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THREE-DIMENSIONAL PRINTING IN PHARMACEUTICS AND HEALTHCARE: TECHNOLOGIES, APPLICATIONS, PERSONALIZED MEDICINE AND FUTURE PERSPECTIVES

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ABSTRACT

Additive manufacturing or three-dimensional (3D) printing is an emerging technology in pharmaceutical and medical industries. It allows for the layer-by-layer creation of dosage forms with tailored shape, drug loading, internal architecture, and release characteristics, in contrast to traditional manufacture. This review discusses the essential ideas and workflow of 3D printing, including computer-aided design, STL conversion, slicing, fabrication, and post-processing. Major printing technologies, such as fused deposition modeling, stereolithography, digital light processing, continuous liquid interface production, selective laser sintering, selective laser melting, semi-solid extrusion, and inkjet printing, are reviewed with emphasis on their operating mechanisms, advantages, limitations, and pharmaceutical relevance. Applications in pediatric and geriatric formulations, patient-specific dosage, polypills, immediate-, sustained-, and pulsatile-release systems, osmotic systems, and 3D-printed microneedles are also highlighted in the review. The review also addresses ethical and regulatory considerations related to sterility, material safety, process validation, quality control, and patient safety. Overall, 3D printing represents a versatile platform for customized and controlled drug delivery; however, material limitations, scalability, safety, and regulatory challenges remain important barriers to broader clinical translation.

KEYWORDS: Three-dimensional printing; additive manufacturing; personalized medicine; drug delivery; microneedles; pharmaceutical technology.

INTRODUCTION

Three-dimensional (3D) printing, also known as additive manufacturing (AM), is a fabrication technology that uses computer-aided digital models to construct objects layer by layer. This technology enables the creation of patient-specific dosage forms with adjustable drug loading capacities, dimensions, and release profiles in pharmaceutical applications.[1]

The development of modern 3D printing can be traced to Hideo Kodama's work in 1981, which described an automated method for fabricating three-dimensional objects by sequentially stacking solidified layers using a photopolymerization process. The core concepts of additive manufacturing, including as layer-by-layer fabrication, computer-controlled operation, and photopolymer curing, were established by this method and continue to serve as the foundation for modern stereolithography and digital light processing technologies.[2]

LIMITATIONS OF CONVENTIONAL PHARMACEUTICAL MANUFACTURING

In contrast to 3D printing, which allows for programmable and adjustable fabrication tailored to individual therapy, conventional pharmaceutical manufacturing methods are primarily based on mass production principles designed to produce standardized, fixed-dose formulations. These approaches are effective for large-scale production; however, they have

significant limitations when individualized therapy is required.[1] These limitations include the following:

- Inability to provide patient-specific dosing
- Limited control over complex release kinetics;
- Difficulty incorporating multiple drugs into a single dosage form;
- Inadequate flexibility for precision medicine applications.[1]

ROLE OF 3D PRINTING IN PERSONALIZED MEDICINE

By customizing care based on each patient's unique features, including genetics, age, sex, physiological state, and lifestyle, personalized medicine seeks to maximize therapeutic efficacy and reduce side effects. Healthcare professionals may quickly adjust drug dosage, tablet geometry, release kinetics, and formulation composition in accordance with patient-specific treatment needs thanks to this technology.3D-printed tablets have a number of customization benefits like,

- Adjustable dosage,
- Customized release profiles,
- Controlled-release characteristic that can be programmed,[1]

FUNDAMENTALS OF 3D PRINTING

The method of turning virtual solid model data into tangible things by splitting the model into a number of two-dimensional cross-sections and constructing the part layer by layer is known as additive manufacturing (AM).[3] By adding consecutive layers of material to computer models, three-dimensional printing is an additive manufacturing technology that creates items. Computer-aided design (CAD) software is used to create a three-dimensional model, which is then stored in stereolithography (STL) format and imported into printer software for printing parameter generation and slicing. Then, softened thermoplastic material is deposited from a heated extrusion head to create the object layer by layer. The product is taken off the construction platform after printing and its functional and physical attributes are assessed.[4]

Step 1: Modelling with Computer-Aided Design (CAD)

Using computer-aided design (CAD) software, a three-dimensional model that specifies the intended object's geometry, dimensions, and structural characteristics is first created.

Step 2: Conversion to STL

After that, the CAD model is transformed into a standard file format (STL) file, which is the standard file format for the majority of additive manufacturing platforms and depicts the item surface as a mesh of connected triangular facets.

Step 3: Slicing

The STL file is imported into slicing software, where the three-dimensional model is divided into a series of thin two-dimensional layers and converted into printer-specific instructions or toolpaths.

Step 4: Fabrication Layer by Layer

The additive manufacturing system builds the object layer by layer until the final structure is finished by systematically depositing, curing, or fusing material in accordance with the sliced data during printing.

Step 5: Post-processing

To obtain the required dimensional accuracy and functional performance, the printed item is taken off the build platform after fabrication and put through post-processing procedures such cleaning, surface finishing, support removal, and property enhancement.[3]

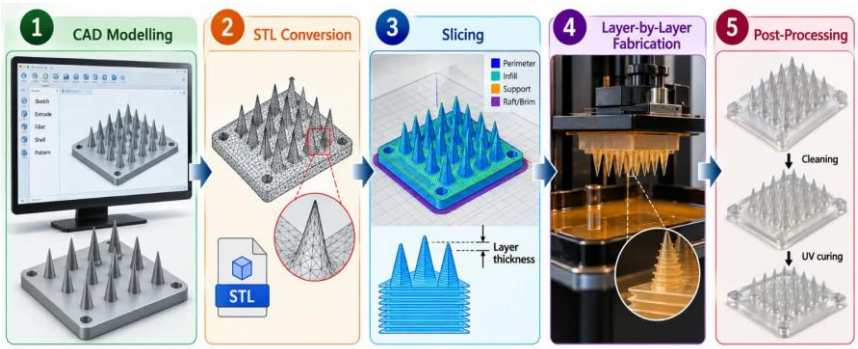

Figure 1: Diagrammatic depiction of the typical 3D printing process.

CLASSIFICATION OF 3D PRINTING TECHNOLOGIES

1. MATERIAL EXTRUSION

Fused Deposition Modeling (FDM)

Principle

A thermoplastic filament is fed into a heated nozzle, softened or melted, and then deposited in consecutive layers to create a three-dimensional item using fused deposition modeling (FDM), a material extrusion-based additive manufacturing technology. Controlled extrusion and solidification of polymeric material in accordance with a digital design form the basis of the process.[4]

Working Mechanism

The printing process in fused deposition modeling (FDM) starts with the creation of a three-dimensional model using computer-aided design (CAD) software, which is then transformed into machine-readable instructions (G-code) using slicing software. Two counter-rotating rollers constantly feed a thermoplastic filament, like Polylactic Acid (PLA), into the extrusion system after it has been coiled on a spool. The filament is heated to a molten or semi-molten condition as it travels through a heated liquefier and nozzle.

The molten material is then deposited onto the build platform in a preset pattern by the nozzle moving in three degrees of freedom in accordance with the programmed toolpath. The material cools and solidifies after deposition, creating a firm link with the layer that was previously placed. After each layer, the build platform or print head is moved, and this procedure is repeated until the desired dimensions and shape are obtained. Depending on the material used, the part is either snapped off or soaked off the build platform after printing is finished. To enhance its surface appearance and functional performance, the printed component may subsequently go through post-processing procedures including cleaning, sanding, polishing, painting, or machining.[5]

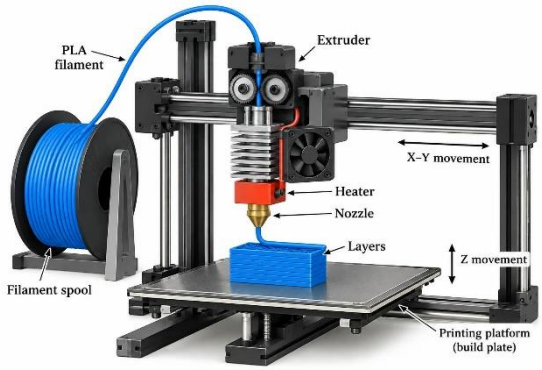

Figure 2: Working mechanism of fused deposition modeling.

2. VAT PHOTOPOLYMERIZATION

Stereolithography (SLA)

Principle

A liquid photosensitive resin containing monomers or oligomers and a photoinitiator is selectively exposed to ultraviolet (UV) or visible light, which causes the exposed regions to polymerize and form a solid cross-linked polymer network. This process is the foundation of stereolithography (SLA). Chain polymerization of the resin molecules is started by the photoinitiator, which absorbs light energy and produces reactive species like free radicals. The object is made layer by layer in accordance with a digital design since only the lighted parts are polymerized. SLA is especially appropriate for thermolabile active medicinal components since it enables the creation of extremely precise dose forms without subjecting the medication to high temperatures.[6]

Working Mechanism

In stereolithography, a STL file is created by first designing the intended dosage form using computer-aided design (CAD) software. This file is then cut into a number of thin two-dimensional layers. A resin vat is filled with a liquid photosensitive resin that contains photopolymerizable monomers or oligomers, a photoinitiator, and, if necessary, the active medicinal component. The build platform is positioned between 25 and 100 µm, which is the thickness of the first layer. The areas that correspond to the first layer are selectively irradiated by a concentrated ultraviolet (UV) laser beam or projected light pattern.

The exposed liquid is transformed into a solid polymer layer when the photoinitiator is activated by the absorbed light, producing free radicals that start the polymerization and crosslinking of the resin. In order to allow fresh uncured resin to flow over the previously hardened layer, the build platform is moved vertically by one layer thickness after curing. After that, the next layer is exposed and polymerized, creating a solid connection with the layer underneath. Until every layer is created and the entire three-dimensional structure is produced, this process of selective light exposure, photopolymerization, and platform movement is repeated. After that, the printed item is taken out of the resin vat, cleaned to remove any remaining uncured resin, and post-cured under UV light to finish polymerization and enhance structural stability and mechanical strength.[7,8]

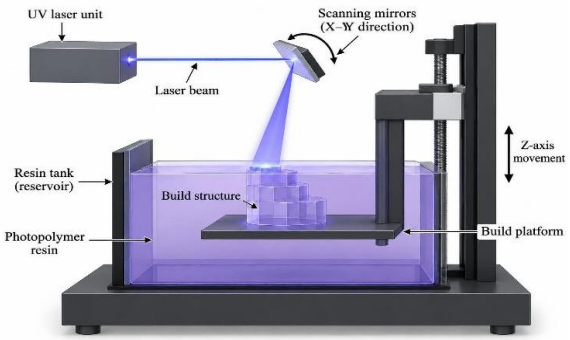

Figure 3: Working mechanism of stereolithography.

Digital Light Processing (DLP)

Using ultraviolet (UV) light, Digital Light Processing (DLP), a vat photopolymerization-based 3D printing technique, selectively cures liquid photoreactive resins into solid objects layer by layer.[9]

Principle

Using a Digital Micromirror Device (DMD) to photopolymerize liquid resin is the foundation of DLP printing. In accordance with a digitally created pattern, the DMD's hundreds of tiny mirrors selectively reflect UV light onto particular areas of the photoreactive

polymer surface. While the unexposed areas stay liquid, the exposed areas go through polymerization and solidify. A complete three-dimensional object is created by repeating this technique layer by layer. DLP cures an entire layer at once, as opposed to stereolithography (SLA), which uses a laser to scan the resin surface point-by-point. This results in faster manufacturing and more efficiency. The technology primarily depends on.

- UV light source
- DMD, or digital micromirror device
- Resin that is photoreactive
- Layer-by-layer curing process using photoinitiator.[9]

Working Mechanism

Digital Light Processing (DLP) 3D printing is an additive manufacturing method based on vat photopolymerization that selectively cures liquid photopolymer resin into solid structures layer by layer using ultraviolet (UV) light. A three-dimensional computer-aided design (CAD) model is first prepared. It is then divided into several thin layers, each of which is transformed into a two-dimensional digital mask image. A Digital Micromirror Device (DMD), which has thousands of tiny mirrors that selectively reflect light in accordance with the intended pattern, is used to direct UV light from a projector system during printing. The liquid resin's surface is exposed to reflected UV radiation, which causes the exposed areas to polymerize and solidify while the unexposed areas stay liquid. The process is repeated until the entire three-dimensional item is created. Once one layer has hardened, the build platform moves vertically to allow fresh resin to cover the previously solidified layer. DLP produces quicker printing speeds, higher resolution, and better dimensional accuracy than traditional stereolithography (SLA), which uses a laser beam to cure material point-by-point.[10]

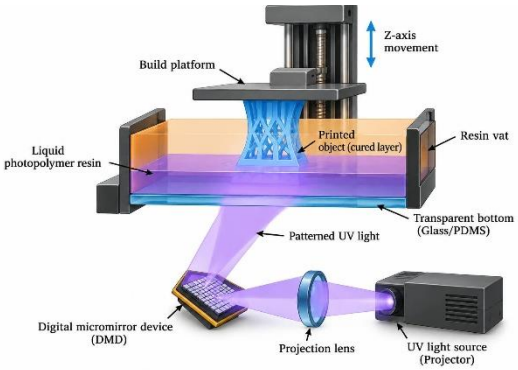

Figure 4: Working mechanism of digital light processing.

Continuous Liquid Interface Production (CLIP)

Principle

Continuous Liquid Interface Production (CLIP) is a sophisticated vat photopolymerization-based 3D printing technique that constantly creates three-dimensional polymeric structures from liquid photoreactive resin using ultraviolet (UV) light and controlled oxygen inhibition. The establishment of an oxygen-inhibited "dead zone" between the curing window and the surface of the polymerizing component forms the basis of CLIP. This dead zone allows for continuous resin flow and uninterrupted printing by preventing the cured polymer from sticking to the glass. In contrast to traditional stereolithography, which creates objects layer by layer, CLIP produces much quicker production speeds and smoother structures by continuously curing resin while the item is steadily dragged upward from the resin solution.[10]

Working Mechanism

A liquid photopolymer resin is applied over a UV-transparent, oxygen-permeable window in CLIP printing. Through this window, a continuous series of UV pictures produced by a digital light projection system are projected onto the resin. The "dead zone," a thin, uncured liquid interface created by oxygen seeping through the permeable window, inhibits photopolymerization. When the resin is exposed to UV light above this dead zone, it undergoes polymerization and solidification. Meanwhile, the build platform keeps moving upward, pulling the finished object out of the resin bath. Fresh liquid resin constantly flows beneath the printed structure at the same time, enabling continuous production without the need for separate layer separation procedures. Variables including photon flux, oxygen permeability, photoinitiator concentration, and resin curing characteristics all affect how thick the dead zone is. To avoid adhesion between the cured object and the window surface, this oxygen-inhibited layer must be properly maintained.[10]

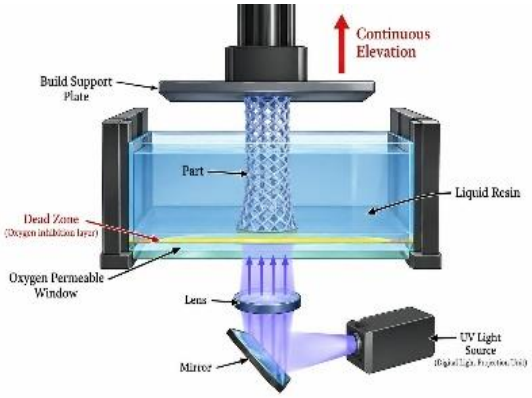

Figure 5: Working mechanism of continuous liquid interface production.

Table 1: Comparison of SLA, DLP and CLIP 3D Printing Techniques.

Feature	SLA	DLP	CLIP
Working principle	A focused UV laser selectively cures the resin point-by-point according to the cross-section of each layer.	A digital projector exposes an entire 2D layer at once using a mask image.	A digital projector continuously cures the resin while an oxygen-permeable window creates a "dead zone" that prevents adhesion, allowing continuous printing
Light Source	Focused UV laser	UV LED + Digital Projector (DMD)	UV LED + Digital Projector (DMD)
Curing Mechanism	Point-by-point scanning and curing	Layer-by-layer exposure and curing	Continuous exposure and curing with oxygen-inhibited "dead zone"
Build Movement	Platform moves vertically after each layer	Platform moves vertically after each layer	Platform moves continuously upward
Speed	Slow (point-by-point)	Faster (whole layer at once)	Very fast (up to hundreds of mm/hour)
Resolution	High (25–100 µm)	High (25–100 µm)	High (<100 µm)
Surface Finish	Good	Good	Excellent with smoother surface and minimal layer lines
Advantages	High accuracy, good for fine detailed parts, wide material availability	Faster than SLA, simple optical setup, good accuracy	Very high speed, smooth surface, high accuracy, continuous process, suitable for complex parts and controlled drug delivery
Limitations	Slow printing, laser scanning increases fabrication time, limited build volume in some systems	Layer-by-layer process slower than CLIP, visible layer lines, possible light scattering limitations	Limited to photocurable resins, requires precise control of oxygen and resin properties, trade-off between speed and resolution, possible drug degradation and cytotoxicity
Applications	Dental models, prototypes, surgical guides, biomedical models, microfluidics	Prototypes, dental devices, hearing aids, engineering components	Biomedical devices, drug delivery systems, brachytherapy spacers, tissue engineering scaffolds, microstructures

3. POWDER BED FUSION

Selective Laser Sintering (SLS)

Principle

A powder bed fusion-based additive manufacturing process called selective laser sintering (SLS) creates three-dimensional objects layer by layer by fusing powdered materials together using the energy produced by a laser beam. In pharmaceutical applications, solid oral dosage forms with regulated geometry, porosity, and drug release properties are created by selectively sintering thermoplastic polymer powders containing active pharmaceutical components in accordance with a computer-aided design (CAD) model.

Working Mechanism

Before being sent to the printer software, the dose form in SLS printing is first created using CAD software and transformed into an STL file. To create a thin powder layer, powder is placed into a reservoir platform and evenly distributed around the build platform using a sled. The chamber is heated to a temperature lower than the polymeric material's melting point or glass transition temperature prior to printing. The powder bed is then scanned by a blue diode laser along the X and Y axes in accordance with the predetermined geometry. Through thermal sintering, the laser energy partially or totally unites nearby powder particles. The build platform lowers, a fresh layer of powder is applied, and the laser scanning procedure is repeated layer by layer along the Z-axis until the final structure is achieved.

After printing, extra unsintered powder is brushed away and the printlets are taken out of the powder bed. During fabrication, the leftover loose powder also serves as a self-supporting framework, doing away with the necessity for further support elements.

Selective Laser Melting (SLM)

Principle

Selective Laser Melting (SLM) is a powder bed fusion-based additive manufacturing process that creates three-dimensional structures directly from computer-aided design (CAD) models by fully melting and fusing fine metal powder particles layer by layer using a high-energy laser beam. SLM creates totally dense structures by completely melting and solidifying the powder material, in contrast to selective laser sintering (SLS), which partially fuses powders. To avoid oxidation during laser melting, the procedure is conducted in an inert gas atmosphere, such as nitrogen or argon.[13]

Working Mechanism

Selective Laser Melting (SLM) starts with the creation of a three-dimensional computer-aided design (CAD) model, which is then transformed into STL format and cut using specialist software into several thin cross-

sectional layers. During printing, a recoating roller or blade mechanism evenly applies a small layer of metallic powder to the build platform. After that, a scanning mirror system directs a high-energy laser beam onto the powder bed, where it selectively scans the areas that correspond to the object's required cross-section.

SLM uses a far greater laser power density to fully melt and fuse the metallic powder particles together, producing dense and structurally robust structures, in contrast to Selective Laser Sintering (SLS), which only partially fuses powder particles. After being exposed to a laser, the molten metal quickly hardens, creating a layer on the build platform. After a layer is finished, a new layer of powder is applied over the previously formed layer while the build platform descends by a predetermined layer thickness. Until the entire three-dimensional structure is created, the laser scanning and melting procedure is then repeated for the ensuing layers.[14]

Semi-Solid Extrusion (SSE)

Principle

An extrusion-based additive manufacturing method called semi-solid extrusion (SSE) 3D printing is used to create three-dimensional structures out of semi-solid or paste-like materials with the right rheological characteristics. In order to create the desired structure, gels, hydrogels, or viscous pastes are extruded via a nozzle, often at room temperature or under mild processing conditions, and deposited layer by layer in accordance with a predetermined computer-aided design (CAD) model. Following deposition, the printed object solidifies either spontaneously or with post-processing methods such chemical crosslinking, freeze-drying, or drying. Because SSE does not require high-temperature melting during printing, it is especially useful for thermosensitive pharmaceuticals.[15]

Working Mechanism

The creation of the drug-loaded semi-solid formulation, material extrusion, layer-by-layer deposition, and post-processing or solidification are the four main steps in the SSE printing process. To create a printable gel or paste, the active pharmaceutical ingredient (API) is first mixed with a semi-solid matrix of polymers, solvents, and excipients. Because the material must have enough viscosity to retain structural integrity after deposition while yet being extrudable through the nozzle, the formulation's rheological behavior is crucial.[15]

A syringe-based extrusion system is filled with the prepared mixture. Piston-driven or screw-driven mechanisms operating under regulated mechanical or pneumatic pressure can extrude material. Extrusion pressures often fall between 3 and 5 bar.[16]

In accordance with the CAD-generated toolpath, the semi-solid material is constantly extruded through a nozzle and deposited layer by layer onto the build platform during printing. The deposition pattern is determined by the nozzle's movement along the X–Y axes, but vertical layer stacking and the creation of three-dimensional objects are made possible by movement along the Z-axis. To enhance mechanical stability, structural integrity, and drug-release characteristics, the manufactured item may go through further post-processing steps such solvent evaporation, drying, freeze-drying, or chemical/physical crosslinking after printing.[15] Nozzle diameter, extrusion pressure, extrusion rate, nozzle movement speed, and the rheological characteristics of the formulation all have a significant impact on the printing performance of SSE systems. Although smaller nozzle diameters increase printing resolution, they also necessitate higher extrusion pressures and raise the possibility of structural collapse because of longer printing times.[16]

Inkjet Printing

Principle

The controlled creation and deposition of microdroplets onto a substrate without direct contact between the printhead and the substrate is the basic idea behind inkjet printing. Using computer-aided designs, the droplets are created digitally and deposited in accordance with predetermined coordinates.[17]

Two systems are primarily used in inkjet printing.

- Drop-on-Demand Inkjet Printing (DoD)
- Continuous Inkjet Printing (CIJ)

In order to eject droplets from the nozzle in the direction of the substrate, the principle depends on overcoming surface tension forces. DoD printing is typically utilized in pharmaceutical applications because it reduces material waste and provides exact control over droplet volume. The technology makes it possible.[17,18]

- Accurate dosage deposition
- Fabrication layer by layer
- regulated release of drugs
- Manufacturing customized medications
- High-volume drug testing

Working Mechanism

Continuous Inkjet Printing (CIJ)

In CIJ systems, pressure is used to push a constant stream of liquid ink via a nozzle. The stream splits into homogeneous droplets as a result of Rayleigh instability and surface tension effects. Unused droplets are recycled back into the reservoir, while chosen droplets are electrically charged and directed onto the substrate using electrostatic plates.

Mechanism

- Formulation is continuously supplied by the ink reservoir.
- A liquid stream is produced by a high-pressure pump.
- The stream splits into droplets.
- Droplets are selectively charged using electrodes.
- Droplets that are charged are aimed at the substrate.

- Droplets that are not used are recycled.[18]

Drop-on-Demand Inkjet Printing (DoD)

Droplets are only ejected by DoD systems as necessary. This technique is frequently used in pharmaceutical printing because it offers more precision and less drug waste. DoD printing is further divided into.

- Piezoelectric Inkjet Printing (PIJP)
- Thermal Inkjet Printing (TIJ)
- Electrostatic Inkjet Printing
- Electrohydrodynamic Inkjet Printing (EHD)[18]

Piezoelectric Inkjet Printing (PIJP)

Piezoelectric crystals are affixed to the printhead chamber of piezoelectric printers. Applying an electric voltage causes the crystal to mechanically deform, creating pressure waves that force droplets out of the nozzle. Droplet creation does not involve any heating, in contrast to thermal systems.

Mechanism Steps

- Electrical pulse applied
- Piezoelectric crystal deforms
- Pressure wave generated
- Ink droplet expelled
- Chamber refills.[17]

Thermal Inkjet Printing (TIJ)

The printhead of thermal inkjet printers is equipped with tiny resistors. The resistor quickly warms the ink to about 200–300°C for a brief period of time (~2 µs) when an electric pulse is applied. Droplets are forced out through the nozzle by the abrupt expansion of vapor bubbles created by this heating. Following droplet ejection.

- The bubble bursts
- There is negative pressure.
- The chamber is refilled with fresh ink.[18]

Electrostatic Inkjet Printing

Electrostatic forces are used in electrostatic systems to create and guide droplets. Electrostatic fields direct the droplets toward the substrate, while mechanical impulses cause displacement in the fluid chamber. Its resolution is decreased by variations in the electric field during multilayer printing.

Features

- Absence of thermal stress
- Ideal for inks that incorporate cells
- Excellent for printing with hydrogel[18]

Electrohydrodynamic Inkjet Printing (EHD)

Strong electric fields between the nozzle and substrate (0.5–20 kV) are used in electrohydrodynamic printing. Surface tension is overcome by the electric energy, creating a fine jet known as the "cone-jet mode."

Features

- incredibly tiny droplet size
- Printing with high resolution

PHARMACEUTICAL APPLICATIONS OF 3D PRINTING

Personalized Medicine

One of the most revolutionary uses of pharmaceutical 3D printing is personalized medication. 3D printing makes it possible to create patient-specific dosage forms with configurable drug content, geometry, release characteristics, and combinations of active pharmaceutical ingredients (APIs), in contrast to traditional mass-manufacturing techniques that create fixed-dose pharmaceuticals. Precise control over dosage strength, tablet architecture, porosity, and interior structure is made possible by computer-aided design (CAD) software, enabling tailored treatment based on pharmacokinetic requirements, age, body weight, and illness state.[19,20]

Patient-Specific Dosing

The capacity of 3D printing to create tablets with exact medication amounts customized to each patient's needs is one of its main benefits. This is especially helpful for medications with limited therapeutic indices, pediatric patients who need weight-adjusted dosages, and older patients who need dose adjustments because of changed pharmacokinetics. On-demand production of customized medications is made possible via layer-by-layer fabrication, which allows for variable dose variation without requiring a change in manufacturing equipment.[19,22]

By altering tablet dimensions, infill density, geometry, and internal architecture, 3D printing allows for precise drug content customization. This feature is especially useful for medications with limited therapeutic indices and for patient populations that need customized dose titration. Dosage strengths can be changed using computer-aided design (CAD) without changing the manufacturing infrastructure, enabling really customized pharmacotherapy.[21]

Polypills

The creation of polypills with several medications in a single dosage form is made easier by 3D printing. Incompatible medications can be accommodated in separate compartments that have different release characteristics. This feature lessens the burden of pills, increases patient compliance, and streamlines complicated treatment plans that are frequently seen in long-term conditions including diabetes, hypertension, and cardiovascular problems. Polypills are the result of additive manufacturing's capacity to separate several active pharmaceutical ingredients (APIs) into a single dose form. These systems minimize drug-drug interactions while incorporating medicines with different physicochemical characteristics and release kinetics. By lowering pill load and streamlining treatment plans,

polypills increase patient adherence, particularly in chronic conditions needing multimodal therapy.[19,21]

Pediatric Applications

Children frequently need age-appropriate formulas and adjustable dosage. Chewable tablets, quickly disintegrating formulations, and customized dosage levels are all made possible by 3D printing. To increase patient acceptance and adherence, tablet size, shape, color, and taste-masking techniques can be changed. Age-appropriate formulations and flexible dosing are often necessary for pediatric patients. Chewable tablets, quickly dissolving dose forms, and strengths that may be adjusted based on age and body weight are all made possible via three-dimensional printing. Additionally, altering the size, shape, color, and flavor of tablets can increase pediatric populations' compliance.[19]

Geriatric Applications

Polypharmacy and dysphagia are common in elderly people. Orodispersible tablets, modified-release formulations, and multi-drug dose forms that increase treatment adherence while lowering dosing frequency can be made thanks to three-dimensional printing. The quantity of tablets needed each day might be reduced using customized medication combinations.[19]

Dysphagia, polypharmacy, and altered pharmacokinetics are common in elderly individuals. The creation of customized dosage forms with altered release properties and less frequent administration is made easier by additive manufacturing. For senior patients, customized multi-drug tablets can greatly increase adherence and therapeutic efficacy.[21]

Modified Release Systems

By controlling tablet architecture, infill density, shell thickness, and surface-area-to-volume ratio, additive manufacturing's geometric flexibility allows for exact adjustment of drug release kinetics. As a result, 3D printing has become a potent tool for creating sophisticated modified-release systems.[19,24]

Immediate Release Systems

Drug release is expedited by highly porous structures created by selective laser sintering and binder jetting processes, which provide quick dissolution media penetration. Immediate therapeutic action and quick pill breakdown can be achieved by optimizing the internal architecture. Highly porous features that facilitate quick drug release and dissolving media penetration are used to create immediate-release formulations. Rapidly disintegrating tablets have shown great promise because to technologies like selective laser sintering and binder jetting.[19]

Sustained Release Systems

Diffusion channels, infill %, and polymer composition can all be changed to ensure sustained release. Long-term drug release over several hours or days while preserving therapeutic drug concentrations is made possible by hydrophilic matrices, biodegradable polymers, and multilayer structures.[24]

Drug distribution, infill density, polymer composition, and shell thickness can all be changed to manage sustained drug release. Biodegradable polymers and hydrophilic matrices enable extended therapeutic effect while lowering dosage frequency.[25]

Pulsatile Release Systems

Drug release in segregated dose forms with preset lag times is made possible by three-dimensional printing. When administering medication in accordance with the circadian rhythms of an illness, such methods are very helpful for chronotherapeutic treatment.[24]

Drugs are released via pulsatile mechanisms after a certain lag time. Additive manufacturing-fabricated multi-compartmental structures allow for exact temporal control of drug release, which makes them appropriate for chronotherapeutic applications.[26]

Osmotic Systems

Additive manufacturing techniques can be used to create complex osmotic pump structures. Controlled osmotic pressure-driven medication release with little impact from gastrointestinal circumstances is made possible by precise control over membrane thickness, pore geometry, and drug compartment design.[24]

Complex osmotic devices with drug reservoirs, semipermeable membranes, and controlled-release orifices can be made thanks to three-dimensional printing. These devices provide consistent release kinetics regardless of physiological fluctuations.[26]

Multi-Drug Polypills

One of the most promising uses of pharmaceutical 3D printing is multi-drug polypills. A single dosage form with distinct release kinetics can contain several APIs thanks to segmented architecture. These methods facilitate the management of chronic illnesses needing combination therapy, increase adherence, and lower prescription mistakes.[19]

Microneedles

Therapeutic substances can be delivered minimally invasively through the stratum corneum using microneedle-assisted transdermal devices. The creation of extremely accurate microneedle geometries suited for medication distribution and penetration efficiency is made possible by three-dimensional printing.[24]

Solid Microneedles - Drugs then diffuse through the temporary microchannels that solid microneedles produce in the skin.

Hollow Microneedles - Internal lumens in hollow microneedles allow liquid formulations to be actively infused into the dermal layers.

Coated Microneedles - Coated microneedles use a surface coating that quickly dissolves after insertion to administer medication.
Dissolving Microneedles - Biodegradable polymers with encapsulated medications are used to create dissolving microneedles. The drug payload is released when the matrix dissolves after implantation.
Hydrogel-Forming Microneedles - After being inserted, hydrogel-forming microneedles absorb interstitial fluid, swell, and establish diffusion channels that link dermal tissue to an external drug reservoir.[24]

Regulatory and Ethical Considerations of 3D Printing in Pharmaceuticals and Medical Devices

Significant ethical and legal issues have arisen as a result of the quick uptake of three-dimensional (3D) printing in the pharmaceutical and medical industries. Although 3D printing makes it possible to create customized drug delivery systems, personalized implants, and patient-specific therapies, current regulatory frameworks were created for traditional mass-manufacturing processes and frequently fail to take into account the special features of additive manufacturing. Therefore, strong quality control, process validation, repeatability, sterility assurance, intellectual property protection, and patient safety procedures have been highlighted by regulatory bodies including the FDA, EMA, and IMDRF.[27,28]

FDA Regulations

The Food and Drug Administration (FDA) in the United States regulates 3D-printed medical products based on their intended use and risk classification. Medical devices are divided into Class I, Class II, and Class III categories, and as patient risk increases, so do the regulatory requirements. Before being approved for marketing, high-risk implantable devices usually need to undergo a thorough safety and performance evaluation.[29]

Regulatory Pathways

For high-risk 3D-printed devices, manufacturers generally must obtain.

- **Investigational Device Exemption (IDE)** for clinical testing.
- **Premarket Approval (PMA)** demonstrating safety and effectiveness.
- **Humanitarian Device Exemption (HDE)** for devices intended to treat rare diseases.

The FDA places considerable emphasis on

- Design control
- Risk management
- Process validation
- Material characterization
- Device performance testing
- Post-market surveillance

Because current regulatory frameworks were initially created for conventionally manufactured products rather than customized, additively manufactured systems, the growing use of three-dimensional (3D) printing in the pharmaceutical and biomedical industries has created significant regulatory challenges. The unique features of additive manufacturing, such as customization, digital design workflows, and on-demand production, necessitate specialized regulatory oversight to guarantee product quality, safety, and efficacy, according to regulatory organizations like the International Medical Device Regulators Forum (IMDRF), the European Medicines Agency (EMA), and the United States Food and Drug Administration (FDA).[30,31]

CONCLUSION

Three-dimensional printing has emerged as a versatile additive manufacturing platform with considerable potential to transform pharmaceutical and healthcare applications. Its ability to fabricate dosage forms with customized geometry, drug loading, internal architecture, and release characteristics provides important advantages over conventional manufacturing approaches, particularly for personalized medicine. Technologies including fused deposition modeling, stereolithography, digital light processing, continuous liquid interface production, selective laser sintering, selective laser melting, semi-solid extrusion, and inkjet printing offer different processing capabilities and opportunities depending on the properties of the drug and intended dosage form. Pharmaceutical applications extend from patient-specific dosing and paediatric and geriatric formulations to polypills, immediate-, sustained-, pulsatile-, and osmotic-release systems, as well as 3D-printed microneedles. Despite these advances, challenges related to material selection, drug stability, printing reproducibility, scalability, quality control, sterility, and regulatory requirements continue to limit widespread clinical translation. Future progress will depend on improved printable pharmaceutical materials, robust process validation, standardized quality-control approaches, and appropriate regulatory frameworks. Overall, the integration of 3D printing with emerging digital and intelligent manufacturing technologies offers significant opportunities for developing safer, more flexible, and patient-centered drug delivery systems.

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