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3D Printing In Novel Drug, Dosage Forms

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A B S T R A C T

3D printing is a modern way of making things by adding materials layers by layer from digital designs. It is used in many areas like making automobiles, pharmaceutical industry. In medicines it helps create personalized drugs and medical devices, such as implant and different forms of medicine that fit individual needs. The first 3D printing was approved in "2015". Which opened new possibilities for making complex medicines that release drugs in a controlled way and allow personal dosing.

However, there are still challenges to solve, including technical problems and rules to follow before this technology can be widely used in healthcare. Once these challenges are met, 3D printing can help provide more personalized care for patients. This review explains the common 3D printing methods used in making medicines and medical devices, including examples of drugs made with this technology that are still being developed or are already available.

Overall, 3D printing shows great potential to change how medicines and healthcare products are made by allowing for customization, faster production, and creating new types of treatments, improving healthcare for people.

KEY WORDS:- Three-dimensional printing, 3D printing technology, Medical devices, Solid oral dosage forms, Personalized medicines, Implant, Digital design, Manufacturing techniques, FDA approved 3D drug product (eg- spritam).

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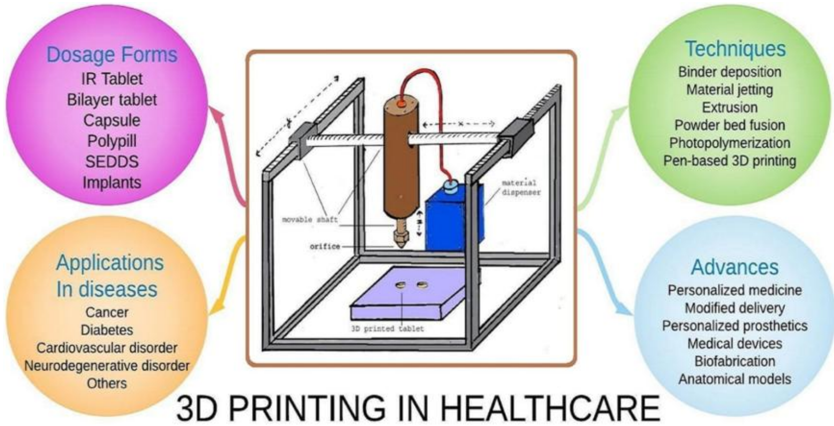
3D printing is a modern manufacturing method where objects are created by adding material layer by layer, using materials like plastics, metals, drugs, or even living cells. [1] This technology also called additive manufacturing, builds three-dimensional shapes from digital designs. It has many useful applications in fields such as healthcare, automobiles, aerospace, food technology, chemicals, and toy. In healthcare, 3D printing is particularly helpful for making customized drugs, prosthetics, implant, medical devices, and even engineered tissues and organs.[2] 4D printing is an advanced form of additive manufacturing where the printed object can change its shape or function over time when exposed to external factors such as temperature, pressure, moisture, or light. Similarly, 3D printing is a developing technique that creates living tissues by layering cells and biomaterials using special bio-inks.[3]. The manufacturing process starts with a computer created 3D model, which guides the printer in building the object. This method enables making drug dosages with precise release rate, ensuring better absorption, safety, and effectiveness and helping patients follow their treatment more easily.

printing is expected to change medicine and manufacturing by making prosthetic limbs, implants, dental devices, and organs more accessible and customizable. Studies predict that by 2019, more than 10% of people in developed countries might use 3D printed medical devices, and 35% of surgeries could involve 3D printed parts. As technology improves, around 10% of drugs and other products may by 3D printing. However challenges such as production consistency, quality control, and regulatory issues still remain, highlighting the need for further research and development.[4]

The FDA approved the first 3D printed drug (Spritam for epilepsy) which encouraged lots of research into 3D



HISTORY:-

3D printing also called additive manufacturing started in the early 1980s when Charles hull developed the first method known as stereolithography. In the beginning, this technology was mainly used in industries to create models and prototypes not for medicines. During the late 1990s and early 2000s, researchers slowly started exploring 3D printing in the medical field. This led to the first experiments in pharmaceuticals, where scientists tried different printing techniques such as inkjet printing and fused deposition modeling to make drug-loaded structures. These early studies showed that 3D printing could prepare tablets with unique shapes, personalized doses, and controlled drug release. A major turning point came in 2015, when the U.S. FDA approved Spritam® (levetiracetam) as the first 3D-printed drug. This medicine was made using ZipDose technology and showed that 3D printing could be safely used to make oral dosage forms. [5]

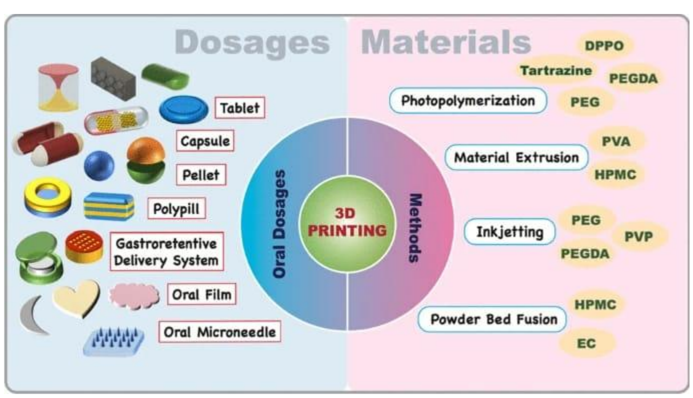
This approval encouraged many researchers to focus on this area. Since then, 3D printing has grown rapidly in the pharmaceutical field. It is now used to develop many novel drug dosage forms, such as orally disintegrating tablets, polypills, floating tablets, implants, microneedles, and personalized pediatric formulations. Advancements in printing materials, filaments, and computer-aided design have made it easier to prepare patient-specific medicines with improved drug release and better treatment outcomes.

Today, 3D printing is considered a promising and modern technique that can help produce personalized and on-demand medicines, especially useful in hospitals and specialized healthcare centers. As research continues, 3D printing is expected to bring major changes to how medicines are designed and manufactured in the future.[6]

WORKING MECHANISM:-

In 3D printing of medicines the process starts with making a digital design of the tablet on a computer. This design shows the shape, size, dose and how the drug should be released. The computer then cuts this design into many thin layers. Next the drug is mixed with suitable material like polymers to prepare filaments, powders, gels or liquids that the printer can use. Sometimes nanomedicine systems such as nanoparticles or nanoemulsions are also added to improve drug absorption.

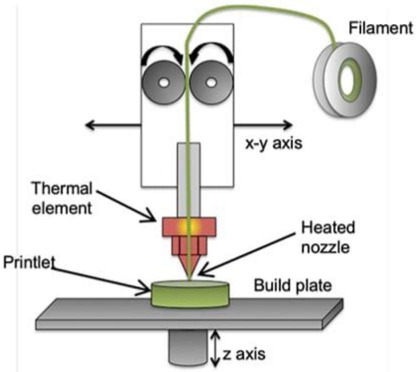
The 3D printer then builds the tablet layer by layer using different methods like melting a filament pressing out a gel curing a liquid with light or fusing a powder with a laser each layer becomes solid and slowly forms the final tablets inside design like pores or compartments which helps in controlling how fast or slow the drugs come out. After taking the printed dosage form it dissolves or breaks down and release the drug or nanocarrier in the body improving its action.[7]



Finally the finished product undergoes drying, curing, and quality checks like hardness, weight variation, drug content and dissolution testing to ensure safety and accuracy. Overall 3D printing helps in making personalized medicines with the exact dose, size and release pattern needed for each patient.

3D printing provides advanced features that improve the performance of medicines. It can produce tablets with different release pattern such as immediate, sustained release by modifying the internal structure. Multiple drugs can be loaded into separate compartments of a single tablet making treatment easier for patients who take many medicines. [8]

TYPES OF 3D PRINTING:-



Fused Deposition Modeling (FDM)

Different types of 3D printing technology are used to make solid oraldosage forms (tablets and capsules). They are mainly grouped into extrusion-based printing, vat photopolymerization, powder-based printing, and inkjet printing. All these methods start with designing the dosage form using computer-aided design (CAD) software. The design is then converted into thin layers using slicer software, and the printer builds the final structure layer by layer. Some techniques may need extra steps like drying, curing, removing excess powder, or polishing. Extrusion-based 3D printing is the most commonly used method in pharmaceuticals.[9] Here, the material is pushed out through a nozzle to build the tablet. Based on whether the material needs melting or not, extrusion-based printing is divided into two types:

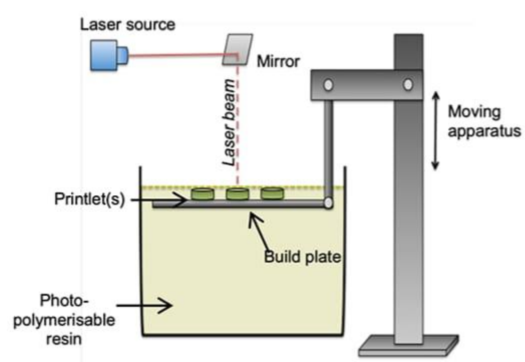
1. Fused Deposition Modeling (FDM) – requires melting the polymer.

2. Pressure-Assisted Microsyringe (PAM) - used when no heating is required and semi-solid materials can be printed.

Fused Deposition Modeling (FDM) works by heating a drug-loaded polymer filament and depositing it layer by layer to form the tablet. The drug can be added to the filament by soaking, mixing during extrusion, or filling an empty printed shell. FDM printers are low-cost and allow easy control over shape, structure, and drug- release patterns. They can also print tablets containing more than one drug. Another advantage is that no post-processing is required because the printed object is already solid. However, FDM has some limitations it needs high temperatures that may degrade heat-sensitive drugs, drug loading may be low, and only a limited number of pharmaceutical-grade polymers can be used. Also some complex shapes may need support materials to help them stick to the print bed, which must be removed after printing. [10]

Hot Melt Extrusion – Based Printing

Extrusion based 3D printing is one of the most commonly used method in the pharmaceutical field because it is simple and reliable. In this technique the printing material is pushed out through a nozzle using mechanical force. Based on whether the material needs to be melted before coming out of the nozzle the method is called Fused Deposition Modelling (FDM). But when the material can be printed without melting and only needs pressure to be pushed through the nozzle the technique is known as the Pressure Assisted Microsyringe (PAM)[11].



Stereolithography

SLA is a type of 3D printing where a laser cures liquid resin layer by layer to form a object. The laser moves according to the CAD design using mirrors to guide its path. After one layer is cured the build platform moves and the next layer is formed. Printed parts are usually washed with isopropyl alcohol to remove extra resin and then kept under UV light for final curing.

The resolution of SLA depends on the laser spot size, scanning speed, exposure time, and laser power.

SLA can make large and highly detailed models but printing can be slow because the laser must scan point. In this materials used include low molecular weight polyacrylates and epoxy based macromers.[12]

3D Bioprinting

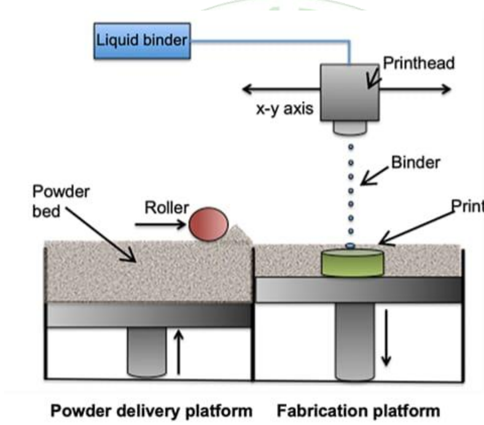
3D bioprinting is an advanced type of 3D printing used to create living tissues such as skin, cartilage, or small organ like structures. Instead of plastic or resin this method uses bio inks which contain living cells mixed with biocompatible material like hydrogels. In bioprinting the printer deposits the bio ink layer by layer following a digital design of the tissue or organ after printing the structure is kept in special conditions bioreactor so the cells can grow and form functional tissue.[13]

Inkjet Printing

Inkjet printing is a technique that creates tiny liquid droplets and places them exactly where needed. It has two types:-

1. Continuous Inkjet Printing:–A continuous stream of liquid comes out of the nozzle due to surface tension this stream breaks into small droplets.
2. Drop-on-Demand Printing:- Ink droplets are released only when required based on an electrical signal. These droplets are very small 10-50 micrometers.

The idea behind this droplet formation is based on Lord Rayleigh's Theory(1878), which explains how liquid streams naturally break into droplets.Originally inkjet printers were used to print picture by spraying ink on paper. But in pharmaceuticals the ink is replaced with drug containing solution and the paper becomes edible films. The dose can be controlled by adjusting no. of printed layers, size of printing area. [14,15].



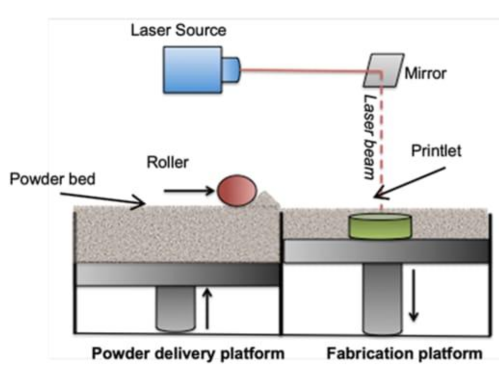
Binder Jetting

Binder jetting also known as drop-on-solid is a 3D printing process where a liquid binder is sprayed onto a bed of powder. The binder may contain the drug (API) or may be drug free. When the binder droplets fall on the powder the powder particles become wet and start sticking to each other.

This causes layer to become solid the solidification occurs either because the powder slightly dissolves in the binder and then re-crystalize.After each layer is printed the platform moves down and a fresh layer of powder is spread on top using a roller repeating the process until the full object is formed after printing the tablet is removed and loose powder is cleaned off this method was used to make spritam, the first FDA- approved 3D printing oral tablet. [16,17].

Selective Laser Sintering

Selective laser sintering also known as powder bed fusion is a 3D printingmethod introduced in 1989 by Carl Deckard and Joseph Beaman.

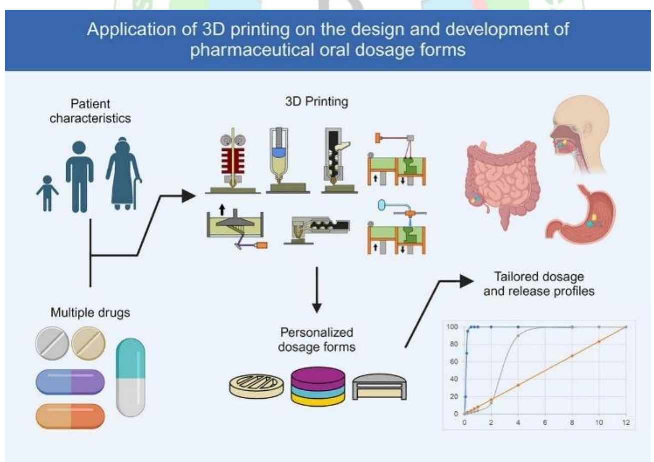


It works by using a high energy laser to fuse powdered material layer by layer. SLS can make tablets with different shapes and controlled drug release but its use is limited because high laser heat may affected drug stability.[18]

APPLICATION:-

3D printing is becoming an important technology in pharmacy because it allows medicines to be designed exactly according to a patient's needs. It can create complex shapes, multiple- drug combination and controlled release system that are difficult to make with traditional methods.

1. Personalized Medicine:-3D printing can produce tablets with customized doses, shapes, and release rates. This is useful for Children, Elderly patients, Patients with special dose requirements.
2. Controlled and Modified ReleaseTablets:-3D printers can make tablets with different internal structures, allowing:- Immediate release, Extended release, Pulsatile release, Zero-order release. This helps in better drug absorption and stable therapeutic effect.
3. Multi-Drug (Polypill) Tablets:-3D printing can combine different drugs in one tablet, each with its own release profile. This reduces pill burden and improves patient compliance.
4. 4.Fast-DisintegratingTablets:-Using porous structures (like ZipDose technology), 3D printing can create tablets that dissolve quickly in the mouth, helpful for patients who have difficulty swallowing.
5. Complex Geometries:- 3D printing allows the creation ofHollow tablets, Ring-shaped tablets, Multi-layered or core-shell structures.These designs help in controlling how fast or slowly the drug is released.
6. Implantable Drug Delivery Systems:- Biodegradable implants can be printed todeliver drugs slowly for weeks or months.
Applications include: Cancer therapy, Hormone delivery, Local antibiotic release.
7. Transdermal and Topical Systems:- 3D printing can producer: Microneedle patches, Customized wound dressings, Drug-loaded scaffolds. These help in painless drug delivery and faster wound healing.
8. Oral Films and Buccal Systems:-Thin, flexible films with precise drug doses can be printed for quick absorption mouth.
9. Pediatric and Geriatric Dosage Forms:- 3D printing helps prepare, Flavored tablets, Chewable forms, Small-dose individualized medicines.This improves acceptance and adherence in children and elderly patients.
10. Tissue Engineering & Regenerative Medicine:-
Bioprinting supports the creation of Drug testing tissue method, organ on chip system, cell loaded scaffolds for regenerative therapy. [19,20,21]



HOW 3D PRINTING IS APPLIED IN NOVEL DRUG DOSAGE FORMS (NDDF)

3D printing is applied in NDDF by designing and fabricating medicines layer by layer using computer-controlled printers. This allows the creation of dosage forms that cannot be made using traditional tablet machines.

1. Designing the Dosage Form (CAD Model):-The shape, size, dose, and release profile are designed on a computer. This digital model guides the printer.

2. Selecting the Printing Technology:-

Different printing methods are used depending on the drug and formulation:

- SLA/DLP - for high-accuracy structures
- FDM-for drug-loaded filaments
- SLS/Powder bed - for porous tablets
- Inkjet printing - for printing drug layers or films
- Bioprinting for cell or tissue-based systems [22]

3. Preparing the Printing Material:-

- The drug is mixed with:
- Polymers
- Resins
- Powders
- Hydrogels (in bioprinting)
- This becomes the raw material (ink/filament/powder) for printing.

4. Layer-by-Layer Manufacturing:-

- The printer deposits the material layer by layer, forming:
- Tablets
- Capsules
- Films
- Microneedles
- Implants
- This allows very accurate control of dose and structure.[23]

5. Creating Special Structures:-

- Printing enables
- Hollow tablets
- Core-shell systems
- Porous structures
- Multi-drug polypills
- These structures help achieve controlled release, fast disintegration, or targeted delivery.

6. Post-Processing:-

- Depending on the technique, printed products may need
- Drying
- UV curing
- Powder removal
- This ensures proper strength and stability.

LIMITATIONSAND CHALLENGS:-

Some 3Dprinting method can formtablet that are porous, uneven, or irregular inshape, which makes them hard for patients to swallow.This reduces patient acceptance in few techniqueslike inkje based printing the tablets is exposed to heat. Which can leave behind more residual solvents than the allowed limit because of these issues the process needs careful control to make sure the final dosage is safe and of good quality.

CONCLUSION:-

3D printing is becoming an important technology in the development of drug dosage forms, because it allows precise control over drug release, dose, and tablet shape. Itmakes itpossible to create personalized medicines,complex release profiles, and even multi-drugtablets in a single unit. Although there are somelimitations, such as process complexity andquality control challenges, ongoing researchcontinues to improve the technology. Overall, 3D printing offers great potential to change the future of pharmaceutical manufacturing and provide better, patient-centered treatments.

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