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3D PRINTING IN PHARMCEUTICAL PRODUCTS

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Abstract: Three-dimensional printing technology, also called additive manufacturing technology, is used to prepare personalized 3D-printed drugs through computer aided model design. In recent years, the use of 3D printing technology in the pharmaceutical field has become increasingly sophisticated. In addition to the successful commercialization of Spritam in 2015, there has been a succession of Triastek's 3D-printed drug applications that have received investigational new drug (IND) approval from the Food and Drug Administration (FDA). Compared with traditional drug preparation processes, 3D printing technology has significant advantages in personalized drug manufacturing, allowing easy manufacturing of preparations with complex structures or drug release behaviors and rapid manufacturing of small batches of drugs. This review summaries the mechanisms of the most commonly used 3D printing technologies, describes their characteristics, advantages, disadvantages, and applications in the pharmaceutical industry, analyzes the progress of global commercialization of 3D printed drugs and their problems and challenges, reflects the development trends of the 3D printed drug industry, and guides researchers engaged in 3D printed drugs.

Keywords: Three-dimensional printing technology, Food and Drug Administration, personalized medicine, Research status Additive Manufacturing.

1. INTRODUCTION

In contrast to the traditional manufacturing techniques of “subtractive manufacturing”, 3D printing is an “additive manufacturing” technology, where a model is constructed using computer-aided design software, sliced, and transferred to a printer, and the 3D product is then constructed layer by layer using the principle of layered manufacturing. With the research and development of 3D printing technology, many new 3D printing technologies have emerged one after another. As each 3D printing technology uses different materials, deposition techniques, layering manufacturing mechanisms, and final product characteristics, the American Society for Testing and Materials classified 3D printing technologies into seven categories according to their technical principle, namely material extrusion, binder jetting, powder bed fusion, vat photopolymerization, material jetting, directed energy deposition, and sheet lamination. Three-dimensional printing technology is widely used in automotive, construction, aerospace, medical, and many other fields. In the pharmaceutical sector, research into 3D printing technology is currently experiencing a global boom. Compared to traditional preparation technologies, 3D printing offers flexibility in the design of complex 3D structures within drugs, the adjustment of drug doses and combinations, and rapid

manufacturing and prototyping, enabling precise control of drug release to meet a wide range of clinical needs, a high degree of flexibility and creativity to personalize pharmaceuticals, and a significant reduction in preparation development time, driving a breakthrough in drug manufacturing technology and transforming the way we design, manufacture, and use drug. Three-dimensional printing technologies have been used to manufacture a variety of medicinal products, such as immediate release tablets, controlled-release tablets, dispersible films, microneedles, implants, and transdermal patch. The main 3D printing technologies used in pharmaceuticals are BJ-3DP, FDM, SSE, and MED in material extrusion, and SLA describes the characteristics of these technologies at each stage of drug preparation and assesses the advantages and disadvantages of each technology.

2. DEFINATION

3D printing, also known as additive manufacturing, is a process of creating three-dimensional solid objects from a digital file. The object is built layer by layer using materials such as plastic, metal, resin, or ceramic. Unlike traditional manufacturing methods that involve cutting or drilling (subtractive manufacturing), 3D printing adds material only where it is needed, allowing for more complex designs, less waste, and faster.

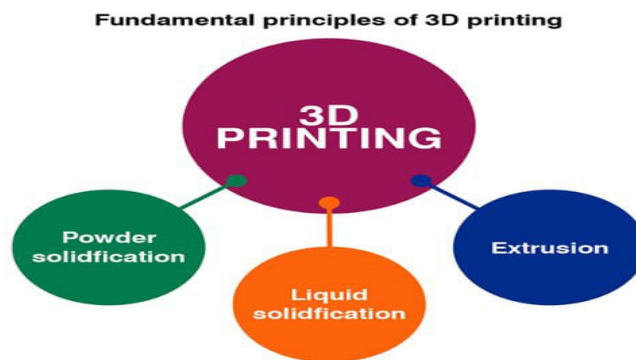


APPLICATIONS OF 3D PRINTING IN PHARMACEUTICAL PRODUCTS

1. Personalized Medicine: Customized dosage forms tailored to individual patient needs.
2. Complex Dosage Forms: Creation of complex tablet shapes and structures.
3. Modified Release Formulations: Controlled release profiles.
4. Multi-Drug Formulations: Incorporation of multiple active pharmaceutical ingredients.
5. Patient-Centric Designs: Dosage forms designed for specific patient populations.

BENEFITS

1. Improved Therapeutic Outcomes: Enhanced efficacy and reduced side effects.
2. Increased Patient Compliance: Customized dosage forms.
3. Flexibility in Design: Enables creation of complex dosage forms



EXAMPLES

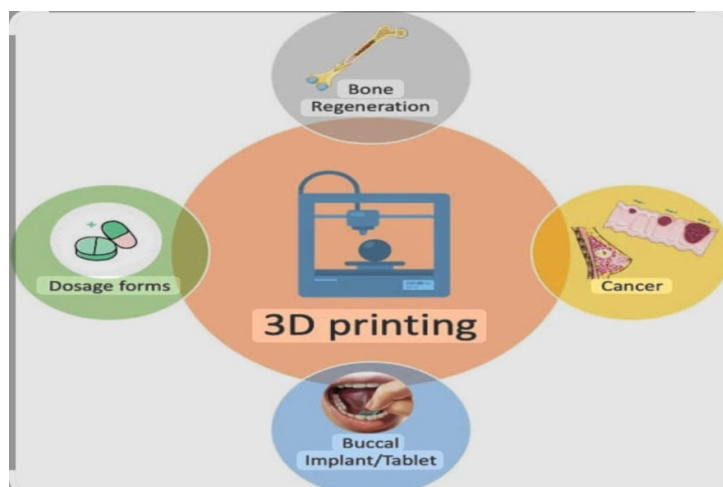
1. Printlets: 3D-printed tablets with controlled release profiles.
2. Polypills: 3D-printed tablets containing multiple active ingredients.

FUTURE DIRECTIONS

1. Regulatory Frameworks: Developing regulatory frameworks for 3D-printed pharmaceuticals.
2. Scalability: Scaling up 3D printing technology for commercial production.
3. Material Development: Developing pharmaceutical-grade materials suitable for 3D printing.

3. PRINTING PROCESS

Three-dimensional printing refers to the process of creating physical objects from digital models. A virtual 3D design file is created by computer-aided design (CAD) software using a 3D modeling program, a 3D scanner, or medical scanning techniques. The CAD data are then converted into multiple 2D cross-section layers. Following the predefined 2D pattern, a 3D printer manufactures a 3D structure without any need for an intermediate molding step. The advantages of 3D printing include design liberty, automation, manufacturing velocity, accuracy, customization, and minimal waste generation. The technique of producing a 3D-printed object consists of three critical steps, including data acquisition, image processing, and 3D printing of object.



The image shows a single orange pill labeled "3D PRINTED" among several white pills, highlighting the emerging technology of 3D printing in the pharmaceutical industry.

3D PRINTED PILLS

This technology, also known as Additive Manufacturing, involves depositing material layer by layer to create a three-dimensional object based on a digital model.

PHARMACEUTICAL APPLICATIONS:

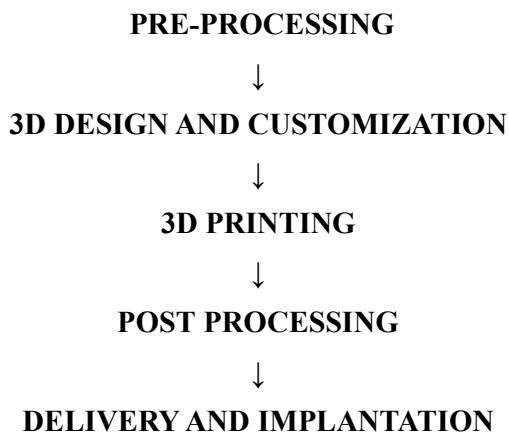
3D printing is being explored in pharmaceuticals to create customized medications with precise dosages and release profiles, potentially offering personalized medicine solutions.

ADVANTAGES:

This method can allow for complex geometries and drug combinations within a single pill, potentially improving drug delivery and patient adherence.

Example:

Spritam (levetiracetam) was the first 3D-printed drug approved by the FDA in 2015, used.



4. CONCLUSION

3D printing represents a transformative advancement in pharmaceutical science, offering unprecedented precision, personalization, and flexibility in drug formulation and delivery. By enabling the production of patient-specific dosage forms, complex drug-release profiles, and on-demand manufacturing, it addresses many limitations of conventional pharmaceutical methods. Despite challenges such as regulatory hurdles, material limitations, and scalability issues, ongoing research and technological innovations continue to expand its potential. As the field progresses, 3D printing is poised to play a crucial role in the future of personalized medicine, improving therapeutic outcomes and enhancing patient compliance. Continued interdisciplinary collaboration between pharmaceutical scientists, engineers, and regulatory bodies will be essential to fully realize and safely implement this technology in clinical practice.

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