WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 15, Issue 2, 807-828. Review Article ISSN 2277–7105

3D PRINTING TECHNOLOGIES AND ARTIFICIAL INTELLIGENCE IN PERSONALIZED SOLID ORAL DOSAGE FORM DESIGN: CURRENT PROGRESS AND FUTURE PERSPECTIVES

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Article Received on 15 Dec. 2025,
Article Revised on 05 Jan. 2026,
Article Published on 16 Jan. 2026,

https://doi.org/10.5281/zenodo.18265425

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How to cite this Article: Imran Fareeth A. M.[2], Vignesh M.[1]*, DR.Selvaraju K.[3], Alex Pandiyan J.[2], Dhanush Narayanan R.[2] (2026). "3D PRINTING TECHNOLOGIES AND ARTIFICIAL INTELLIGENCE IN PERSONALIZED SOLID ORAL DOSAGE FORM DESIGN: CURRENT PROGRESS AND FUTURE PERSPECTIVES". "World Journal of Pharmaceutical Research, 15(2), 807–828.

ABSTRACT

Three-dimensional (3D) printing is transforming oral drug delivery by enabling the precise fabrication of solid dosage forms with patient-specific doses, geometries, and release profiles, thus supporting the paradigm of personalized medicine. Unlike conventional batch manufacturing, additive manufacturing techniques such as fused deposition modeling, binder jetting, and allow rapid, on-demand production of complex tablets and polypills, including multi-layer and compartmentalized structures that can combine several active pharmaceutical ingredients (APIs) with distinct release kinetics in a single unit. This flexibility is particularly valuable for populations requiring fine dose titration or simplified regimens, such as paediatric, geriatric, and polymorbid patients, and for chronic or complex diseases like epilepsy, diabetes, and cardiovascular disorders Artificial intelligence (AI) significantly amplifies this potential by learning quantitative relationships between formulation composition, printing parameters, and in vitro performance, then using these models to automatically propose tablet architectures that meet predefined therapeutic or pharmacokinetic targets.AI-driven tools can predict excipient–drug compatibility, optimize printing conditions, and implement real-time monitoring and adaptive control, thereby reducing trial-and-error, enhancing

process robustness, and enabling consistent quality in both centralized and point-of-care manufacturing settings. Despite these advantages, widespread adoption is constrained by challenges in standardizing materials and printers, ensuring long- term stability and reproducibility, and the absence of harmonized regulatory frameworks tailored to decentralized, small-batch production. Continuing integration of Quality by Design principles, digital quality control, and AI-based decision support is essential to translate AI-guided 3D printing of oral dosage forms from experimental platforms into routine, clinically integrated personalized therapy.

KEYWORDS: 3D printing, Personalized medicine, Artificial intelligence, Fused Deposition Modelling.

INTRODUCTION

The emergence of three-dimensional (3D) printing, also known as additive manufacturing, has revolutionized several industries, including the pharmaceutical sector. Personalized medicine demands accurate dosing, enhanced compliance, and targeted drug delivery systems. 3D printing provides a transformative solution by fabricating complex dosage forms layer by layer, using computer-aided design (CAD) to convert digital models into physical objects. Its ability to precisely control drug geometry, release kinetics, and dosage customization makes it one of the most promising technologies for future healthcare. The idea of personalized medicine, which entails customizing medical care for every patient, has surfaced in recent years. Traditionally, pharmaceuticals are produced in huge quantities in a few number of distinct strengths, mostly utilizing technologies They were created about 200 years ago. Importantly, the chosen dosage schedules reflect the necessary dosage for a therapeutic and safe effect in the "average" patient. However, it is now clear that no dose works for everyone; in the UK, up to 70% of patients do not benefit from conventional mass manufacturing methods, 90% of medications only work for 30– 50% of the population, and 7% of hospital admissions are caused by adverse drug reactions.[1]

The US Precisions Medicine Initiative was started in 2015 with the goal of understanding how a patient's lifestyle, environment, and genetics can influence the optimum course of action for illness prevention or treatment. Additionally, the UK has made personalized medicine a priority. agenda for healthcare. The NHS released a paper titled "Improving outcomes through personalised medicine" in 2016. More recently, the UK government released the "UK Genome Strategy 2020" and the "Life Sciences Vision 2021," both of which

prioritise personalised medicine in the provision of healthcare services.[2]

These projects outline how to shift from the "one-size-fits-all" approach to personalization, mandating that medications be customized for each patient, taking into account things like physiology, concurrent therapy, drug reaction, genetic makeup, and illness state as well as additional variables (such as age, weight, and sex). Improved medication adherence, less adverse drug responses, and better therapeutic outcomes are only a few benefits of customizing treatments using medications (e.g., mixing multiple drugs into a single tablet or choosing suitable dosages).

Three-dimensional printing (3DP), also known as additive manufacturing, is a revolutionary technology that creates actual objects from computer models by piling on material. The 3D printer's ability to fabricate medications layer by layer with thicknesses ranging from 0.001 to 0.1 inches is a special feature that allows for the alteration of shapes, patterns, or fill density, which improves the drugs' geometric complexity. The intricate geometries allow for better patient-specific dosage customization and controlled medication release. Since the first 3D-printed orodispersible tablet Spritam® (levetiracetam) anti-epileptic medication was approved by the Food and Drug Administration, applications and research on drug administration utilizing this technology have accelerated and FDA in 2015. Pharmacists can now swiftly create bespoke pharmaceutical formulations by altering their design using computer-aided design (CAD) files thanks to 3D printing. In order to treat patients with numerous ailments, personalized medication can also be used by printing a single solid dosage form that contains multiple APIs, hence removing the need to administer different medications. Unlike traditional manufacturing techniques, which often entail taking material from a larger block or molding it into shape, 3DP creates products from the ground up, making it immensely effective and versatile. Since its inception in the 1980s, 3DP has rapidly developed and is now used in a number of industries, including consumer goods, healthcare, automotive, and aerospace.[2,3]

A CAD model is the first phase in the process, serving as an object's blueprint. The printer applies layers of resin, metal, or plastic after reading a digital file until the thing is fully produced. Complex geometries and customized products that would be difficult or impossible to create using traditional processes could be produced using this technique. Precision medicine can benefit from the whole chain application of three-dimensional printing technology, which includes image acquisition, segmentation, modeling, printing, post-

processing, and quality control. As a result, it has a broad variety of market demand in the medical industry, and its industrial scale keeps growing.

The first step in the 3DP process is creating the basic design of the part to be modeled. This design has been developed using computer software that is compatible with 3D printers. The program then generates a specific file type that is transmitted to the printer. After decoding this file, the 3D printer builds the product by stacking layers on top of each other. Layering is used in almost all 3DP methods to construct a part. Instead of reading each component as a single, whole thing, the printer interprets it as a collection of distinct two-dimensional layers.

Due to its sustainable features, which include low post-processing costs, less material waste, and inexpensive pricing even for complicated parts, 3DP has been recognized as a technology of the future. 3DP's ability to recycle, reuse plastics, and reduce emissions has further improved sustainability.[1,2]

More accurate drugs are what personalized medicine promises. These enhance patient compliance, are more economical, and are safer and more effective. In three- dimensional printing, sometimes referred to as additive manufacturing or 3D printing, material is deposited layer by layer to progressively create a solid model. In order to create the necessary objects, it employs computer-aided design (CAD) software to send the signals to a 3D printer, which transforms the digital model into two- dimensional (2D) sections and creates solid layers. It has been extensively utilized in many different industries, including the biomedical, pharmaceutical, automotive, and aerospace sectors. In addition, it is utilized in jewelry, art, fashion, entertainment, and building construction. It has been used in the pharmaceutical industry to fabricate a range of pharmaceutical products, including gastrofloating tablets, polypills, orodispersible films, and controlled release tablets. transdermal patches, microneedles, and self-emulsifying drug delivery devices. Ink jet printing, binder jet printing, fused deposition, selective laser sintering, stereolithography, and pressure-assisted microsyringe are some of the several printing technologies.

Pharmaceuticals could significantly alter the way they are designed, used, and manufactured via 3D printing of several medicinal items. Even though they are less expensive, conventional manufacturing techniques can be labor-intensive and time- consuming for large-scale production. Additionally, the doses in traditional production procedures are difficult to adjust to the demands of the patient. By customizing the drug for each patient, 3D printing can

revolutionize healthcare through personalized medicine and increase patient compliance. To provide the finest medical treatment, this can be accomplished through on-demand manufacturing in clinical settings.[3]

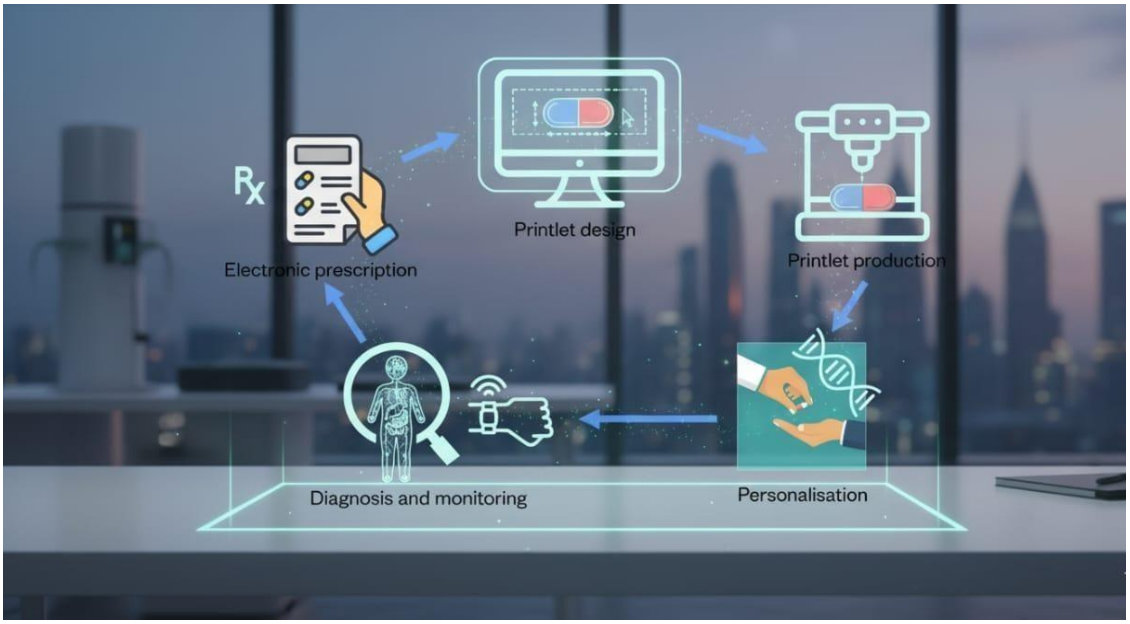


Fig. 1: The Five Components of Digital Pharmacy Era.

Evolution of 3D Printing in Pharmaceuticals

3D printing originated in the 1980s with the invention of stereolithography by Charles Hull. Initially applied in prototyping and manufacturing, it gained pharmaceutical relevance in the 21st century as researchers began exploring drug printing for controlled release and complex dosage forms. The first FDA-approved 3D-printed drug, Spritam (levetiracetam), developed by Aprecia Pharmaceuticals in 2015, demonstrated the feasibility of large-scale drug printing using ZipDose technology. Since then, 3D printing has expanded into bioprinting, tissue engineering, and personalized formulations.[4]

Types of 3D Printing Technologies Used in Pharmaceuticals

Various 3D printing techniques are used for pharmaceutical applications, each offering unique advantages. These include extrusion-based printing such as Fused Deposition Modelling (FDM) and Pressure-Assisted Microsyringe (PAM), vat photopolymerization techniques such as Stereolithography (SLA) and Digital Light Processing (DLP), inkjet-based systems like Continuous Inkjet (CIJ) and Drop-on- Demand (DoD), and powder-based methods such as Selective Laser Sintering (SLS) and Binder Jetting. Each method differs in material compatibility, resolution, printing temperature, and formulation versatility.[5]

Advantages of 3D Printing in Drug Development

1. Personalized dosing for paediatric, geriatric, and special patient groups.
2. On-demand manufacturing reduces waste and inventory costs.
3. Complex geometries allow for tailored release profiles and multi-drug polypills.
4. Enhanced bioavailability and controlled release.
5. Potential for decentralised, point-of-care drug production.

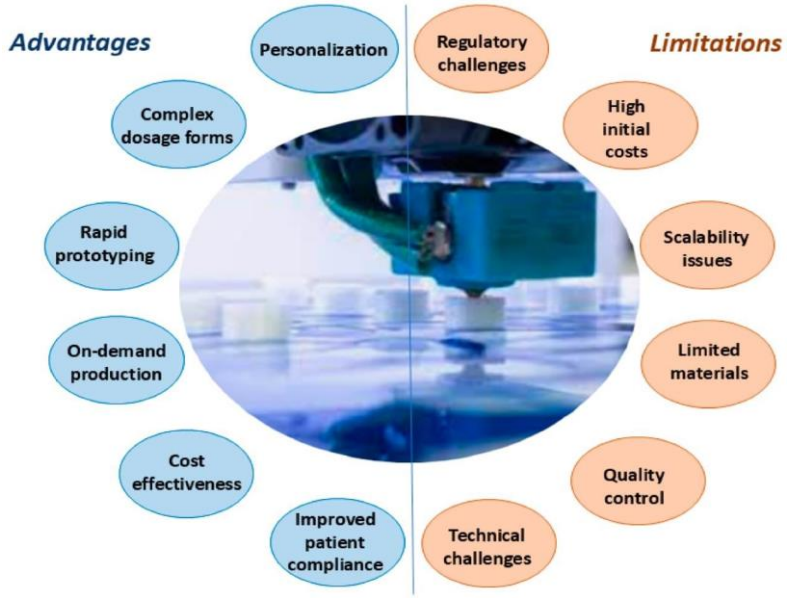


Fig. 2: Advantages of 3D Printing.

Working Principle of 3D Printers and Polymers

3D PRINTERS	WORKING PRINCIPLE	FORMULATIONS	COMMERC IALLY AVAILABLE 3D PRINTERS	POLYMERS USED
Fused deposition modelling	Software controlled layer by layer deposition of a molten thermoplastic filament (API& POLYMER)	Immediate release tablets Sustained release tablets Modified release tablets Polypills	Ultimaker S5 MakerBot Replicator Series Hyrel 3D Printers Mojo FDM Printer	PVP, PEG, PLA, HPMC Soluplus Kollidon VA64 & Kollid on 12PF-exterminate drug degradation problem in FDM printing technology
Pressure Assisted Micro- syringe	Extrusion of a semisolid materials (hydrogels & pastes) at room temperature from a computer- controlled microsyringe onto a build plate in a layer by layer design (melting of filament is not required)	Mucoadhesive films Paediatric dosage forms Semisolid pastes Hydrogels	CELLINK INKREDIBLE Series (Pharmaceutical formulations) EnvisionTEC 3D-Bioplotter series Ystruder Replistruder 4	Pluronic F 127 (Poloxamer 407) PVA, HPMC Carbopol Chitosan PEG Eudragit
Stereolithography	A laser beam that scans	Medical and dental	Formlabs Form 3BL	Polyethylene Glycol

(SLA)	over the resin tank and causes the liquid resin to cure onto the build platform	applications	Kudo3D Titan series ProX 800 Nobel 1.0A	diacrylate(PE GDA) Gelatin methacrylate (GelMA) Polycaprolact one
Digital Light Processing(DLP)	A digital light projector projects UV light through an oxygen permeable, UV-transparent window. The light cures the photo polymer resin layer by layer in the desired shape	Immediate release tablets Poly pills (two layered tablets) Microneedle patches	EnvisionTEC Perfactory series Perfactory 4 Carbon M Series (M1, M2, M3)	Polyethylene Glycol diacrylate (PEGDA) Gelatin methacrylate (GelMA) Polycaprolact one Olyvinyl alcohol Methacrylate (PVA-MA)
Continuous Inkjet Printing	A high pressure pump directs liquid ink (APIs in solution) through a nozzle, creating a continuous stream of droplets. These droplets are electrically charged and deflected by an electrostatic field to precise locations on a substrate, forming the desired pattern	Transdermal DDS Rapid prototyping	Its adoption in pharmaceutic al 3D printing is still emerging	HPMC, PVP, Gelatin Methacryloyl (GelMA)
Drop- on – Demand (DoD)	DoD 3D printing operates by ejecting individual droplets of a formulation onto a substrate only when required, offering high precision and minimal material waste	Fabricating dosage forms with complex geometries and controlled drug release profiles. Personalization of paediatric and geriatric dosage forms	Aprecia Pharmaceutic als: Developed the FDA approved Spritam (levetiracetam) using Zipdose technology, which employs a form of DoD printing to create rapidly disintegrating tablets.	PVP HPMC PEG Methacrylate based polymers (Eudragit)
Selective Laser Sintering (SLS)	SLS employs a high powered laser to selectively fuse powered materials layer by layer, following a digital 3D model. The process involves: powder layering, pre heating, laser sintering, layer by layer construction	Complex geometries Rapid prototyping On demand Manufacturing: Supports decentralized production, potentially reducing the need for large scale manufacturing facilities	Formlabs Fuse 1 Sintratec S2	PVP HPMC PCL Eudragit polymers
Binder Jetting	Liquid binding agent is selectively deposited onto a bed of powdered material. It involves: Powder layering, binder deposition, layer by layer construction, post processing	Complex geometries Rapid prototyping Tablets with high drug loading Fast dissolving tablets	ExOne Binder Jetting System 3D systems project series Huskyjet Binder Jet 3D Printer	HPMC PVP PVA Gelatin Methacryloyl

FUSED DEPOSITION MODELLING

FDM was created by Stratasys, which has its headquarters in Eden Prairie, Minnesota. Using a nozzle that follows the cross-sectional geometry of the part, a plastic or wax substance is extruded layer by layer. FDM is the second most used fast prototyping method after SLA. It's is one of the most widely accessible and widely used 3DP technologies. Thermoplastic filament is extruded through a heated nozzle to place material on the build platform layer by layer. The CAD model is first sliced into thin layers by the printer's software.

After then, the FDM printer follows the software's recommended path, depositing material in layers until the thing is fully produced.[9]

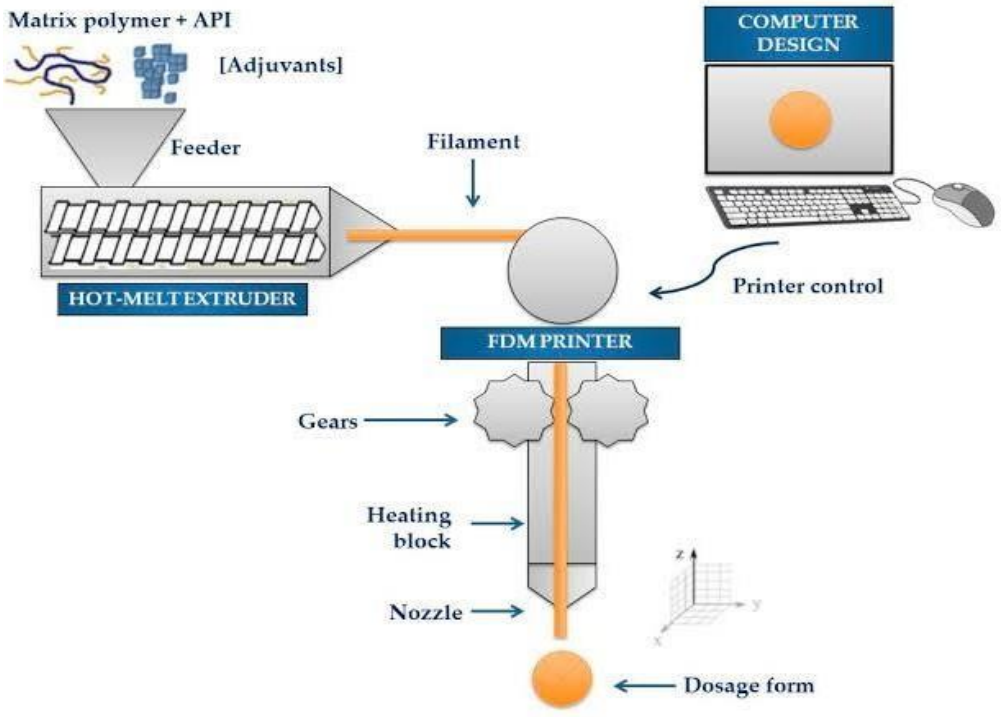
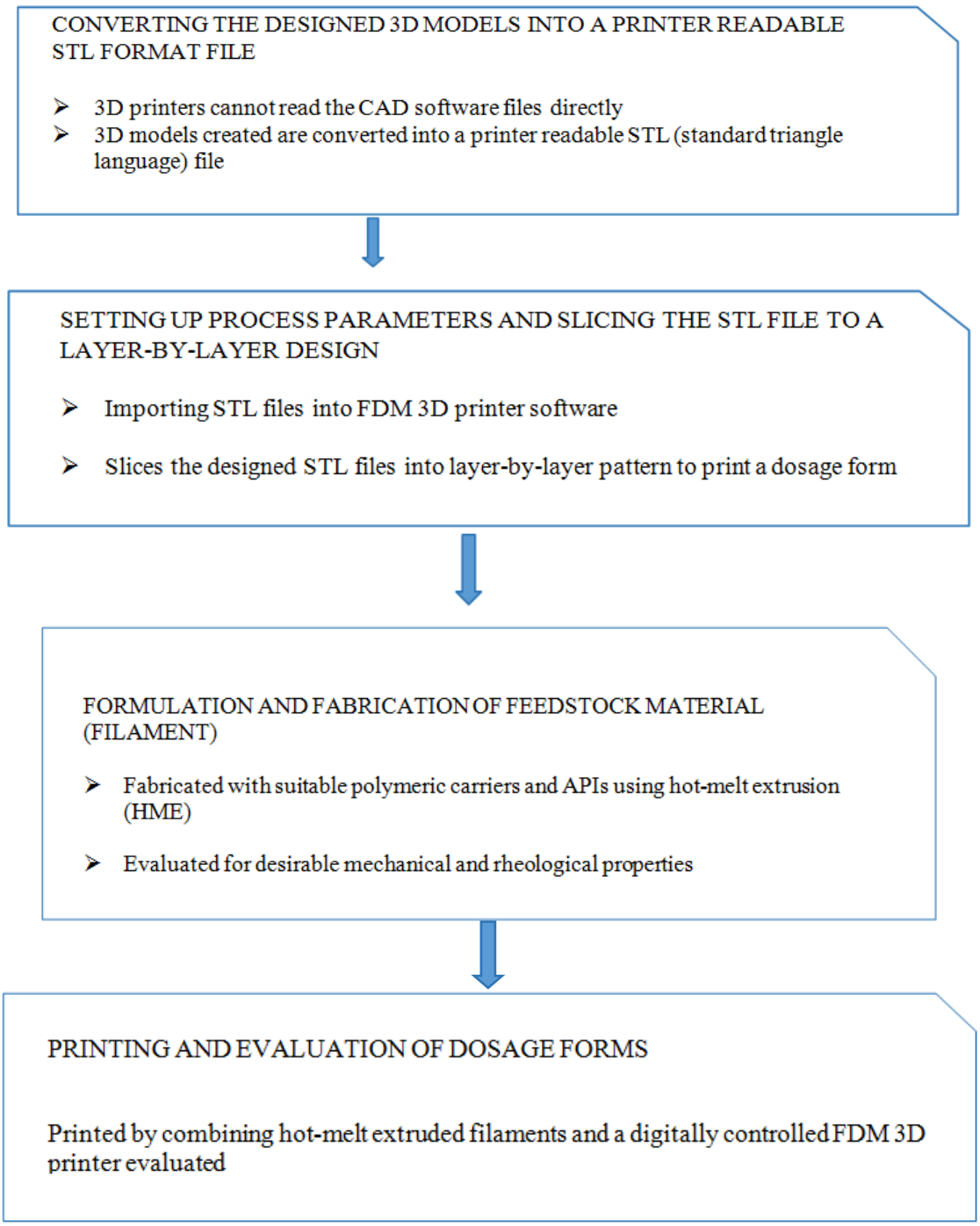


Fig. 3: Fused Deposition Modelling.

WORKING PRINCIPLE OF FDM

DESIGNING A 3D DIGITAL DOSAGE FORM

- Designing the digital structure
- Dosage forms with different fill levels and shapes can be designed using CAD software
- Designed using Microsoft 3D builder, Tinker cad and Autodesk



PROCESS PARAMETER CONSIDERATIONS

A number of process variables have a significant impact on the end product's performance and quality in the additive manufacture of pharmaceutical dosage forms. Printing temperature, nozzle and build-plate temperature, and printing speed are important 3D printing process parameters that affect material flow, layer bonding, and structural accuracy. Drug release properties and mechanical strength are also greatly influenced by the dosage form's geometry, including its length, width, height, and diameter. Porosity, mechanical robustness,

and disintegration behavior are also directly impacted by the internal structure, which includes infill density, infill pattern, shell or wall thickness, and top/bottom thickness.[7,8]

Equally significant are the characteristics of the printing filament. Extrudability, brittleness, flexibility, and stiffness are examples of parameters that affect the printed object's stability and ease of processing. With tools like a Brookfield CT3 texture analyzer with TexturePro CT software, which allows for accurate assessment of material deformation and flow characteristics, the injectability or printability of the formulation may be quantitatively evaluated. For 3D printing technology to consistently produce high-quality dosage forms, these factors must be tuned collectively.[12,13]

RECENT ADVANCES IN 3D PRINTING TECHNOLOGY

The creation of highly customized dose forms has been made possible by recent developments in pharmaceutical 3D printing technology. By combining many APIs, including aspirin, statins, and antihypertensives, into a single, customizable tablet, polypills made by fused deposition modeling (FDM) and inkjet-based printing improve patient adherence and dose flexibility. The viability of such multi-drug structures for customized therapy has been shown by numerous research groups, including teams from top international pharmacy schools.[11]

For use in pediatric and geriatric applications, orodispersible films and tablets produced by inkjet or semi-solid extrusion 3D printing have drawn a lot of For use in pediatric and geriatric applications, orodispersible films and tablets produced by inkjet or semi-solid extrusion 3D printing have drawn a lot of interest. These systems, which have been successfully created with medications like sildenafil, aripiprazole, and paracetamol, allow for quick breakdown and better ingestion convenience. Their suitability for age-specific dose requirements is highlighted by their capacity to adjust medication distribution and breakdown characteristics interest. These systems, which have been successfully created with medications like sildenafil, aripiprazole, and paracetamol, allow for quick breakdown and better ingestion convenience. Their suitability for age-specific dose requirements is highlighted by their capacity to adjust medication distribution and breakdown characteristics.[6,7]

The creation of floating gastro-retentive tablets utilizing FDM is another developing field. These dose forms are designed to stay buoyant in the stomach, extending the gastric

residence duration. This is especially advantageous for medications like levodopa, metformin, and gabapentin that have limited absorption windows. Research has demonstrated that 3D-printed floating systems decrease dose frequency while increasing drug bioavailability.[13,14]

Chemo therapeutics or antibiotics can be released in a customized, site-specific manner using implantable drug delivery systems made of biodegradable polymers like PLA and PCL. For illnesses requiring long-term administration, these custom-fit implants and micro needle arrays provide minimally invasive and sustained targeted therapy.[14]

Research consistently shows that 3D printing offers unprecedented control over drug- release behavior compared to traditional compression methods. FDM-printed modified-release tablets, such as nifedipine-loaded constructs, show how infill percentage, shell thickness, and internal geometry can be precisely manipulated to achieve programmable release kinetics.

Research shows that additive manufacturing allows structural customization of porosity and drug-distribution patterns, improving antimicrobial efficiency and tissue regeneration. 3D-printed hydro gel-based antibiotic dressings containing agents like gentamicin and ciprofloxacin have shown great promise in wound-care applications. These scaffolds enable localized, moisture-retentive, and infection-responsive delivery, improving healing outcomes in both acute and chronic wounds.[16]

ZIP DOSE TECHNOLOGY

The first and only USFDA-approved medication formulation platform that uses additive manufacturing for oral dosage forms is ZipDose® technology, which is based on powder bed fusion 3D printing. In contrast to traditional tablet manufacture, this 3DP method uses an aqueous solution to bind successive layers of powdered medication rather than relying on compressive forces, punches, or dies. When taken with a sip of liquid, the resulting structure creates a firm but extremely porous tablet that allows for quick disintegration. ZipDose®'s distinctive porous architecture allows for the creation of high drug-load formulations while preserving superior dissolving and disintegration characteristics. A thin coating of the powder mixture is deposited during the production process, and then a binding fluid that fuses the particles is applied. To create the final dosage form with constant quality and performance, this process of fluid binding and powder deposition is performed several times.[15]

SPRITAM® (levetiracetam), a prescription drug intended to treat partial-onset seizures in

individuals four years of age and older, is formulated using ZipDose technology. Additionally, it can be used in conjunction with other treatments to treat primary generalized tonic-clonic seizures in patients six years of age and older with certain types of generalized epilepsy, as well as myoclonic seizures in people twelve years of age and older with juvenile myoclonic epilepsy. SPRITAM is a solidoral tablet that comes in individual packaging, doesn't need to be refrigerated, can be taken without spoons or droppers, and dissolves quickly—usually in 11 seconds. Partial pills must not be utilized, and the entire tablet should not be ingested. The tablet is administered by placing it on the tongue with dry hands, then taking a sip of liquid and letting it dissolve in the mouth before swallowing. This technology demonstrates improvements in patient-friendly dosage, especially with regard to the utilization of 3D printing to improve treatment adherence and convenience of administration.[19]

EVALUATION OF 3D PRINTING

A crucial part of the quality-by-design (QbD) strategy, which seeks to identify the crucial process parameters and crucial quality features of raw materials, intermediates, and end products, is the characterization of 3D-printed solid oral dosage forms (SODFs). These formulations are assessed using a range of analytical methods. Drug content, hardness, drug distribution, and solid-state characteristics are evaluated using spectroscopic instruments like near-infrared (NIR) and Raman spectroscopy. The spatial distribution of medications and polymers within the printed tablet can also be verified using Raman confocal spectroscopy. The solid-state properties of the materials are ascertained by differential scanning calorimetry (DSC), and their crystallinity is shown by X-ray powder diffraction (XRPD). The interior structure, density, and porosity of 3D-printed tablets are examined using micro-optical coherence tomography. The morphological characteristics of tablets, capsules, and oral films can be seen in great detail using scanning electron microscopy (SEM). The structural characteristics of the 3D-printed objects are also captured and interpreted with the aid of image analysis techniques. To guarantee the functionality and dependability of 3D-printed SODFs, basic quality evaluations including medication content, weight homogeneity, film thickness, hardness, friability, disintegration time, and dissolving profiles are also crucial.[17]

CHALLENGES AND REGULATORY CONSIDERATION

There are several obstacles and regulatory factors to take into account while developing and implementing 3D-printed pharmaceutical dosage forms. The high cost and regular calibration

of printing equipment is one of the main drawbacks. Furthermore, formulation flexibility is hampered by the scarcity of biocompatible materials, which could affect the final products' quality. Drug deterioration might result from poorly established methodologies, hence it is crucial to ensure strong analytical methods for quality control. Thermo-resistant medications and excipients cannot be used with several 3D printing processes since they rely on UV light or high energy sources. Similar to this, heat-sensitive materials cannot be processed using techniques that call for high temperatures; instead, biocompatible and biodegradable polymers that don't produce hazardous byproducts are frequently required. The removal of support materials is one of the post-processing steps that increase complexity and lengthen the production time. To achieve final product stability, extra steps like removing excess resin and subsequent curing are needed in stereolithography (SLA) and digital light processing (DLP) methods. The physical and aesthetic qualities of printed dosage forms are also problematic because leftover plastic beads or particles can cause uneven or rough surfaces, which deters patients from using the products. The lack of official regulatory guidelines specifically for 3D- printed pharmaceuticals continues to be a major obstacle to widespread adoption, highlighting the need for standardized standards and more transparent regulatory pathways.[18,19]

UTILIZATION OF ARTIFICIAL INTELLIGENCE FOR FURTHER 3D PRINTED MEDICATION ADVANCEMENT

Artificial intelligence would promote the concept of a customized drug and hasten the introduction of 3D-printed pharmaceutical and medical formulations and devices to the medical community. The so-called "Internet of Things" (IoT), a modern application of technology, could incorporate artificial intelligence with interconnected hardware networks. The "IoT" is combined with devices that have unique characteristics to carry out integrated processes. It is anticipated that the growing field of IoT will contribute to the creation of additional products based on 3D printing. Numerous intelligently automated processes are produced by augmenting IoT and artificial intelligence. In order to obtain the highest tensile force of a hand exoskeleton constituent, the 3D printing process was computationally adjusted using genetic algorithms and artificial neural networks. Using fused filament fabrication technology and Cura 0.1.5 software, the designed component was 3D printed. To determine the highest tensile strength value for the exoskeleton, samples were tested using INSTRON 5966 university testing apparatus. For machine learning models to perform at their best, a balanced dataset is essential. A more illustrative dataset of over a thousand

formulations was created by combining in-house and literature-mined data on hot-melt extrusion and fused filament fabrication 3D-printed formulations. The web program could speed up the formulation development process, opening the door to many advanced pharmaceutical 3D print-based research outcomes. Workflow replication could be used to create pharmaceutical products made of fused filament. Artificial intelligence and machine learning models use data from the literature to predict the quality of in vitro solutions and the crucial components of the 3D printing process. For the hot-melt extrusion process, the machine learning algorithms were able to learn and provide high accuracy values.

Additionally, by correlating data from the composition of formulations with other input variables, machine learning was able to predict the drug release from 3D-printed preparations. The interactive interface between the average user and the 3D printing robot is lacking because artificial intelligence integration is still in its early stages. Collaborative human professionals should share and manage the printing task that artificial intelligence understands. The current barrier to pharmaceutical 3D printing and artificial intelligence integration—the lack of adequate AI experience—should be taken into account.[20,21,22]

APPLICATIONS

3D-Printed Drugs in Epilepsy

3D-printed medications have the potential to greatly enhance the treatment of complicated illnesses that call for individualized care. A chronic neurological condition with a wide range of clinical manifestations, epilepsy is characterized by abnormal electrical activity in the brain that results in recurrent seizures. Anti- epileptic medications, lifestyle changes, and occasionally surgery are used as treatment methods. Fixed-dose anti-seizure drugs (ASMs) are the primary treatment for epilepsy.[25]

Personalized treatment for epileptic patients may be made possible by 3D-printed medications. Aprecia Pharmaceuticals, a pharmaceutical company, produced 3D- printed tablets on a large scale for commercial use using a patented BJP platform called ZipDose technology. On August 3, 2015, the US Food and Drug Administration (FDA) approved Spritam. Drug particles are dispersed into thin layers as part of the printing process, which then uses selective jetting to bind the particles into thin, porous layers. This process increases the surface area of the 3D-printed LEV tablet by creating a highly porous internal environment with micron-scale pore sizes. It was found that Spritam's efficacy was on par with that of the conventional pressed tablet. However, due to its porous and soluble matrix, it

has a shorter solubilization time, resulting in ultra-rapid drug dissolution and a quicker onset of action. Spritam is made to dissolve quickly. it was developed in liquids to help children who have trouble swallowing large pills and patients with dysphagia. Consequently, despite having a high active drug dosage (1000 mg), Spritam is the first fast-acting, immediate-release dosage form of LEV that dissolves and disperses entirely in less than five seconds. On the other hand, a typical LEV breaks down in less than 60 seconds. Personalized treatment approaches for epilepsy are improved by the advantageous pharmacokinetics of LEV and the novel delivery method of 3D-printed Spritam.[27]

To enable the individualized treatment of epileptic patients, this technology can be further enhanced. More precisely, treatment with multiple drugs or varying dosages of the same drug would be possible with 3D-printed tablets with multiple compartments. This makes it possible to precisely modify drug dosages in accordance with individual patient needs, increasing efficacy and lowering adverse effects. Sequential release of each compartment's contents at predetermined intervals can be accomplished by varying the wall thickness and excipient composition of each compartment. This implies that each medication or dose will be released at a different time throughout the day, even though the patient will take a tablet once daily.[23]

Application of 3D-Printed Drugs in Other Diseases

The FDA-approved LEV for epilepsy and other recent developments in the creation of 3D-printed drugs demonstrate how this technology has the potential to revolutionize the treatment of numerous other diseases. 3D printing can make managing diabetes easier. development of customized tablets that, depending on the patient's particular metabolic profile, release glucose-regulating medication. This lessens the possibility of overdosing or underdosing, which could cause hyperglycemia or hypoglycemia, respectively. The use of 3D printing technology in other diabetes treatments has also been investigated. For example, two antidiabetic medications with different daily dosage schedules, metformin and glimepiride, were combined to create a bilayer formulation. According to dissolution studies, metformin was released within 480 minutes and glimepiride within 75 minutes, respectively. Additionally, another study revealed the creation of metformin HCl-loaded polyvinyl alcohol (PVA) in 3D- printed tablets using an advanced aqueous solvent diffusion technique. The development of kid-friendly metformin-containing 3D-printed gummies shows how this technology can be used to create patient-friendly dosage forms that enhance adherence and

enable precise control of drug release profiles. In particular, this formulation improves palatability by preventing metformin from being released in the oral cavity.[24]

Patients with cardiovascular disease frequently suffer from a variety of illnesses, including heart failure, dyslipidemia, hypertension, and arrhythmias. As a result, they are prescribed various medications at various times and dosages. 3D-printed polypills that combine antihypertensive medications, Anticoagulants, statins could greatly improve clinical outcomes and patient compliance. For the treatment of metabolic syndrome, Khaled et al. created a five-in-one dose combination polypill with specified immediate and sustained release profiles of atenolol, pravastatin, ramipril, aspirin, and hydrochlorothiazide. Another study shows that a multi-compartment tablet that delivers three medications via two distinct release mechanisms—diffusion through gel layers and osmotic release through a controlled porosity shell—can be successfully 3D extruded. As a result, glipizide and nifedipine have sustained release kinetics that depend on the API/excipient ratio, while captopril exhibits a zero-order release. Therefore, more complex drug-release profiles that correspond with circadian cycles, such as morning spikes in blood pressure or coagulation processes, can be developed using 3D printing.

3D-printed tablets can combine different chemotherapeutic medications into a single formula for sequential or regulated release, improving tumor targeting and lowering toxicity and side effects. Using 3D-printed porous materials is an additional strategy. absorbers, which can lessen systemic toxicity to healthy tissues by removing leftover chemotherapy drugs from the blood. Chemotherapeutics can also be administered orally using 3D-printed implantable scaffolds. By enabling prolonged and sustained drug release for up to several months, these drug delivery systems prevent hospitalization during chemotherapy.[26]

APPLICATIONS OF 3DP in Oral solid dosage forms

Controlled release

Drugs' subsequent absorption and therapeutic effect are significantly influenced by their release from dosage forms. For the majority of oral formulations to be absorbed, immediate release (IR) is necessary. Slow drug release is made possible by sustained release, which lessens variations in drug levels linked to the regular administration of several immediate release (IR) dosage forms. Both patient convenience and therapeutic benefit could result from this Because traditional sustained-release tablets go through an absorption process in the gastrointestinal tract (GIT), which results in a non-constant release of drugs, their overall

surface area is decreased. This problem is solved by additive manufacturing, which creates tablets with intricate geometries. This enables products with a customized release profile in addition to a sustained release dissolution profile.[28]

Polypills

Polypharmacy is being used by more patients, particularly the elderly, which has sparked worries about medication errors because of the complexity of the regimen. Certain illnesses, like cardiovascular disease, call for several prescription drugs. Poorer adherence and consequently worse health outcomes may be linked to an increase in the number of medications in a person's regimen. Patient comfort and adherence would rise as a result of the medication's simplification. Dosage accuracy is not very important because 3D printing is a precise process. Additionally, incompatibility issues can be resolved by chemically separating the medications with an appropriate excipient or by dividing each medication into distinct tablet components.[27,28]

Oro-Dispersible

Patients most frequently and extensively use the oral route of administration. However, some populations may find oral dosage forms like tablets, capsules, and liquids problematic. including patients with dysphagia, the elderly, and children. Oro dispersible tablets are designed to break down in the mouth. It can be consumed without water. Oro-dispersible tablets have a fast dissolution profile because of their porous structure. Because 3DP ignores the high compressive forces needed for the conventional production method, the structure becomes more porous and degrades more quickly.[27]

Paediatric formulations

Children are a unique population with different pharmacokinetic and pharmacodynamic characteristics than those of adults. As a result, dosages in this population need to be carefully adjusted to prevent toxic side effects. Although syrups are available in pediatric formulations and are dose-adjustable, many of them have unpleasant tastes and are prone to dosing errors. The miniprintlet, a 3D printed mini- tablet, is a novel solution to this issue. Because they are smaller and have less taste than syrups, mini-tablets are simpler to take. Additionally, by varying the quantity of material used, additive manufacturing (AM) can modify doses. It has been demonstrated that SLS or FDM can accomplish this.[20]

PERSONALIZED MEDICINE

Conventional mass manufacturing of dosage forms has a success rate of only 30% in achieving the intended therapeutic outcomes because of the "one-size-fits-all" approach, which fails to take into account the unique needs of individual patients (Khalid and Billa, 2022). This problem is especially serious. When it comes to SODFs, splitting or crushing tablets is the only way to alter the dosage. However, this can lead to inadequate medication or damage to the film coating. As a result, there is an increasing interest in creating more effective medications that can be customized to meet the unique requirements of each patient. Numerous studies have been carried out to investigate the possible advantages and difficulties of utilizing 3DP in the pharmaceutical industry, even though the field of creating customized medication in tablet form is still relatively new. offers an summary of the produced SODFs. The formulation of SODFs, which call for exact, customized dosages for neurological conditions like Parkinson's disease (PD) and attention deficit hyperactivity disorder (ADHD), is one particularly promising application. ADHD, which is usually diagnosed in childhood and may persist into adulthood, is regarded as a chronic disorder of considerable impact. Stanojevic and associates investigated the potential for Drug release rates can be customized from immediate to prolonged by adjusting tablet thickness and drug loading. Additionally, the researchers wanted to develop predictive models for the release rate of atomoxetine (ATH) from tablets made with DLP 3DP technology. They developed a poly(ethyleneglycol)diacrylate (PEGDA), poly(ethyleneglycol) (PEG) 400, water, a photo initiator, and ATH as the model medication in a photoreactive mixture. The amount of ATH varied from 5% to 20% (w/w), but the PEGDA to PEG 400 ratio remained constant at 3:1. They made 3D cylindrical tablets with the same diameter but varying thicknesses using this mixture. They were able to produce tablets with both immediate and modified release profiles, with doses ranging from 2 mg to 37 mg.[8]

The researchers found it challenging to maintain the printability and reproducibility of the 3D-printed dosage form while choosing the right hydrophilic polymer and reaching the intended API release rate. If the formulation and excipient combination had not been optimized, these difficulties might have affected the study's overall viability and success. This demonstrates the importance of meticulous formulation development and optimization in the design of 3D-printed DDS. The quality characteristics and performance of the finished product can be greatly impacted by the selection of suitable excipients, API loading, and printing parameters. The challenges faced by the the complexity of creating 3DP drug

delivery systems and the necessity of a systemic approach to resolving these challenges are highlighted by the researchers in this study. Achieving the intended therapeutic effect while preserving product stability and quality requires careful optimization and validation.[29,30]

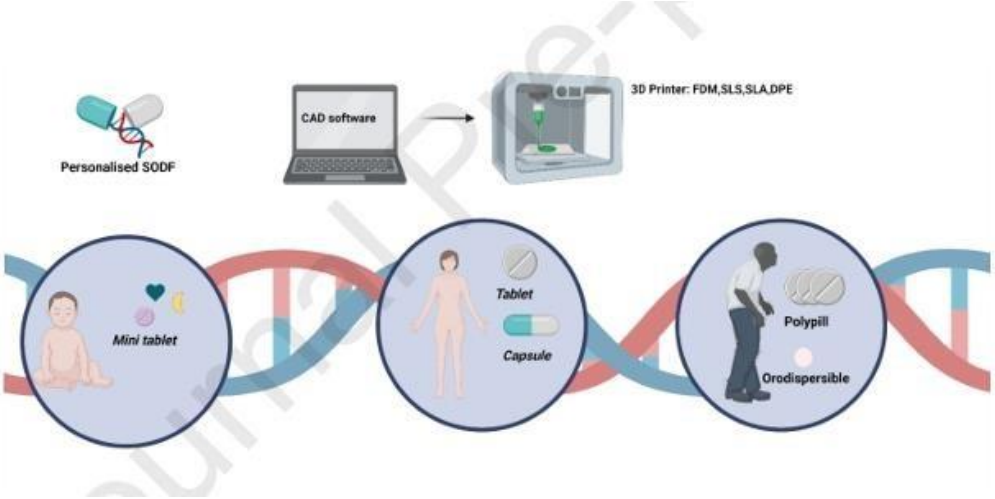


Fig. 4: Schematic overview of 3DP SODFs within the area of personalised medicine.

CONCLUSION

The pharmaceutical industry is adopting three-dimensional printing as a new manufacturing technique to shift from mass production to customized pharmacotherapy. Important parameters that impact the mechanical strength of the printed tablet are covered in the study, including hardness, tensile strength, friability, and infill content. Binder jetting, fused deposition modeling, semi-solid extrusion, selective lasersintering, and stereolithography were among the technologies used to create 3D printed tablets, and their benefits and drawbacks were examined. Numerous uses of 3D printing in pediatric formulations, orodispersible tablets, modified release, biphasic release, gastro-coating tablets, and sustained release tablets were found through a review of the literature. Lastly, 3D printing technologies combined with computational and artificial intelligence techniques are useful tools for predicting structural characteristics and subsequent drug release, resulting in a significant decrease in experimental effort.

"ONE SIZE DOES NOT FIT ALL"

"MEDICATION MUST BE INDIVIDUALIZED"

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