Advances In 3d Printing For Pharmaceutical Dosage Form Design And Application.

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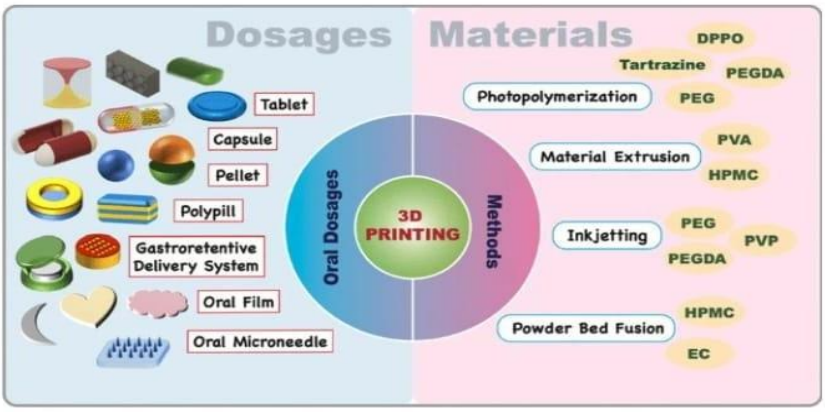
Abstract: 3D printing, also known as additive manufacturing, is a new technology used to make customized medicines through computer-based designs. Its use in the pharmaceutical field has increased rapidly in recent years. This emerging technology offers great potential by enabling precise construction of dosage forms, versatile drug-release profiles, and patient-centric treatments such as personalized dosing and formulations for specific disease states or patient groups. It also supports digital drug development and manufacturing. This review highlights how 3D printing accelerates early- stage drug development, aids pre-clinical and early human studies, and supports late-stage manufacturing. The advantages, current progress, and challenges in large-scale production and personalized dosing are outlined, along with regulatory considerations for the adoption of 3D printing in pharmaceuticals.

Graphical Abstract



Keywords: 3D printing technology, three-dimensional printed drug, drug delivery, personalized medicine, research status, Oral dosage form, Early phase clinical trials, large scale manufacturing, Personalized dosing, Regulatory consideration.

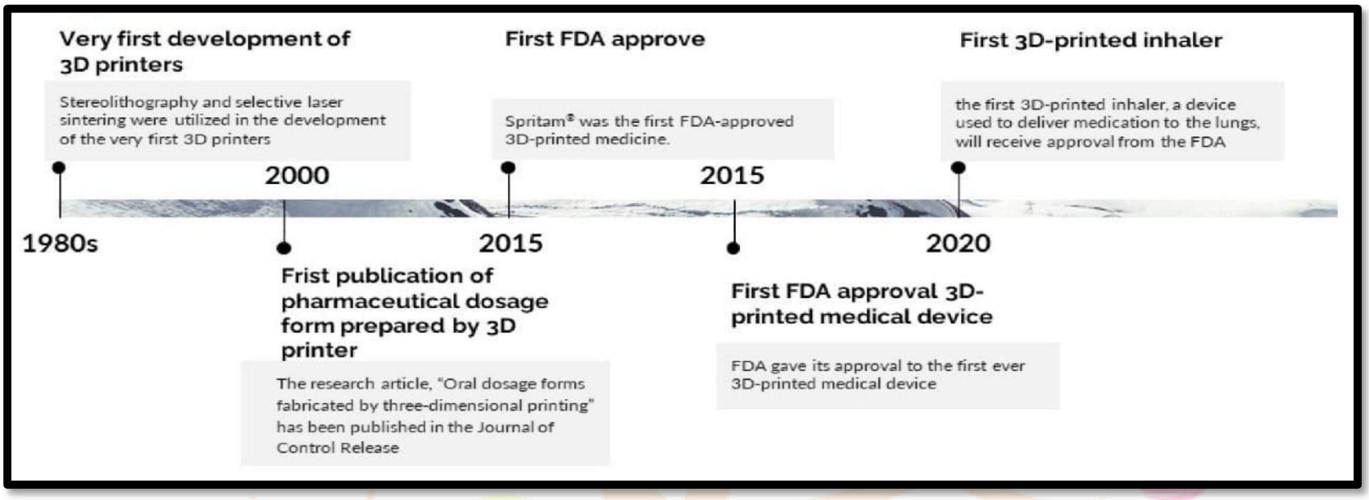
Introduction:

Three-dimensional (3D) printing, as defined by ISO, involves creating objects by depositing materials through a print head or nozzle. Unlike traditional subtractive or formative methods, it is an additive manufacturing (AM) process where components are built layer by layer from digital 3D models, also known as rapid prototyping (RP). AM offers benefits such as shorter prototyping time, reduced cost, flexibility in design changes, and the ability to produce small or customized products that conventional methods cannot easily achieve. Since 2012, its use in science and engineering has expanded significantly.[1] All 3D printing methods rely on digital data that defines the exact position of each element using three coordinates. Computer-aided design (CAD) software is commonly used to create accurate digital blueprints, allowing precise material placement beyond what is achievable with traditional manufacturing. This precision is valuable in dosage forms for accurate drug delivery. 3D printing also enables unique shapes, controlled material distribution, and functions such as modified drug release or separate compartments within a single unit. Because these processes are free-form or selectively solidify materials in a bed, the size and volume of dosage forms can be easily adjusted.[2]

History:

A major breakthrough in pharmaceutical 3D printing started in the early 1990s at MIT, where Sachs and colleagues developed and patented a rapid prototyping method called "three-dimensional printing techniques.".[3] Earlier, in 1980, Dr. Kodama made foundational contributions to additive manufacturing by introducing stereolithography, a process that used UV light to solidify photosensitive resin.[4]

Timeline of Key Milestones in 3D Printing for Medicine and Pharmaceuticals.



A major regulatory milestone for 3D-printed pharmaceuticals began with the FDA's clearance of the first additive- manufactured medical device—a tracheal splint for infants. In 2016, the FDA approved the first 3D-printed titanium cranial implant, followed by a 2017 pilot program to assess 3D printing in medical manufacturing. By 2018, a 3D- printed drug-eluting stent received approval, and in 2020, the FDA authorized a once-daily triple-therapy inhaler for asthma and COPD, highlighting growing acceptance of 3D-printed healthcare technologies.[5]

3D Printing Workflow

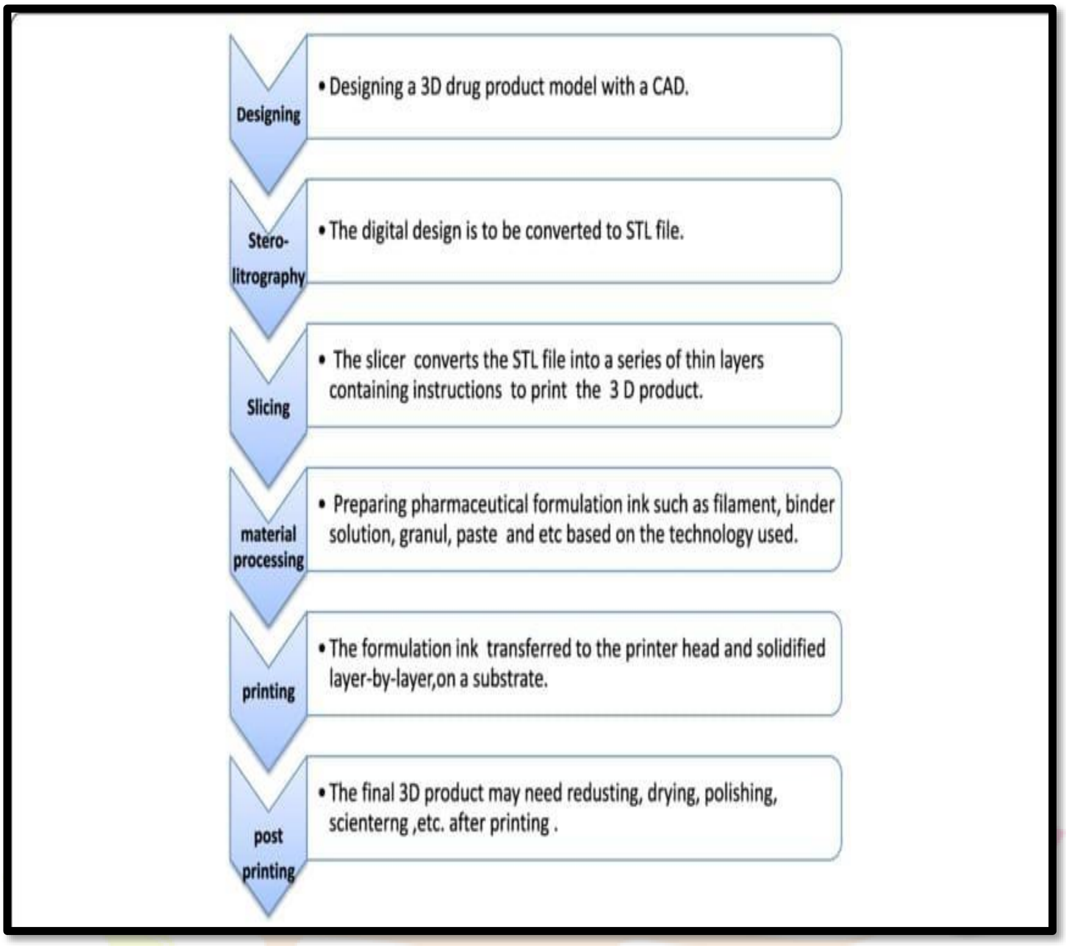


Figure No.1. 3D Printing Workflow.

Application of 3D printing

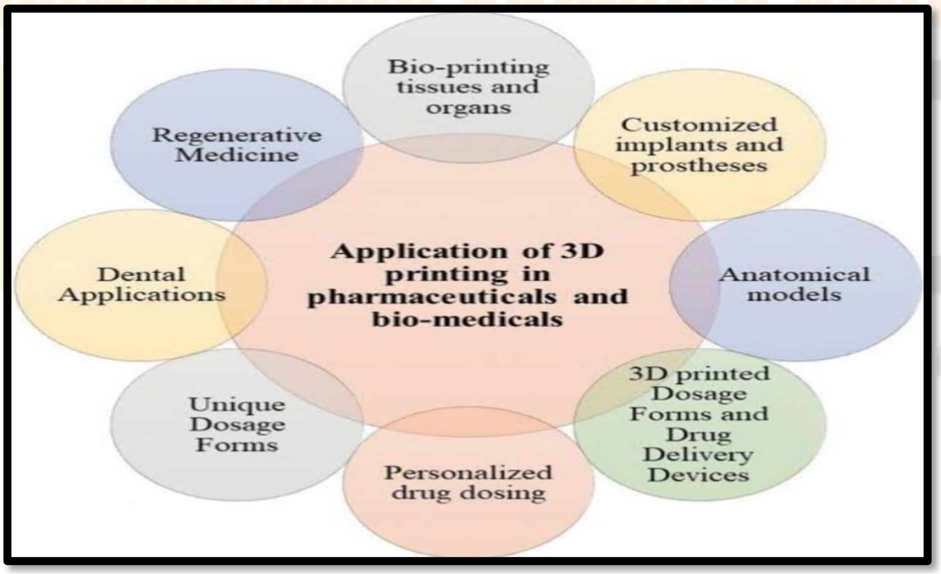


Figure No.2.Applicaion of 3D printing in pharmaceuticals and bio-medical.

3D printing techniques

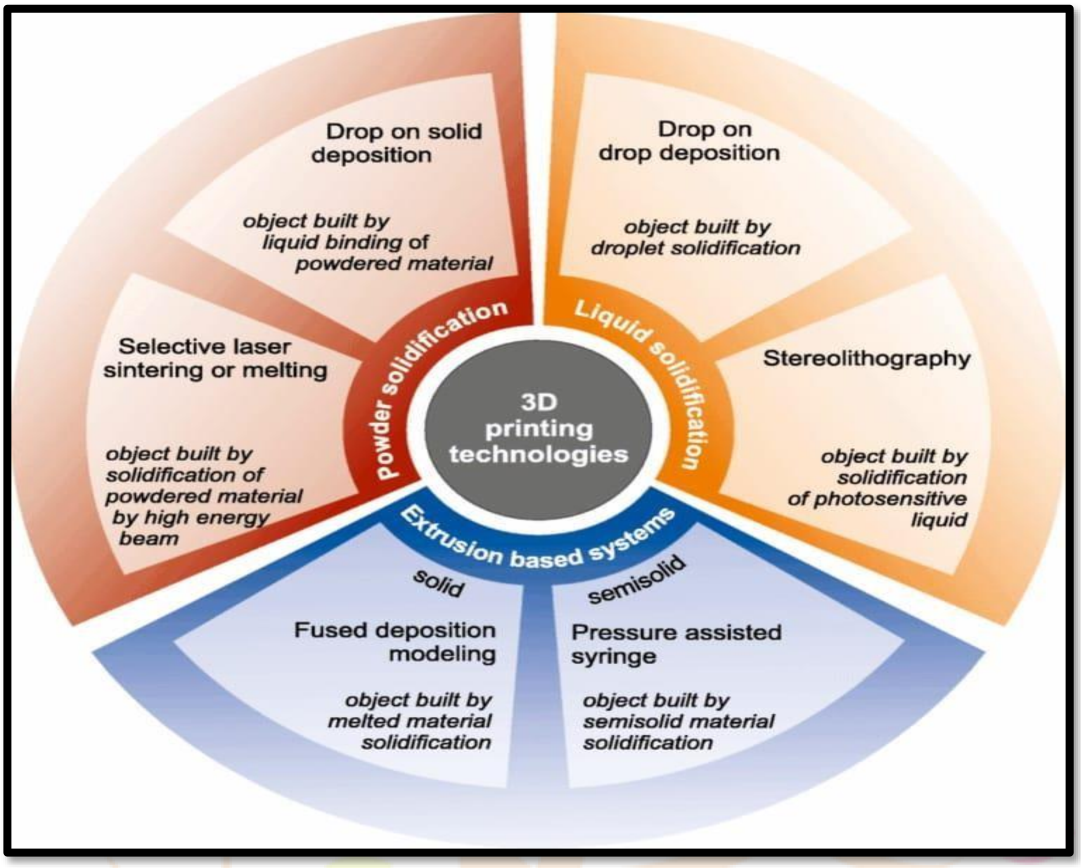


Figure No.3. 3D Printing technologies

1. **Extrusion-based Printing:** Extrusion-based additive manufacturing uses computer-controlled deposition of molten or semi-molten polymers, pastes, solutions, or dispersions through a movable nozzle. The most common techniques are Fused Filament Fabrication (FFF) and Direct Ink Writing (DIW). These methods are popular due to their low cost, rapid production, minimal waste, and ability to create complex 3D structures.[6]

A. Fused Deposition Modeling (FDM).

Fused Deposition Modeling (FDM) is an additive manufacturing (AM) technique that builds 3D objects from digital designs. Its use has expanded rapidly in recent years, proving valuable across many industries due to its ability to process various materials, including thermoplastics, waxes, gels, pastes, and clays [7]. In pharmaceuticals, FDM enables accurate production of dosage forms such as oral tablets, implants, scaffolds, iodine carriers, rectal/vaginal formulations, transdermal patches, meshes, and catheters [8]. Key factors affecting printing quality include extrusion temperature and rate, print-head speed, nozzle size, layer height, and infill percentage. The method is cost-effective and easy to operate, making it widely accessible.[9]. Fused Deposition Modeling (FDM) builds objects layer by layer by depositing melted or softened material through a heated nozzle that moves along the X and Y axes, while the platform lowers along the Z-axis (Gibson et al., 2010). The process typically uses filament feedstock produced by hot melt extrusion (HME), originally made from materials like ABS and PLA. With increasing interest in FDM, filament development has become an important research area [10]. In pharmaceuticals, various 3D-printed drug delivery systems have been created using FDM. Tablets are the most common dosage form, accounting for about 67% (n = 69) of studies, followed by capsules at 17% (n = 17). Tablets are preferred because they generally meet required physical- mechanical standards such as hardness and friability according to the British Pharmacopeia [11]. FDM is anticipated to continue advancing and may become the leading technology for producing drug delivery systems in the pharmaceutical field [9].

B. Hot Melt Extruction (HME).

In Hot Melt Extrusion (HME), drug and excipient powders are fed into an extruder with rotating screws and processed at temperatures above the polymer's melting (Tm) and glass transition (Tg) temperatures. The molten mixture of API, polymers, and plasticizers is then extruded into filaments used as intermediates for 3D printing. HME is advantageous because it is a solvent-free process and avoids additional drying steps [12]. HME has been used to produce HPC- and ethyl cellulose–based filaments as feedstock for printing FDM shells. These shells were combined with directly compressed theophylline tablet cores. The goal was to create floating tablets with pulsatile drug release after a lag time to enhance asthma therapy [13].

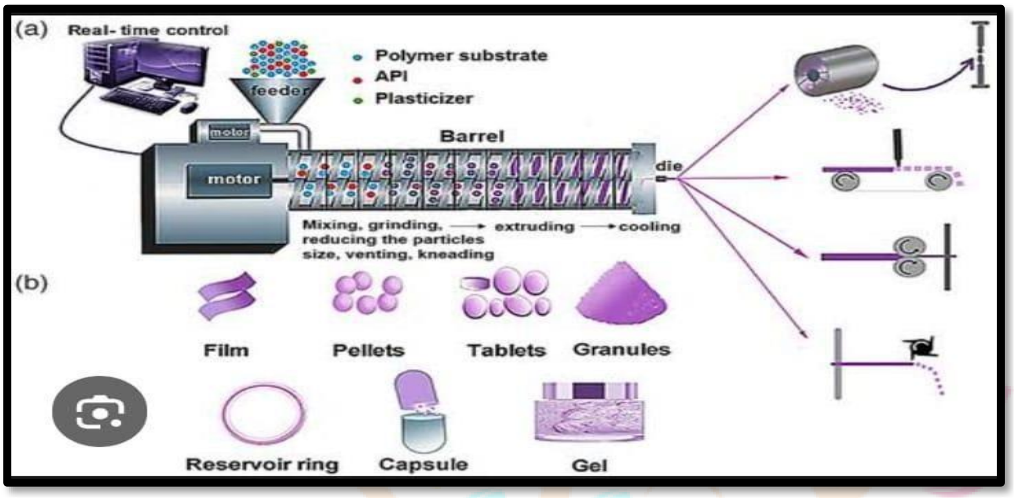


Figure No.4.Hot melt extruction process.

The extruder is the central unit of the HME system and consists of a motor, an extrusion barrel, rotating screws, and a die at the outlet. The barrel is divided into bolted segments with integrated heaters that soften or melt the materials. As the screws rotate, they generate shear and intense mixing, ensuring uniform melting through frictional and external heat. The molten mass is conveyed toward the die by screw movement. A central electrical control system regulates key parameters, including screw speed (RPM), feed rate, temperature settings across barrel zones and the die, and vacuum level for devolatilization. The screw in the hot melt extrusion (HME) process is essential for determining mixing efficiency and overall extrusion performance. Figure 4 shows the main design parameters of a typical screw configuration used in HME systems [14].

C. Semi sllid extraction.

Among additive manufacturing techniques, semi-solid extrusion (SSE) is notable for its low processing temperature and suitability for thermolabile drugs, making it valuable for pharmaceutical applications. It allows precise fabrication of patient-specific oral dosage forms, especially important in pediatric therapy. Recent advancements in automated SSE systems have improved accuracy, scalability, and customization. Incorporating real-time quality control can further enhance reliability and uniformity, supporting wider clinical adoption of personalized treatments [15].

2. Lamination based printing

A. Laminated Object Manufacturing (LOM):

In the Laminated Object Manufacturing (LOM) technique, traditional photosculpturing and relief mapping are replaced by a computer-aided, automated layer-by-layer fabrication system. Three-dimensional geometries generated by software are built as stacked layers using sheet materials. First commercialized by Helisys Corporation (later Cubic Technologies Inc.) in 1986, the process allows sheets to be laminated before cutting—reducing errors and enabling unused material to act as support—or cut before lamination, depending on the setup.

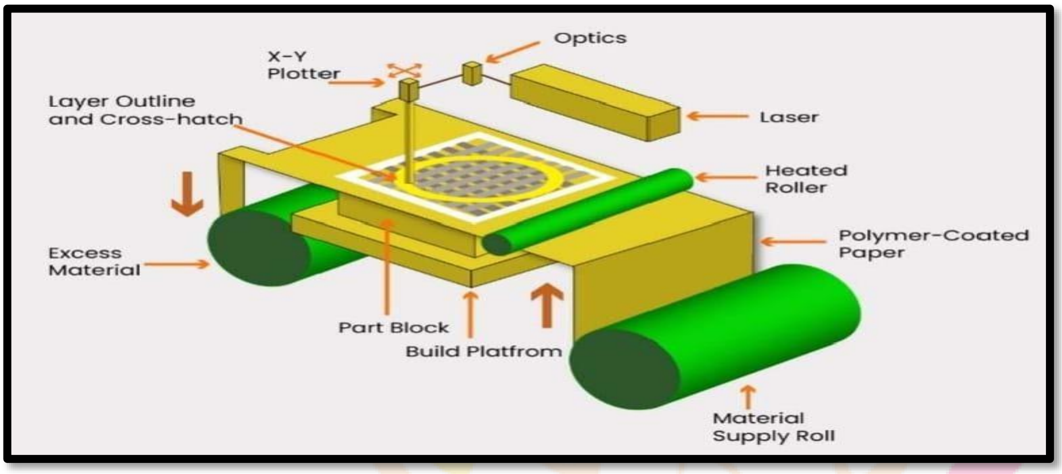


Figure No.5 Laminated object manufacturing.

Like other additive manufacturing (AM) methods, Laminated Object Manufacturing (LOM) is recognized as a key technology in the Fourth Industrial Revolution (Industry 4.0). AM enables efficient, cost-effective, and sustainable production of customized components across scales—from micrometers to meters—while reducing material waste and environmental impact [16].

3. Photo-polymerization based Printing.

Photopolymerization-based 3D printing, a type of vat photopolymerization, has gained strong interest in pharmaceuticals due to advances in photochemistry, polymer science, and optical engineering.

New Trends in Photopolymerization 3D Printing for Customized Drug Delivery.

1. Oral Drug Formulation

Oral tablets are the most common drug delivery form and a major focus of photopolymerization-based 3D printing, with progress in innovative formulations and controlled, patient-specific drug release.

2. Customized Microneedles

Microneedle transdermal systems are increasingly explored because they provide minimally invasive delivery, improved efficiency, consistent release, lower doses, and greater patient convenience [17].

A. Digital Light Processing (DLP)

Digital Light Processing (DLP) is a widely used additive manufacturing technique valued for its high precision and resolution. It works by initiating photopolymerization in photosensitive resins using a projected light pattern. Unlike traditional methods, DLP cures an entire layer at once, increasing speed and reducing material waste. Using a digital projector rather than a laser provides greater detail, while the digital micromirror device (DMD) enables pixel-level accuracy through its thousands to millions of adjustable micromirrors [18].

B. Stereolithography (SLA)

In stereolithography (SLA) 3D printing, a build platform is positioned in a transparent vat of photosensitive resin. A laser scans and cures specific regions based on the sliced STL model, forming each layer. After each layer is cured, the platform moves vertically by the set layer thickness. This process repeats until the complete 3D structure is fabricated [19].

4. Powder-based Printing

A. Selective Laser Sintering (SLS): Selective laser sintering (SLS) uses a focused laser to scan and fuse polymer powders heated just below their melting point, while selective laser melting (SLM) fully melts the powder to form solid layers. SLS is widely used for polymer-based drug delivery devices (DDDs), whereas SLM—suited for metals—is rarely applied in pharmaceutical manufacturing. Although both offer similar quality and resolution, SLS provides thinner layers and greater design flexibility [20].

5. Printing-based Inkjet Printing

3D inkjet printing (material jetting) is an advancement of traditional inkjet printing, enabling vertical, layer-by-layer fabrication based on CAD models, with slicer software defining each layer [21]. Inkjet printing (IJP) deposits tiny liquid droplets through a nozzle and is classified into two main types based on droplet generation: continuous inkjet printing (CIJP) and drop-on-demand (DoD) inkjet printing.

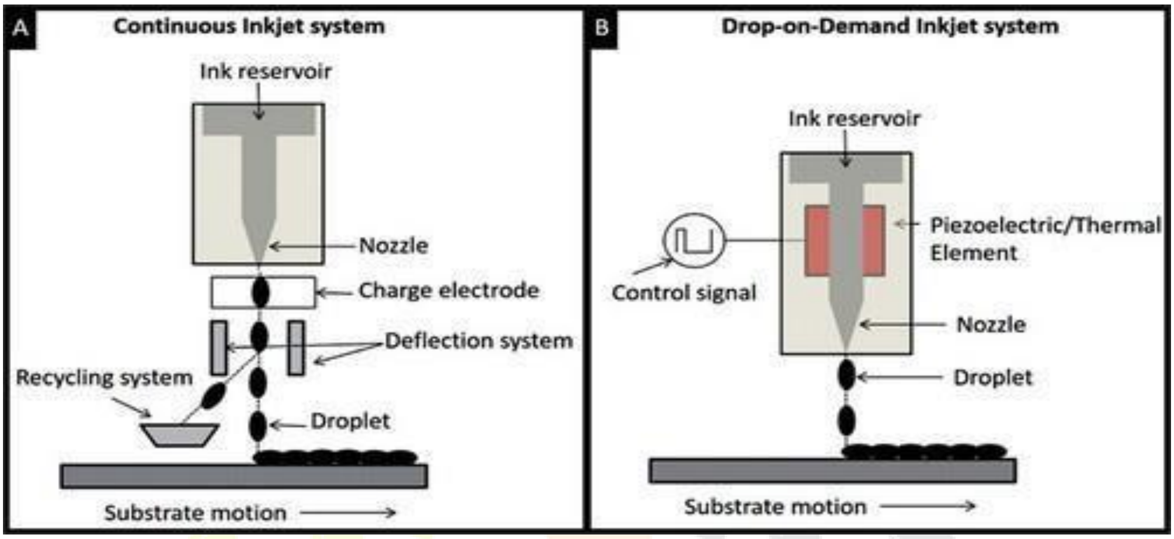


Figure No.6 Schematic representations of A) continuous inkjet printing (CIJP) and B) drop-on-demand (DoD) inject printing system.

In continuous inkjet printing (CIJP), a high-pressure pump pushes ink through a nozzle to form a continuous stream that breaks into droplets. Selected droplets are electrically charged and deflected toward the substrate, while uncharged droplets are recirculated. Drop-on-demand (DoD) printing is more commonly used in pharmaceuticals because it offers high precision and automation, allowing accurate control of ink volume and placement.

Smart pharmaceutical

A key advantage of inkjet printing (IJP) in pharmaceuticals is its ability to easily customize printing patterns. This has led to innovations such as data-enriched edible pharmaceuticals (DEEPs), which include machine-readable designs like QR or data-matrix patterns. These patterns can store drug dose information along with patient identifiers, batch details, administration routes, and dosing instructions. By embedding this data directly into the dosage form, DEEPs act as both medication and a digital information carrier, scannable by smartphones or other devices to support digital health and patient self-management [22].

Recent advances in 3D printing dosage form

1. **Oral dosage forms**

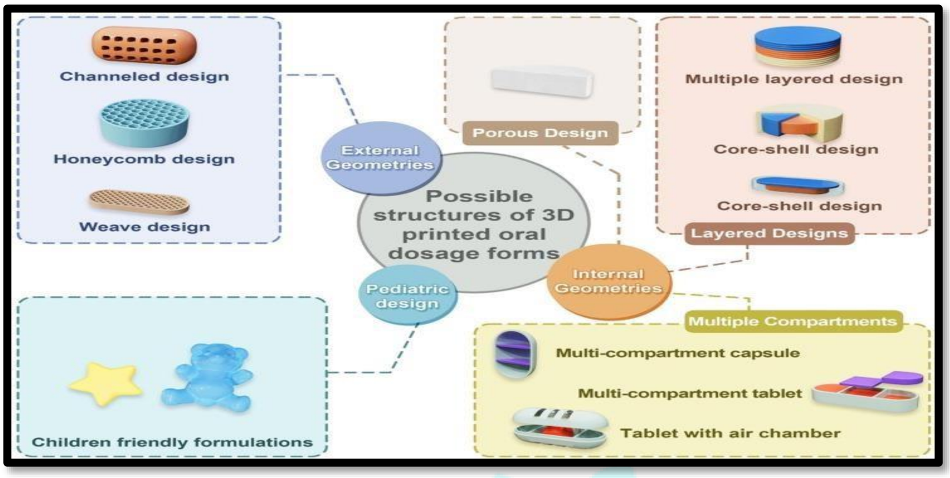


Figure No. 7 possible structure of 3D printed oral dosage form.

Tablet: The oral route is the most preferred method of drug administration due to its convenience and high patient compliance. Tablets, produced by compressing powdered ingredients, are the most common oral dosage form [23]. A study reported the fabrication of immediate-release paracetamol tablets using extrusion-based 3D printing, achieving a high drug loading of about 80% w/w—significantly higher than conventional direct compression. PVP K25 was used as the binder and croscarmellose sodium (NaCCS) as the disintegrant. The tablets showed fast disintegration (within 60 seconds) and released most of the drug within five minutes. With a 100% filling fraction, the printed tablets had high density and good mechanical strength [24].

Development of multi-drug (polypill) systems

The "polypill" is a major advancement in 3D-printed personalized medicine, allowing multiple active ingredients to be combined into a single tablet for patients on polypharmacy, especially the elderly. This approach simplifies therapy, improves adherence, and reduces daily pill burden. One study developed 3D-printed polypills containing three drugs for managing diabetes with hypertension [25]. Another group produced PVA-based polypills with four drugs— lisinopril, amlodipine, rosuvastatin, and indapamide—in single-matrix and multilayer designs. Single-matrix tablets showed slower release, while multilayer tablets exhibited release rates depending on each drug's layer position. Martinez et al. also created multilayered polypills with six drugs using SLA printing, using a modified printer that allowed resin changes between layers to form distinct drug-loaded structures [26].

Orodispersible Tablet

Orally disintegrating tablets (ODTs) dissolve quickly in the mouth without needing water. Regulatory limits vary: the European Pharmacopoeia requires disintegration within 3 minutes, while the FDA specifies 30 seconds or less. ODTs are commonly produced by direct compression, lyophilization, or molding [2]. Recently, 3D printing has emerged as a promising method for ODT fabrication. For example, researchers produced carbamazepine orodispersible tablets using semi-solid extrusion (SSE), incorporating cyclodextrins to improve solubility and bioavailability [24].

Personalized medicine

Personalized medicine moves beyond the "one-size-fits-all" approach by tailoring treatments to individual patients, supported by advances in pharmacogenetics, pharmacogenomics, and metabolomics. In this field, 3D printing is a promising method for producing customized, on-demand medicines. It offers benefits such as lower production costs and reduced space requirements compared with traditional manufacturing. However, challenges remain, including limitations in printing precision and restrictions on final product size [27].

Therapeutic Potential of Three-Dimensional Printing in Personalized Medicine.

In pharmaceuticals, 3D printing enables patient-specific medicines and medical devices, supporting fully individualized therapy. By tailoring dosage forms to each patient, it can improve adherence, patient experience, and therapeutic outcomes. This technology allows precise control of features such as drug release behavior to meet clinical and nutritional needs. Designing dosage forms with predictable release profiles enhances drug absorption and distribution, improving both safety and effectiveness [28].

Trending to pediatric

Swallowing difficulties in young children make oral dissolving films, fast-disintegrating tablets, and 3D-printed mini- pills suitable options. Studies show that children prefer mini-tablets of about 4 mm. Adherence can be improved by offering appealing flavors and colors. Goyanes et al. used 3D printing to create flavored and colored chewable isoleucine tablets for managing MSUD, which were well received by pediatric patients. Other work has also shown successful production of child-friendly chocolate-based chewable dosage forms.

Trending to geriatric

Older adults often face polypharmacy due to multiple chronic conditions. 3D-printed polypills can combine several drugs into one personalized dosage form, reducing pill burden. For patients with cognitive decline, such as dementia, 3D-printed tablets can include embossed symbols indicating the time or day of dosing, helping improve medication adherence [26].

Bioprinting

Moroni and colleagues define bioprinting as the computer-guided placement of living and non-living materials into precise 2D or 3D patterns to create engineered biological structures. This technology enables the fabrication of complex, functional constructs that support cell growth and tissue formation. Its potential to produce fully developed tissues or even entire organs marks a major advancement in regenerative medicine [29].

In Situ 3D Bioprinting

In situ 3D bioprinting deposits living biomaterials directly onto damaged or diseased tissue. It can be performed using robotic systems or handheld bioprinters and commonly uses inkjet, laser-assisted, or extrusion-based methods, with extrusion being most popular for on-site delivery. Robotic-assisted in situ bioprinting integrates surgical robotics with bioprinting, using a portable three-axis system to control the print head, while slicer software defines the printing path [30].

Machine-Learning Principles Used in 3D Bioprinting

3D printing has transformed industries such as manufacturing, healthcare, and robotics. In tissue engineering, bioprinting uses cell-based bioinks and biomaterials to fabricate human tissues and organs. It enables the creation of functional tissue replacements and miniature constructs or organoids, which are useful for disease modeling and testing new therapeutic compounds [31].

Clinical trials

Clinical trials involving 3D printing (3DP) face several challenges, including regulatory and ethical approvals, meeting standards, recruiting suitable participants, and maintaining patient compliance. Financial requirements, extended timelines, and administrative delays between protocol approval and trial initiation also add to the complexity of conducting such studies [32].

Large-scale manufacturing

Although 3D printing is well known for prototype development and small-batch or personalized production, recent advances show its potential for large-scale pharmaceutical manufacturing. As production moves from prototypes to clinical and commercial batches, multiple tableting machines with different output capacities—and blending systems of various sizes—are required to meet increasing batch demands [33].

Role of Artificial Intelligence in 3D Printing

Artificial intelligence, especially neural networks, is increasingly used to improve 3D-printed scaffold design and drug- release prediction. Studies show that ANNs can assess how factors like layer thickness, delay time, and pressure affect scaffold porosity and strength. They have also been integrated with fused deposition modeling to predict diazepam release, where models using self-organizing maps and multilayer perceptrons closely matched experimental drug- release profiles, as confirmed by f2 similarity factors [24].

Quality Control Frameworks for 3D-Printed Pharmaceuticals

As 3D printing becomes accepted for decentralized drug manufacturing, existing QC frameworks must be adapted. The appropriate QC strategy depends on the distribution model for personalized point-of-care printlets. Regulatory discussions have identified three potential pathways, each varying in how feedstock formulations are prepared, processed, and dispensed [34].

3D Printing and Industry 4.0

Industry 4.0—the Fourth Industrial Revolution—focuses on automated, smart, and interconnected manufacturing systems enabled by technologies such as IoT and machine-to-machine communication. Because of its digital, flexible, and automated nature, 3D printing aligns closely with these goals and is considered a core Industry 4.0 technology. The rise of 4D printing, using stimuli-responsive materials, further enhances its relevance. By supporting digitalization, real-time data exchange, rapid customization, and decentralized production, 3D printing plays a key role in achieving highly autonomous and connected industrial environments [35].

Future perspective

3D printing is poised to become a transformative force in pharmaceutical manufacturing, driven by advances in materials science, digital technologies, and regulatory adaptation. As the demand for personalized medicine grows, additive manufacturing will shift from a niche approach to an essential part of drug development and clinical practice. At the industrial level, 3D printing is expected to complement traditional batch manufacturing by supporting small- batch, flexible production—especially for orphan drugs, clinical trial supplies, and personalized therapies. With evolving, standardized regulatory guidelines, wider commercial adoption will become achievable. Automation and real-time quality control will be critical, with future printers likely integrating in-line monitoring, AI-based feedback systems, and predictive modeling to adjust parameters instantly and maintain product quality without halting production.

Conclusion

3D printing has emerged as a transformative technology in pharmaceutical science, providing new opportunities to design and manufacture dosage forms with precision and personalization beyond conventional methods. Advances in additive manufacturing—such as fused deposition modeling, selective laser sintering, stereolithography, and inkjet systems—now enable tailored drug delivery platforms, complex geometries, multi-drug combinations, and patient- specific medicines. These technologies support improved pediatric and geriatric dosing, polypills for chronic diseases, and other individualized therapies. Furthermore, the integration of computational modeling, artificial intelligence, and quality-by-design principles has enhanced predictability, process optimization, and overall product performance

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