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A Review on 3d And 4d Printing of Pharmaceuticals: A Prospective Technology in Developing Personalized Formulations

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ABSTRACT:Over the past few decades, three-dimensional (3D) printing has greatly aided in the creation of patient-specific prosthesis, drug administration, tissue and organ manufacturing, and surgery planning. Since the US established its Precision Medicine Initiative in 2015, there has been a surge in interest in personalized healthcare. The term "personalized medicine" basically describes patient-specific medical treatment. However, the biomedical materials used in 3D printing are frequently stable and incapable of responding to or being intelligently and adaptively adapted to the inside environment of the body. A disparity between the printed section and the target portions may result from ex-situ manufacturing of these materials, which involves printing on a flat substrate before releasing it onto the target surface. One technique that could be applied to offer individualized care is 3D printing. The components used in the development of four-dimensional (4D) printing can be adjusted through stimulation.

Recently, a number of academics have begun examining a novel field that combines 3D and 4D printing with medications. Many of these problems are resolved by the development of 4D printing, which also bodes well for thebiomedical sector going forward. Pre-programmed smart materials can be utilized in 4D printing to produce structures that respond interactively to external stimuli.

KEYWORDS: 3D printing, 4D printing, smart material, pharmaceutical, biomedical

I. INTRODUCTION

The combination of cutting-edge 3D and 4D printing technologies is causing a revolutionary shift in the pharmaceutical sector. These developments are opening the door to a tailored, effective, and flexible healthcare system in the future, in addition to improving conventional medication design and manufacturing procedures. These technologies are tackling some of the most important issues in contemporary health, including medication efficacy, accessibility, and patient compliance, by fusing pharmaceutical science with engineering precision.

The pharmaceutical industry has seen a change because to 3D printing, sometimes referred to as additive manufacturing, which makes it possible to precisely manufacture products layer by layer. This technology has opened up previously unheard-of possibilities for quick prototyping, complex geometric designs, and personalized medicine compositions. Its capacity to provide solutions customized for each patient has expanded the realm of what is conceivable in healthcare by providing individualized therapies.

Adding a new level of versatility to 3D printing, 4D printing builds upon its basis. 4D printing has created new opportunities for dynamic and responsive medication delivery systems by using smart materials that can alter their form, characteristics, or functionality in response to external stimuli like light, pH, or temperature. The increasing need for personalized medicine, in which therapies are tailored to each patient's particular physiological and genetic traits, is well matched with this revolutionary breakthrough.

HISTORICAL DEVELOPMENT OF 3DAND 4D PRINTING IN PHARMACEUTICALS

Early Developments of 3D printing in Pharmaceuticals:

Initially, the emphasis was on developing medication delivery and medical device prototypes. Researchers quickly discovered that the ability to produce customized medications using 3D printing might completely transform the drug manufacturing industry.

• 2015: Aprecia Pharmaceuticals' Spritam®, the first 3D-printed medication, received FDA approval. ZipDose® technology was used to produce precisely dosed, quickly dissolving tablets for this epilepsy treatment. This significant achievement proved that 3D printing may be used to create oral dosage forms with customized medication release patterns.

• 2010s: To develop novel medicine formulations, researchers started experimenting with a variety of 3D printing processes, including inkjet printing, selective laser sintering (SLS), and fused deposition modeling (FDM).

• 2020s: Developments in bioprinting made it possible to produce organ models and tissue-like structures, broadening the use of 3D printing in drug testing and regenerative medicine

Early Developments of 4D Printing in pharmaceuticals:

The creation of scaffolds and self-folding capsules was among the first uses of 4D printing in the pharmaceutical industry. Active pharmaceutical components could be encapsulated in these structures and released in a controlled way.

For instance, scaffolds that could changeinto particular forms were made using hydrogels with various curing techniques. This allowed the delicate medications to be encapsulated and protected until they reached their intended location.

THEROLE OF 3D PRINTING IN PHARMACEUTICALS

By providing new opportunities beyond conventional manufacturing techniques, 3D printing is revolutionizing the pharmaceutical sector.

FDA Approval: The first FDA-approved 3D-printed medication was Spritam® (levetiracetam). Patients with epilepsy benefit from its rapid dissolution and enhanced medication absorption.

Advanced Techniques: To build intricate drug forms and delivery systems, technologies such as Selective Laser Sintering (SLS), Stereolithography (SLA), and Fused Deposition Modeling (FDM) are employed. These techniques improve the efficacy of medications and assist regulate their release. Customized medications, such polypills that combine multiple medications into a single tablet, are made easier by 3D printing. This promotes improved patient follow-up and simplifies treatment.

INTEGRATION OF 3D AND 4D PRINTING

Medicine is changing as a result of 3D and 4D printing.

These technologies aid in the development of patient-specific medications and therapies.

- Scientists and governments are fully supporting this innovation.
- The objective is more accurate, adaptable, and patient-centered treatment.
- As technology advances, it may be able to resolve challenging medical issues and increase access to health care globally.

a) 3-Dimensional Printing b) 4-Dimensional Printing

3D AND 4D PRINTING IN PERSONALIZED MEDICINES

Personalized Medicine Using 3D Printing

Customized medications can be made with the aid of 3D printing. Polypills, which are tablets that combine multiple medications into one, are one example. This facilitates treatment and aids in medication adherence.

For patients with chronic illnesses or children who require specific dosages, doctors can create medications that release different medications at different times.

A unique kind known as bioprinting creates tissues using materials and living cells. This is helpful for testing novel medications and creating organ models that aid in surgery.

Personalized Medicine Using 4D Printing

Using materials that can alter shape or behavior in response to stimuli like heat, light, or acidity, 4D printing is similar to 3D printing but more intelligent.

Smart Materials: Under the correct circumstances, these can release medication just in particular bodyparts.

Self-Assembling Devices: These devices are more

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accurate and easier to make because they can developshapes on their own.

These materials' adaptive responses enable them target the right spot and lessen adverse effects by adjusting to changes inside the body.

ADVANTAGES AND DISADVANTAGES OF 3D PRINTING IN PHARMACEUTICALS

Advantages of 3D printing in pharmaceuticals:

1.Flexible Design: By modifying size, shape, and density, 3D printing enables the customisation of medications.
2.Children: It can provide kid-friendly, low-dose medications that look and taste nicer, which will encourage kids to take them.
3.Elderly: For elderly people who have trouble swallowing, loose, porous pills can be helpful.
4.Multi-drug Patients: By combining many drugs into one pill, missed doses can be decreased and safety is increased.
5.Practical Uses: Businesses such as FabRx (UK) employ 3D printing to provide customized medications for kids with unusual illnesses. They have carried out clinical trials and put printers in hospitals throughout Spain.
6. Controlled Drug Release: Customized release patterns and intricate drug designs can be produced via 3D printing.[1]

Disadvantages of 3D printing in pharmaceuticals:

1.Issues with Product Safety
Businesses can't manage every printer, but they can share drug plans for local printing. This may result in defective medications and legal issues.
2.The possibility of hacking
Cybercriminals may make deadly counterfeit medications by stealing drug blueprints.
3.Difficulties with Regulation
Safety and quality control are impacted since it is difficult for organizations like the FDA to keep an eye on every printing activity.
Restricted Resources
4.A limited number of materials are suitable for 3D drug printing, which restricts the range of medications that can be produced.
5.3D printing is slower and more difficult to scale for mass manufacturing than conventional techniques.

ADVANTAGES AND DISADVANTAGES OF 4D PRINTING IN PHARMACEUTICALS

Advantages of 4D printing in pharmaceuticals:

1.More intelligent drug delivery: 4D-printed medications have the ability to alter shape over time, releasing medication precisely where it is needed.
2.Personalized therapies: Drugs can be customized to meet the needs of each individual.
3. Improved Manufacturing:Reduced waste: Utilizes fewer resources, making it more environmentally friendly.
Saves energy: Uses less energy than traditional techniques.
4. Saves Time & Money: Self-changing designs eliminate unnecessary production processes, resulting in afaster process.
Decreased expenses: It is less expensive due to fewer errors and quicker output.
5. Eco-friendly: Green materials: Makes use of sustainable and biodegradable materials.
More errors: Precise printing results in fewer faulty items.
6. New Medical Possibilities: Smart implants: Internally adjusting devices that improve healing.
Ingenious packaging: Containers that respond to their environment to maintain the stability of medications.

Disadvantages of 4D printing in pharmaceuticals:

1. Design Is More Complex: To manage items that alter shape, 4D printing requires additional procedures.
Compared to standard 3D printing, this makes design more difficult.
2. Limited Research: Because it's a relatively young field, there aren't many studies yet.
3. To properly comprehend it, more research is required.
4. Shape-Memory Materials Are Still Being Developed: The usage of materials that "remember" shapes is still in its infancy.
Compared to 3D printing, 4D printing is still in its infancy.
5. Smart Materials Are Exciting but Not Yet Ready: Researchers are experimenting with novel materials.
- They need more refinement, but they have the potential to transform the game.
6. Accuracy Is Difficult: It's challenging to achieve the precise size and shape.
- It's challenging because the printing settings fluctuate a lot.

METHODS OF 3D PRINTING IN PHARMACEUTICALS

1.FUSED DEPOSITION MODELING (FDM):

Modeling of Fused Deposition Compared to Selective Laser Sintering, printers are more affordable and more widely used. Instead of using

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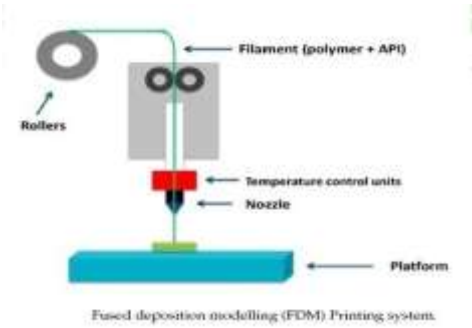
ink, heated plastic beads are ejected from the print head in fused deposition modeling printers, creating thin layers of the item. The polymer, which is applied layer by layer, solidifies to create the exact shape that computer-aided design models intended.

FDM 3D printing has a number of drawbacks, including
• Insufficiently appropriate polymers
• Insufficient assessment of the drug's and additives' miscibility with the polymers; sluggish and occasionally insufficient drug release as a result of the drug remaining trapped in the polymers.[2,3,4]



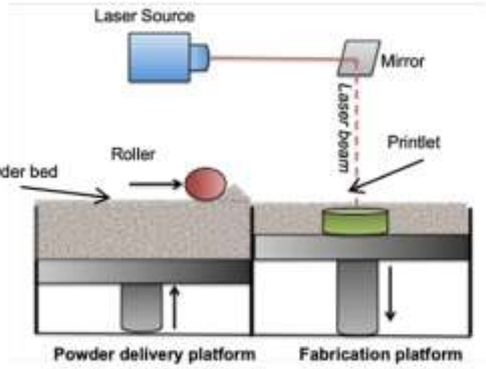
Fused Deposition Modeling(FDM)

2.SELECTIVE LASER SINTERING:

In order to bind powder particles, this method uses a laser that is directed to draw a particular pattern on the powder bed, resulting in selective partial or complete melting. After the layer is sintered, a new layer of powder is applied on top of the sintered material using a roller. To create a 3D-printed medication, the procedure is carried out layer by layer.

Benefits:
• Able to quickly dissolve and generate extremely porous dosage forms:
• able to create a variety of formulation types, such as medical devices and controlled-release or immediate-release dosage forms;
• able to produce complicated geometries using a high resolution process;
•Suitable for polypill manufacture.

The following are drawbacks:
• May not be appropriate for medications that are photosensitive or thermosensitive:
• Post-processing is necessary;
• Precise control over powder flow characteristics is necessary.



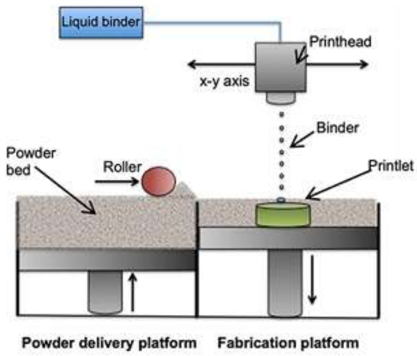
Selective Laser Sintering

3.BINDER JET PRINTING:

A binder liquid is deposited onto a flat powder surface by a nozzle that travels along an x-y axis. Layer solidification results from the liquid binding the powder particles together. Next, the vertical z-axis is used to shift the manufacturing build plate downward.

To create a 3D-printed medication, a small coating of powder is applied on top, and the procedure is repeated one after the other.

Benefits include:
• ability to create formulations for zero order release (a medication released at a steady rate) and delayed release; • utilized to create the first 3D printed medication ever approved by the US Food and Drug Administration (FDA):
• Able to create formulations with both immediate and prolonged release:
• Complex geometries can be formed thanks to high resolution.
The costly procedure and the absence of portable equipment are drawbacks.



Binder jet printing

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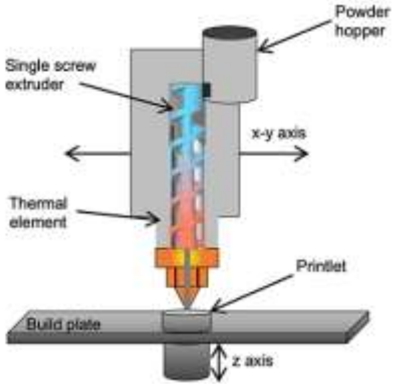
4.DIRECT POWDER EXTRUSION:

A drug-loaded formulation blend is put into a powder hopper using an extrusion-based method. A heated single screw extruder in the print head receives the hopper's feed, producing a molten extrudate that solidifies onto a build plate at room temperature. A 3D-printed medication can be made layer by layer by successively lowering the build plate along the vertical z-axis.

Benefits:
• Able to create formulations with both immediate and sustained release
• By creating amorphous solid dispersions, it is possible to increase the solubility of medications that are weakly soluble:
• Scalable (Triastek proved this by creating an FDA investigational new drug application clearance for a formulation made using a comparable technique).

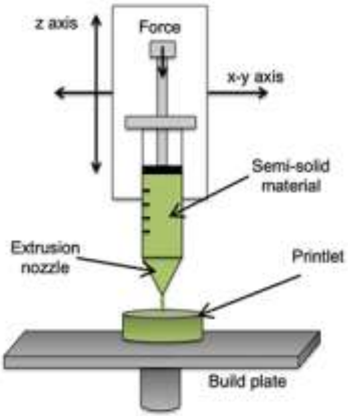
Cons:
• May not be appropriate for medications that are sensitive to heat:
• Pharmaceuticals using relatively new 3D printing technology.



Direct powder extrusion

5.SEMI-SOLID EXTRUSION (SSE) / DIRECT EXTRUSION:
A syringe-based tool head is used to extrude a drug-loaded semi-solid substance (such as gel or paste). The extrudate, which solidifies at room temperature onto a build plate, is released by moving the printer head along the x-y-z axis.
Benefits:
• Suitable for creating chewable and palatable formulations; • Able to create a variety of formulation types, such as oral films, polypills, and immediate-release and controlled-release dose forms.

The following are drawbacks:
• Low resolution in comparison to alternative 3D printing technologies
• Low throughput; only appropriate for medications that can be made semi-solid.



Semi-Solid Extrusion (SSE)

6.STEREOLITHOGRAPHY:

A photopolymerisable resin is exposed to high-energy light, such as ultraviolet light, in order to cause polymerization and material solidification. After the resin has solidified to a certain depth, the platform is lowered vertically along the z-axis, and resin is applied again to the constructed layer. To make a 3D-printed medication, the procedure is repeated.

Benefits:
• Widely investigated for manufacturing medical devices and sustained-release pharmaceutical products:
• Complex geometries can be produced thanks to high resolution and precision (better than other 3D printing technologies):
• Suitable for creating multi-layered polypills; • Capable of increasing the solubility of poorly soluble medications.

Cons:
• May not be appropriate for medications that are photosensitive:
• Possible problems with the toxicity of the materials.

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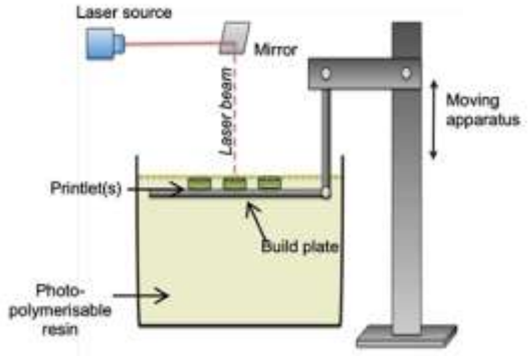


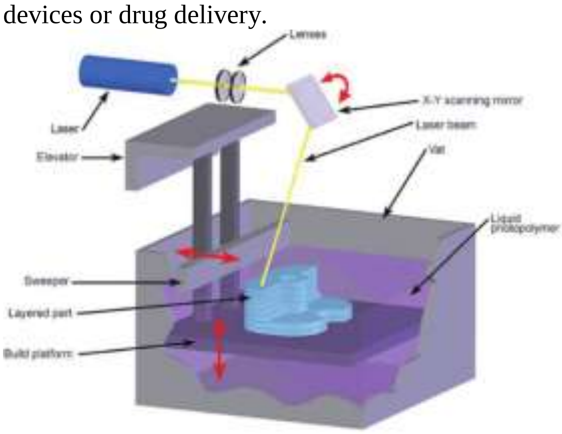
Stereolithography

METHODS OF 4D PRINTING IN PHARMACEUTICALS

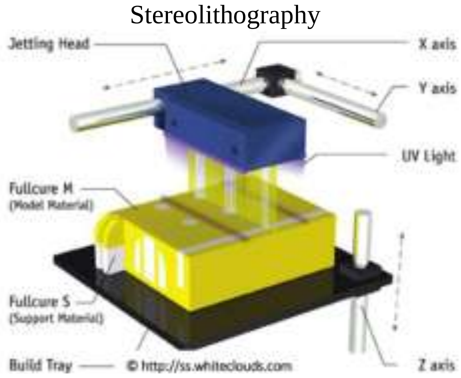
1. The operation of Vat Photopolymerization (SLA & DLP): Layer by layer, a liquid resin solidifies when exposed to UV radiation.

4-D twist: The resin contains unique componentsthat react to light or heat, allowing the object to change shape over time.

Use case: Excellent for printing soft materials, like as hydrogels, which are utilized in small medical devices or drug delivery.



Stereolithography



Digital light processing

2. EXTRUSION OF MATERIALS (FDM & DIW)

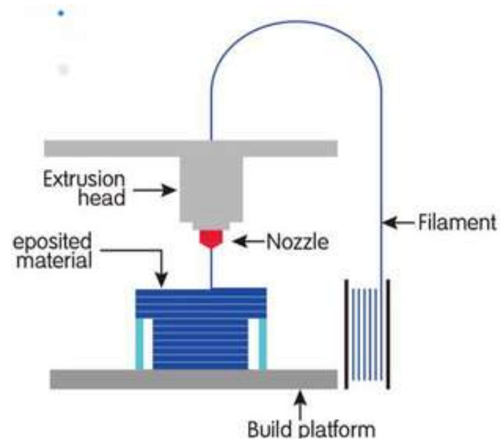
How it operates:

Plastic filaments are melted and deposited in layers using FDM.

DIW: Uses a nozzle to squeeze out thick pastes or inks.

The4D twist

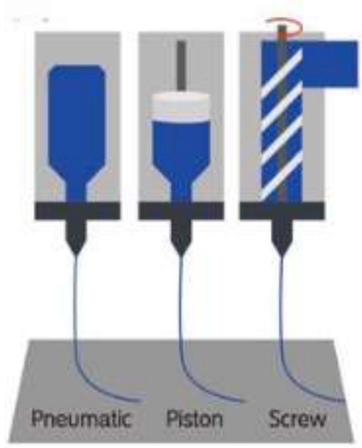
FDM: Makes use of intelligent filaments that, when heated, change shape.



Fused deposition modelling

DIW: Makes use of responsive inks that respond totemperature and moisture.

Use case: Ideal for creating intricate shapes, timed drug-release tablets, and folding devices.



Direct ink writing

3.SELECTIVE LASER SINTERING (SLS):

Principle: To produce a solid item, a laser selectively fuses powdered material layer by layer. Due to material restrictions, 4D adaptation is less frequent for direct pharmaceutical products than vat photopolymerization or material extrusion; nonetheless, it can be applied to powdered smart

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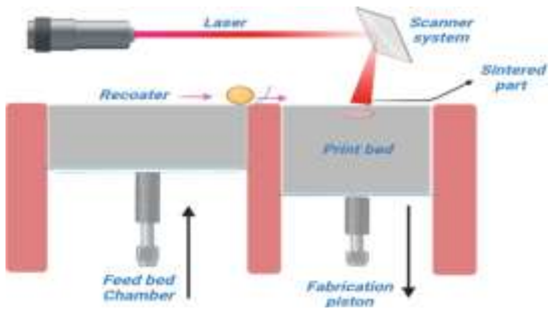
materials whose properties vary in response to external stimuli.

Applications: Investigated for scaffolds or specialty implants where porosity and mechanical strength are essential.



Selective Laser Sintering (SLS)

Stimuli-Responsive Materials in 4D Printing for Pharmaceuticals:

When exposed to a particular stimulus, such as light, pH, or temperature, shape memory polymers (SMPs) can be programmed to take on a momentary shape before returning to its initial form. They are frequently utilized in drug delivery systems that have the ability to alter the body's shape.

Hydrogels are networks of hydrophilic polymers that can expand or contract in reaction to alterations in temperature, ionic strength, pH, or other chemical cues. They are perfect for 4D printed medicine delivery systems because they can encapsulate medications and release them in a regulated manner in response to environmental cues.

When exposed to stimuli like heat, liquid crystal elastomers (LCEs), which combine the characteristics of elastomers with liquid crystals, can undergo large and complicated deformations (such as bending and twisting).[5,6,7,8]

CHALLENGES OF 3D PRINTING IN PHARMACEUTICALS

- Although promising, 3D printing in drug development is still in its formative stages and faces several technical and practical barriers.
- Key issues in the optimization processinclude:
  - Enhancing the device’s adaptability for broader pharmaceutical uses
  - Selecting suitable excipients
  - Implementing effective post-processing treatments
  - Expanding its utility in advanced drug delivery platforms
- Precision parameters like the number of printing passes, head movement speed, layer intervals, and nozzle-powder alignment require fine-tuning to maintain product quality.
- Binder formulations must be optimized and compatible with printer hardware to ensure consistent output.
- Techniques like uniaxial compression and suspension dispersion can boost drug loading, but they often lead to increased complexity and nozzle blockage.
- Some printing methods, such as Fused Deposition Modeling (FDM), use heat that can degrade sensitive compounds—like proteins—making them unsuitable for heat-sensitive drugs.
- Dosing often relies on empirical approaches, which can increase the risk of side effects.
- Scaling production for commercial use remains challenging compared to traditional manufacturing techniques.[9,10]

LIMITATIONS OF 4D PRINTING IN PHARMACEUTICALS

1. Material Constraints:

- Smart materials that respond to stimuli (temperature, pH, light, magnetism) are vital for 4D printing but finding biocompatible and regulatory-approved ones is still limited.
- Achieving reliable mechanical performance and controlled degradation in the body is difficult; degradation products must be safe and easily processed by the body.
- Some materials or their transformation byproducts may be toxic or lose functionality over time—especially those triggered by light.

2. Fabrication Complexity:

- Developing 4D printed systems demands deep expertise in material science and response mechanisms; programming dynamic transformations adds further difficulty.
- Achieving precision, especially at micro/nano scales, is technically challenging and essential for therapeutic reliability.
- Industrial scalability struggles with issues such as slow printing speeds, lack of uniformity, and high cost.
- Printing multi-material devices often leads to compatibility issues and structural instability.
- Additional steps like curing and surface treatment are needed post-printing, adding time and complexity.

3. Regulatory and Ethical Concerns:

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- Current regulatory frameworks are ill-equipped to handle the dynamic nature of 4D pharmaceuticals.
- Ensuring consistent quality, especially for devices that change shape or function over time, is a major hurdle.
- While 4D printing supports personalized medicine, it raises concerns around cost, time, and standardization for individualized treatments.
- Ethical questions also arise regarding the long-term safety of smart materials in the human body and the need for clear usage guidelines.[11-15]

EMERGING FRONTIERS OF 3D PRINTING IN PHARMACEUTICALS

1.Tailored Therapies and Precision Dosing

- A groundbreaking shift in drug production is underway, thanks to 3D printing. It offers the capability to craft personalized medications—fine-tuned for each individual's age, weight, genetic makeup, and medical history.
- Customized Tablets: 3D printing supports the formulation of tablets with exact doses, specific shapes, and combinations of active ingredients. This reduces the need to take multiple pills and improves adherence in vulnerable groups like the elderly or children.
- Point-of-Care Production: Medications can be made directly at hospitals or pharmacies, allowing swift access to treatments for rare disorders.
- Controlled Release: Complex internal tablet designs can enable customized drug release patterns, improving therapeutic outcomes.

2. Next-Level Drug Delivery Systems

The technology unlocks advanced delivery mechanisms once deemed impossible.

- Drug-Infused Implants: Patient-specific stents or prostheses embedded with medications provide targeted and sustained release for conditions like heart disease and arthritis.
- Microneedle Arrays: These tiny, painless patches can deliver medicine through the skin, offering alternatives to injections for conditions like diabetes.
- Multi-compartment Designs: Tablets with separate layers allow incompatible drugs to be administered together, each releasing on a schedule.

3. Accelerating R&D and Trials

3D printing enhances research efficiency, shaving time off drug development timelines.

- Fast Prototyping: Scientists can rapidly test various formulations to identify optimal candidates for clinical trials.
- Eco-Conscious Production: Material waste is minimized, especially helpful when working with high-cost substances.
- High-Fidelity Testing Platforms: Creating cell-based models using bioprinting enables more accurate simulations of human disease environments for testing drugs.

4. Merging with Digital Health

The next chapter involves syncing 3D printers with real-time health data.

- Automated Medication Production: Genomic and diagnostic inputs could guide printers to customize drugs on demand.[16-20]

FUTURE DIRECTIONS OF 4D PRINTING IN MEDICINE

1. Intelligent and Adaptive Drug Release

4D printing introduces drug systems that respond to environmental triggers.

- Smart Timing: Tablets could release drugs when exposed to specific pH levels or temperatures—ideal for gut-targeted treatments.
- Individualized Patterns: Complex geometries and materials allow dosing schedules to be customized for each patient.
- Retention Devices: Shape-shifting tools may stay longer in body areas like the stomach, improving drug absorption.
- Responsive Microneedles and Implants: These devices adjust over time to deliver drugs exactly when needed, such as localized chemotherapy.

2. Personalized Devices and Therapies

4D printing brings truly individualized care.

- Genetically Tuned Formulas: Dosage forms can be tailored based on metabolism and disease type.
- Smart Tools: Devices like stents or catheters may adapt to anatomical changes for better fit and function.

3. Innovation in Excipients

New materials drive the 4D printing revolution.

- Shape-Memory Carriers: Hydrogels and polymers that morph in response to triggers create dynamic delivery systems.
- Biodegradable Options: Materials that dissolve safely reduce the need for surgical removals.

4. Bioprinting for Research and Regeneration

Though outside classic pharmaceutical boundaries, bioprinting is transformative.

- Organs-on-Chips: These lab-grown structures simulate human biology, improving drug testing accuracy.
- Evolving Tissue Scaffolds: Printed scaffolds encourage tissue growth while shifting shape to aid healing.[21-25]

II. CONCLUSION

The advent of 3D and 4D printing in pharmaceutical research signals a transformative shift toward more customized and efficient healthcare solutions. These advanced technologies support intricate drug formulations, combination therapies, and intelligent release systems that adapt to individual patient profiles. While regulatory hurdles, material validation, and production scalability still pose challenges, the field continues to progress rapidly. As these innovations integrate further with digital platforms like artificial intelligence, they are set to revolutionize drug manufacturing and delivery—ushering in a future where therapies are not just effective, but precisely attuned to each person's unique needs.

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