizing the solubility and bioavailability of moderately soluble drugs.[12]

Fused deposition modeling (FDM)

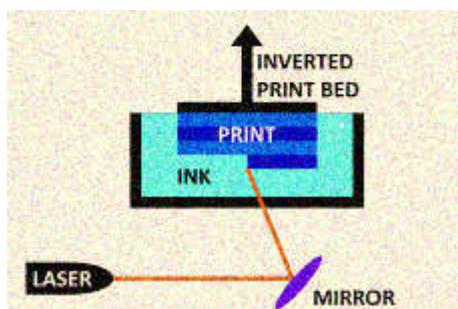


It is a commonly used method in 3D printing, the materials are softer or melt by heat to create objects during printing.

Similar to 3DP, the layout for FDM consists of a print head able to move along x and y directions above a build platform. The polymer is extruded through the heated nozzle and laid down as filaments according to CAD design. The build platform is then lowered and another layer can be built until the scaffold is completed.

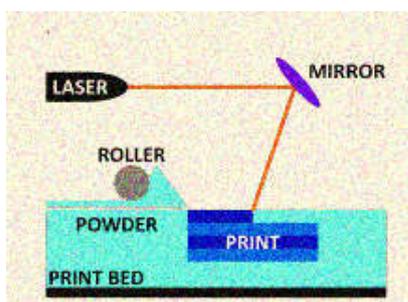
In this method, thermoplastic materials pass down between two rollers to the nozzle tip where it will be subsequently extruded. Before extrusion, the materials are heated by temperature-controlled conditions to ensure their semi-molten form during the extrusion process. Then, the semi-molten polymers solidify, the printing stage is lowered and the same process is repeated until the desired 3D object is obtained.[12]

Stereolithography



Stereo lithography utilizes a laser or projector to solidify material while in a bulk setting. With stereo lithography, also known more generally as photo-polymerization, the drug would be dissolved into a liquid pool of hydrogel or resin material. The material of choice must be photosensitive. When the laser light shines onto the surface of the pool/bed of photosensitive, drug-loaded material, the material cures and solidifies. This method is extremely high resolution and considerably fast, but the nature of the pool of drug-loaded material has an inherent risk of cross-contamination between the fabrications of different drug products.[10]

Selective laser sintering (SLS)



Selective Laser Sintering (SLS) is a rapid prototyping method that enables the creation of detailed geometry by consolidating consecutive powdered material layers over one another. The solidification of layers takes place with the help of CO₂/ Nitrogen lasers counting on the sort of surface end and fusion needed. During this method, the chemical compound powder is employed for the aim of producing the object. The powder may be of thermoplastic, ceramics, glasses, metals, etc. If the powder used is created from metal, then this method is thought of as Direct Metal Laser Sintering (DMLS). SLS printers are composed of two chambers, the transfer of power takes place from the first chamber to the second one, where actual manufacturing occurs. The powder is heated at a temperature below the melting point of the equivalent substance. The leveller or roller present at the top surfaces the powder by forming layers. After the manufacturing is completed, finishing operations are required [12,13,14]

RECOMMENDATIONS

1. Personalized Medication Formulations

Utilize 3D printing to create customized dosage forms tailored to individual patient needs. This can include adjusting strength, combining multiple active ingredients, or producing patient-specific shapes and release profiles, enhancing treatment efficacy and adherence.

2. On-Demand Production and Inventory Management

Implement 3D printing to produce medications on-demand within the pharmacy setting. This reduces inventory costs, minimizes wastage, and ensures rapid availability of medications, especially for complex or rare formulations.

3. Regulatory Compliance and Quality Assurance

Establish strict protocols for validating and controlling 3D printed pharmaceuticals to meet regulatory standards. This includes ensuring consistency, sterility, and accurate dosing, along with documentation for traceability and quality assurance.

CONCLUSION

We stand on the brink of a revolution, where novel technologies such as 3DP are likely to cause a paradigm shift in pharmaceutical manufacture and supply. To date, the long-term benefits of this technology have been forecasted to lie within personalized medicines, leaving a wide range of opportunities underexplored. Indeed, 3DP could also provide many other advantages, ranging from applications in drug discovery, formulation manufacturing processes, global supply and logistics. In the future, 3DP could be used as a digital dispensing tool, supporting operations in hard-to-reach areas such as disaster zones and even within space. Indeed, the adoption of this highly disruptive technology will likely reshape the way that we design, manufacture and use medicines. [15,16]

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