STM JOURNALS

Emerging Trends in
Personalized Medicines

Volume 2, Issue 1, 2025
(Journal):10.37591/ETPM
DOI: 10.37591/ETPM

https://journals.stmjournals.com/etpm

Review ETPM

Personalized Medicines in Pharmaceutics: Drug Delivery System

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Abstract

Pharmaceutics' personalized medicine is a developing area that seeks to customize medical interventions for specific patients. Instead of a one-size-fits-all approach, personalized medicine focuses on developing treatments that consider a person's unique characteristics, such as their genetic makeup, environment, and lifestyle. This allows for more effective treatment outcomes, as drugs are specifically designed to work best for each patient, reducing side effects and improving therapeutic results. In pharmaceutics, this involves creating customized drug formulations, dosages, and delivery methods that cater to the needs of specific patients. Advances in technologies like genomics, proteomics, and bioinformatics, along with digital health platforms that monitor patient data in real-time, are helping to speed up the progress of personalized medicine. These innovations are changing how drugs are discovered, tested, and administered in clinical settings, leading to more accurate and efficient healthcare solutions. However, there are still challenges to overcome, such as the high cost of developing personalized treatments, complex regulations, and managing large amounts of patient data. It offers the opportunity to create more effective, safer, and patient-specific treatments that can transform the way diseases are treated.

Keywords: Customized Treatment, Bioinformatics, Healthcare innovation, Digital Health Platforms, personalized medicine

INTRODUCTION

Precision medicine, another name for personalized medicine, is a cutting-edge method that customizes medical care to each person's particular traits, such as genetic composition, lifestyle, and environmental influences. This ground-breaking methodology departs from the conventional one-size-fits-all model of healthcare, acknowledging the distinctiveness of each patient and their varied responses to medical interventions (1). The significance of personalized medicine in the healthcare sector is profound. By examining a patient's genetic profile and other relevant factors, healthcare professionals can predict how an individual might react to specific treatments, facilitating more focused and effective therapeutic strategies. This customized strategy lowers the risk of unneeded operations and bad responses while also improving patient outcomes, ultimately raising the bar for healthcare. Furthermore, personalized medicine has the potential to completely transform early diagnosis, therapy, and disease prevention (2). It empowers healthcare providers to identify individuals at increased risk for certain conditions and to implement proactive measures aimed at preventing or postponing the onset of disease. This individualized and anticipatory strategy has the capacity to reshape the healthcare environment, delivering care that is more tailored and precise to the specific requirements of patients. Personalized medicine signifies a significant advancement in healthcare, promoting a more accurate, effective,

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Received Date: November 9, 2024
Accepted Date: December 2, 2024
Published Date: December 11, 2024

Citation: R. Shireesh Kiran, Jaggayagari Sarika, Panuganti Pranavi, Kondam Rithikesh, T. Rama Rao. A Review of Drug Design Techniques Assisted by Computers to Combat Diabetes. Emerging Trends in Personalized Medicines. 2025; 2(1): 11–21p

and patient-focused methodology for treatment and prevention. Its value is demonstrated by its capacity to improve health outcomes, lower healthcare expenses, and raise the standard of care for people everywhere (1).

THE ROLE OF TECHNOLOGY IN ADVANCING PERSONALIZED MEDICINE

The advancement of personalized medicine depends on technology, such as data analytics, pharmacogenomics, and genomics. Genomics, which examines an individual's genetic composition, offers critical insights into the relationship between genes and health conditions. By evaluating a person's genetic data, healthcare professionals can identify genetic variations that may influence drug efficacy, disease susceptibility, and treatment results. This knowledge facilitates the creation of tailored treatment strategies that cater to each individual's genetic profile, thereby enhancing effectiveness and reducing the likelihood of adverse reactions. Pharmacogenomics studies the influence of a person's genetics on how they react to drugs. It merges pharmacology, the study of drugs, with genomics to explore how genetic differences can influence medication responses (3). The primary aim of pharmacogenomics is to personalize drug therapies according to the distinct genetic traits of each patient, thereby improving therapeutic results while minimizing side effects. Key components of pharmacogenomics encompass: genetic variations that affect drug metabolism, transport, or response; the role of enzymes in drug metabolism; drug targets, which are receptors or proteins within the body; individualized treatment approaches that allow healthcare providers to predict patient responses to specific medications based on genetic profiles; and the identification of individuals at greater risk for adverse drug reactions due to their genetic backgrounds. The evolution of personalized medicine relies on adjusting treatments to align with the unique characteristics of each patient, thereby maximizing therapeutic benefits and minimizing negative effects. Pharmacogenomic testing is progressively being incorporated into clinical settings to inform treatment choices and improve medication safety and efficacy. Nonetheless, its broader implementation remains a challenge. (1)

Personalized medicine: it takes more than genomics

The global interest in personalized medicine is driven by remarkable advancements in genomics, particularly the potential for resequencing entire genomes at a population scale for a reasonable cost. The influence of genomics manifests through genetic mutations in constitutive proteins within target cells, as seen in the targeted molecular therapeutics pathway, or through the proteins that govern the absorption, distribution, metabolism, and elimination of drugs, which is the focus of the pharmacogenomics pathway (4). Notable examples of the former include tyrosine phosphatase inhibitors used in treating chronic myelogenous leukaemia and the monoclonal antibody trastuzumab, which targets the HER-2 receptor that is overexpressed in specific breast cancer cells. In contrast, the latter pathway is exemplified by genetic polymorphisms in cytochrome C drug-metabolizing enzymes such as CYP2D6, CYP2C19, and CYP3A4, as well as drug efflux transporters like P-glycoprotein and multidrug resistance protein. Pharmacogenomics remains a vibrant field of research, with the Pharmacogenomic Knowledge Base, established in 2000, serving as a vital resource (5). This database cataloges the connections between human genetic variation and drug responses, offering high-quality information and fostering collaboration among researcher (6).

Pharmacogenomics represents a dynamic field of research. A significant asset in this domain is the Pharmacogenomic Knowledge Base, established in 2000 to document the connections between human genetic variations and drug responses. This invaluable resource not only offers high-quality information but also fosters collaboration and idea exchange among researchers. Recently, the National Institutes of Health has allocated funding for 14 additional scientific projects and seven network resources to enhance the translation of genetic information into practical applications. (7)

As shown in Figure 1(6), the evolution of personalized medicine is shaped by a variety of factors beyond genomics. This reality necessitates a fundamental shift in how patients are stratified based on genomic differences in target receptor proteins and those associated with drug pharmacokinetics,

prompting significant changes in clinical trial design (7).

Figure 1. Multifactorial input to personalized medicine.

3D Printing as a Promising Tool in Personalized Medicine

The contemporary landscape of medical treatment is predominantly characterized by a "one size fits all" approach, wherein the majority of patients are administered the same medications at identical dosages and frequencies. However, it has become evident that this model does not apply universally across all treatments (8). The administration of identical active ingredients at uniform doses to diverse individuals has resulted in a range of responses. These responses can be either exaggerated, leading to adverse drug reactions (ADRs), or insufficient, resulting in minimal or no pharmacological effects. Both scenarios may culminate in additional complications for the patient (9). This realization has paved the way for the development of personalized medicine, which involves customizing medications to suit individual patients or groups of patients who share genetic, physiological, or pathological similarities. Emphasizing the principle that "one size does not fit all," the objective is to provide the most appropriate medication at the optimal dosage, tailored to the specific needs of the patient, and administered at the right time. The promises of personalized medicine include more precise, safer, and more effective treatments, which enhance patient compliance and offer cost-effective solutions (8,10).

Three-dimensional printing, often referred to as 3D printing or additive manufacturing, is a technique that constructs solid models by layering material in a systematic manner. This process relies on computer-aided design (CAD) software to communicate the necessary instructions to a 3D printer, which converts the digital model into two-dimensional (2D) layers. (8) as shown in figure 2 (9).

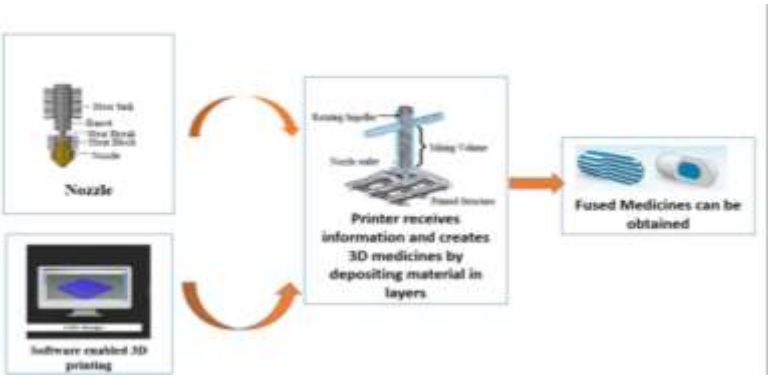

Figure 2. Diagrammatic representation of process of 3D printing (8).

History of 3D Printing

The origins of 3D printing research can be traced back to the late 1970s, during which numerous patents were filed concerning computer-aided additive manufacturing techniques across various platforms. In the mid-1980s, Charles (Chuck) Hull emerged as a key figure in this field by inventing and patenting stereolithography (SLA), a foundational technology in 3D printing. This innovative

process utilized resins that were polymerized with UV light to create the desired objects. These SLA printers were later made commercially available by Hull's company, 3D Systems. A University of Texas student named Carl Deckard developed the technique known as Selective Laser Sintering in 1986, which fused powdered materials using lasers (8). Soon after, in 1989, Scott and Lisa Crump at Stratasys developed fused deposition modeling, which entailed heating and extruding metal or plastic through a nozzle. Later that same year, Emanuel Sachs and his team at MIT created "three-dimensional printing techniques" that involved extruding a binding solution onto a powder bed, a method that became known as "binder jetting." Additionally, Hans Langer focused on direct metal laser sintering in 1989, employing lasers to fabricate 3D objects from computer models. Efforts were made to provide affordable and open-source printers to the public. The Replicating Rapid Prototyping (Rep Rap) project, initiated by Andrew Bowyer at the University of Bath, aimed to develop 3D printers capable of producing most of their own components, leading to widespread collaboration and growth in the field (11).

Since its development, 3D printing technology has found applications in numerous fields. Its initial use in healthcare focused on surgical planning and guidance, as well as the fabrication of implants. The creation of implants infused with active pharmaceutical ingredients also revealed promising opportunities for personalization. Additionally, 3D printing has been leveraged for educational purposes within clinical practice. Presently, this technology has transitioned into the pharmaceutical industry, where it is utilized to formulate various dosage forms (11-12) A landmark achievement occurred in 2015 when the FDA approved Spritam (Levetiracetam), the first 3D printed medication for epilepsy, produced by Aprecia Pharmaceuticals. This drug was created using the binder jet printing process, which enables rapid oral dissolution thanks to its highly porous structure. (8)

3D PRINTING TECHNOLOGIES USED IN PHARMACEUTICAL DEVELOPMENT

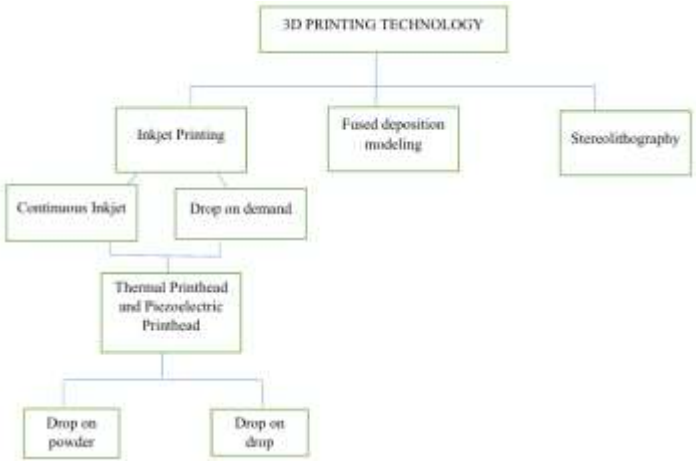

Figure 3. Schematic representation of various 3D printing techniques that are used to design different dosage forms for personalized drug delivery (13).

Inkjet Printing Method

Inkjet printing typically refers to technologies that utilize devices capable of generating patterns to digitally manage and position minute droplets of liquid onto a substrate. In the pharmaceutical sector, precise combinations of active ingredients and compatible excipients, referred to as ink, are applied in small droplets in a sequential manner onto an appropriate substrate. The primary platforms for inkjet printing are Continuous Inkjet Printing (CIJ) and Drop on Demand (DoD). (8)

Continuous Inkjet Printer

Continuous inkjet printers, as indicated by their name, release a continuous stream of liquid droplets onto a substrate, even in the absence of a specific requirement for these droplets. This process involves generating a pressure wave within the ink stream, which causes the ink to break into uniformly sized droplets through the vibration of the nozzle, subsequently ejecting them. The continuous nature of this

technology results in ink wastage (12). The benefits of this printing method encompass rapid droplet generation, which minimizes the likelihood of nozzle clogging. However, it is important to note that this technology is associated with lower resolution and higher maintenance costs (14)

Drop-on-Demand Inkjet Printer

In these printers, droplets of liquid are released from the printhead based on a trigger signal, occurring only when necessary, and are deposited onto a substrate. This type of printer usually contains a large number of nozzles, typically between 100 and 1000, although specialized printheads may consist of a single nozzle (15). Unlike continuous inkjet printers, which utilize external pressure for droplet ejection, drop-on-demand inkjet printers generate the kinetic energy of the droplets from sources positioned near each nozzle within the printhead. This technology is relatively simple, provides high precision, and is cost-effective. It allows for the deposition of small droplets of controllable sizes with good placement accuracy, thereby reducing drug wastage (16). Therefore, it is often preferred over continuous inkjet printing for various printing applications.

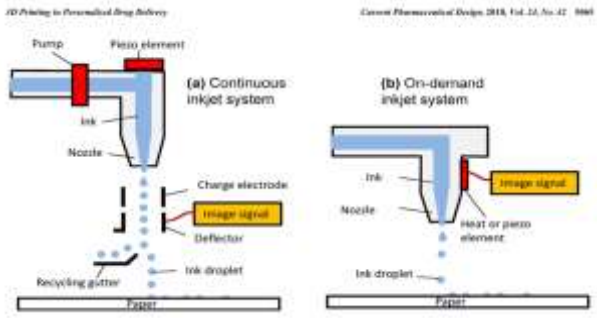

Figure (4). Inkjet printing system (6).

Thermal Inkjet Printer (TIJ)

In this process, thermal energy serves as the mechanism for discharging droplets that subsequently exit the nozzle. The resistors on the printheads come into direct touch with the ink. Heat is produced by these resistors when an electric current is supplied. A bubble in the volatile fluid is created by this heat, and when it expands, it pushes a tiny amount of fluid out of the nozzle, creating a droplet (see Figure 4). The demand for high temperatures (between 200 and 300°C) at the resistor is a major disadvantage of this technique, since it may cause the thermolabile active substances to degrade. (17).

Piezoelectric inkjet printer (PIJ)

With this technology, an electric voltage is applied to a piezoelectric element or actuator, which changes shape. This alteration produces pressure, resulting in the ejection of fluid (ink) from the nozzle (18). Once the element returns to its original shape, the nozzle is replenished with fluid and prepared for subsequent activation. The primary benefits of this method include its functionality at ambient temperatures and the use of less volatile, more biocompatible fluids (16-18).

Applications Pharmaceutical of Inkjet Printing

One of the prominent uses of inkjet printing in the pharmaceutical sector is in the creation of Orodispersible film (ODF) formulations. These films, which can be either single-layer or multilayer, consist of suitable materials that are infused with drugs, enabling the rapid release of the drug in the mouth to form a solution or suspension in saliva without the necessity of chewing or water. Thabet et al. used piezoelectric inkjet (PIJ) printing to apply enalapril maleate on ODFs made of hydroxypropyl cellulose that were either drug-free or included hydrochlorothiazide. Since the inks used were based on either methanol or water, several fixed-dose combinations of enalapril and hydrochlorothiazide could be achieved by customizing the dosages in the films. Moreover, ODFs of propranolol hydrochloride were created utilizing thermal inkjet (TIJ) technology on three distinct edible substrates: coated rice, rice paper, and a solution of water and glycerol.

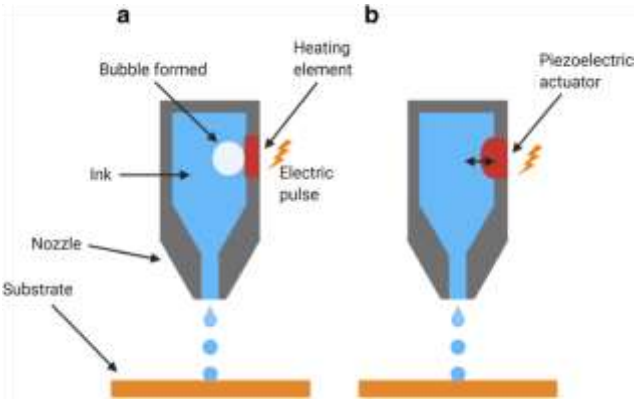

Figure 5. Schematic of inkjet printhead. a Thermal. b Piezoelectric (8).

Binder Jet Printing

Binder jet printing, commonly referred to as the drop-on-powder method, utilizes inkjet printing technology. The printhead in a binder jet printer may be either thermal or piezoelectric. This process involves a powder bed that is fused incrementally (18-19). As it moves along the x-y axis, the printer nozzle that dispenses the binder (and/or medication) fluid is designed to put the liquid onto the loose powder bed. The application of liquid droplets moistens the powder, resulting in the hardening and solidification of each layer. Solidification occurs through the formation of binder bridges or the dissolution and re-crystallization of the particles. Subsequently, the fabrication platform descends along the z-axis, while the powder delivery platform ascends. A roller then transfers a new layer of powder from the bed to the top of the previously bound layer (19). The 3D object is created by repeating this method iteratively. When finished, the item is taken out of the powder bed, and any powder that has come loose is taken out. To remove any residual volatile solvent, thermal sintering is commonly used (20). Based on binder jetting, zip dosage technology was used to create the FDA-approved Spritam. Another binder jetting technique is the Their Form method, a novel microfabrication process that constructs dosage forms layer by layer (21).

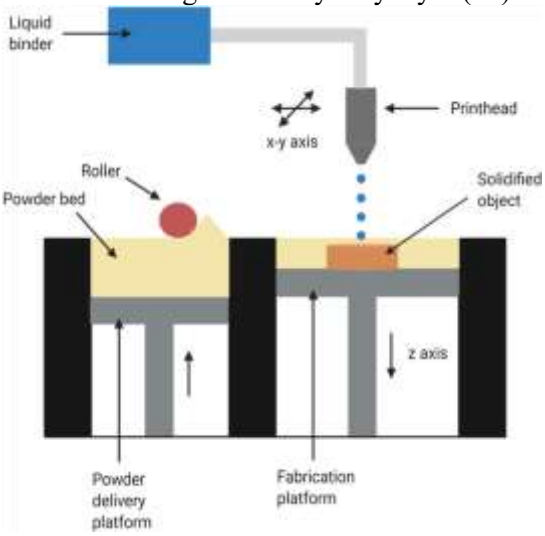

Figure 6. Schematic of selective laser sintering (8)

Pharmaceutical applications of Binder Jet Printing

The body of research surrounding binder jetting applications for tablet fabrication is considerable. The characteristics of tablets produced via binder jetting are significantly influenced by the type and concentration of excipients employed in their manufacture (21,22). Research indicates that using filling agents with high solubility in water, moistening agents with elevated water content, and binders that exhibit high viscosity in solution enhances both hardness and binding strength while extending

disintegration time (22). One study highlighted hydroxy propyl cellulose as a viable binder and revealed that the friability of tablets is closely related to the particle size of the binder utilized (23). Another study analyzed the impacts of 4-arm star and linear polyvinyl pyrrolidone as binders and found that a tablet's compressive strength (8).

PERSONALIZED DOSAGE FORMS PRODUCED USING 3D PRINTING

Using 3D printing technology makes it possible to create customized dosage forms that accommodate for each patient's particular release rates, profiles, and processes.

Immediate Release Tablets

Quick-dissolving dose forms that release their medicinal ingredients are known as immediate release dosage forms. Using hydrophilic polymers in the drug formulation can help achieve this. Potential polymers include povidone, hydroxypropyl cellulose (HPC), hydroxypropyl methylcellulose (HPMC), or graft polymers successfully prepared immediate release tablets containing theophylline and dipyridamole, employing PVP as the polymer, triethyl citrate (TEC) as a plasticizer, and talc as a filler in different ratios (24). Their observations indicated that over 90% of the drug was rapidly dissolved with a 10% loading, underscoring the advantages of utilizing 3D printing technology in the formulation of immediate release tablets.

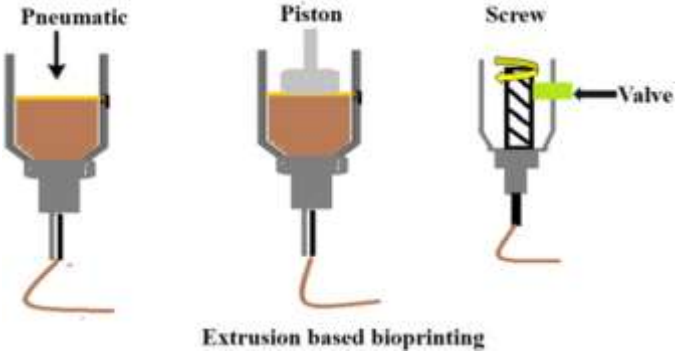

Figure 7. Extrusion based bioprinting (13).

Pulsatile Drug Release Tablets

A novel design of Chronocaps (capsules) has been developed utilizing 3D printing technology. This design is centered around a pulsatile drug delivery system. Conducted a comparative analysis of the performance of this 3D-printed capsular design against that produced by injection moulding techniques (25). The findings indicated that the drug exhibited a lag phase prior to its release, which may provide prolonged relief. Notably, the morphological characteristics of the capsules were found to be similar to those produced via injection molding. Consequently, it was determined that 3D printing could serve as a viable alternative to injection moulding (25, 26).

Monolithic Sustained Release Tablets

Tablets designed for sustained release were produced using fused deposition 3D printing, incorporating 5-Aminosalicylic acid and 4-Aminosalicylic acid as the active components. The drug loading was achieved with commercially available polyvinyl alcohol filaments, resulting in loadings of 0.06% w/w for 5-Aminosalicylic acid and 0.25% w/w for 4-Aminosalicylic acid. Employing the Fused Deposition Modelling (FDM) technique, the tablets exhibited a 90% infill and demonstrated a complete drug release over a four-hour period, confirming the method's effectiveness and cost-efficiency (27). Nonetheless, minor thermal degradation was observed with 4-Aminosalicylic acid, suggesting that this method may not be appropriate for drugs sensitive to heat.

Fast Disintegrating Tablets

A fast-disintegrating tablet was developed by incorporating loose powder through a 3D printing technique. The internal powder area was automatically delineated, and the binder solution was applied

in a layered fashion over the designated region (28,29). The observed disintegration time was 21.8 seconds, while the wetting duration measured 51.7 seconds.

Transdermal Drug Delivery (TDD)

Transdermal drug delivery (TDD) has proven effective in bypassing hepatic first-pass metabolism by enabling the transfer of drugs into systemic circulation through the stratum corneum of the epidermis. Several methods are available for facilitating drug movement through the skin's capillaries, such as transdermal patches, sonophoresis, iontophoresis, and permeation enhancers. Furthermore, 3D printing technology has been utilized to manufacture both patches and microneedle systems for TDD applications (27,13).

Patches

The global interest in transdermal drug delivery was significantly heightened with the launch of the scopolamine patch in the 1970s. This innovative patch was crafted with multiple layers to ensure continuous relief over an extended timeframe. Two distinct strategies were utilized in its design. The first strategy involved the reservoir patch, which contains a compartment for drug storage and a membrane that controls the drug's delivery to the body. This design aimed to provide stable release kinetics; however, there have been reports of overdose linked to membrane failure (13). The second strategy led to the creation of matrix-type patches, which were developed to miigate the shortcomings of the reservoir system. In this configuration, the drug is released from a matrix into the skin. Presently, several patches are available commercially, such as Emsam for treating depression, EvraTM/Ortho EvraTM for contraceptive purposes, and Exelon for managing Alzheimer’s symptoms (29).

Microneedles

In addition to bypassing hepatic first-pass metabolism, microneedles are designed to circumvent the stratum corneum, the most impermeable barrier that restricts the absorption of certain medications, thereby limiting their potential applications. These micro sized devices create small punch(29).

POLYMERS USED IN 3D PRINTING TO DESIGN PERSONALIZED DRUG DELIVERY

Polyvinyl alcohol (PVA)

PVA is recognized as a biocompatible polymer that demonstrates high solubility in water, moderate solubility in ethanol, and is largely insoluble in various organic solvents. It is produced by partially or fully hydrolyzing polyvinyl acetate. This compound is devoid of odour and possesses thermoplastic characteristics (30). PVA has been effectively employed in the production of multilayer polymer structures for additive manufacturing, utilizing the inkjet printing method with the XYPrint100Z Hybrid printer featuring a Konica Minolta KM512 print head. To mitigate the risk of nozzle obstruction, the ink was formulated using aqueous PVA solutions supplemented with humectants like monopropylene glycol. The molecular weight of the ink affects its viscosity, which is a key factor in determining printability. To achieve the appropriate viscosity range and ensure accurate 3D modelling, both high and low molecular weight PVA are utilized. High molecular weight PVA inks are capable of maintaining stability for six months without any discoloration. Furthermore, all inks have been found to exhibit pseudo-plastic and thixotropic behaviour at low shear rates, transitioning to Newtonian behaviour at high shear rates. (29,30).

Poly (lactic acid) (PLA)

The US Food and Drug Administration (FDA) have classified PLA, a biodegradable polymer, as generally regarded as safe (GRAS). It is extensively utilized in various applications, including regenerative medicine, controlled drug delivery, wound healing, stent placement, and tissue engineering. One of the key benefits of PLA is that it does not exhibit toxicity or carcinogenic properties in humans, nor does it produce harmful degradation products during metabolism (31). PLA is readily available for SLA and FDM printing, which enhances its utility in research involving human, animal, and cellular studies. This polymer is a favoured option for biomedical printing applications (13, 20)

Poly (caprolactone) (PCL)

PCL is a vital hydrophobic semicrystalline polymer that tends to exhibit increased crystallinity with a reduction in molecular weight. It is currently under investigation as a biodegradable material for use in printing scaffolds. A study by Beck et al. involved the production of 3D printed tablets made from PCL and Eudragit RL100, which were infused with polymeric nano capsules, utilizing a FDM printer (13). The study's goal was to analyse the effects of the filling process on the tablets. The FDM printer was calibrated to operate at a speed of 90 mm/s, resulting in a complete 100% infill of the tablets. Interestingly, tablets that featured a partially hollow core (50% infill) with Eudragit filament exhibited enhanced drug loading and a quicker release rate, potentially due to their elevated swelling indices (13,32)

Nanocellulose

Nanocelluloses, comprising cellulose nanofibrils (CNF) and cellulose nanocrystals (CNC), are produced from cellulose using a range of methods, including physical, chemical, enzymatic, or a combination thereof. These materials possess distinctive attributes such as remarkable strength, extensive surface area, and varied surface chemistry, facilitating the creation of stable and sustainable products. Notably, CNF is a highly desirable biodegradable substance that readily forms hydrogels characterized by a high abundance of hydroxyl groups. The fibresexhibit considerable flexibility and a strong tendency for entanglement. Furthermore, the elevated zero shear viscosity and significant shear thinning behaviour of CNF hydrogels make them particularly suitable for 3D printing processes (33).

APPLICATIONS OF 3D PRINTING IN PERSONALISED DRUG DOSING

The goal of personalized drug delivery should be to deliver an effective product that aligns more closely with patient requirements and reduces the occurrence of side effects**.**

Multiactive Dosage Forms

The polypill has been designed with a release profile that is both independently controlled and distinctly defined. This innovative approach targets individuals who must manage multiple medications for different ailments. With an immediate release compartment that contains aspirin and hydrochlorothiazide and three sustained release compartments that include pravastatin, atenolol, and ramipril, the polypill serves as a cardiovascular treatment method in this instance. The intended drug release profile has been effectively realized (34).

Cancer Treatment

Antineoplastic medications often struggle to effectively reach their target sites, leading to potential accumulation in critical organs and significant toxicity. Conventional delivery methods, including intravenous and oral administration, frequently fall short due to the inadequate solubility of these drugs, which can intensify the distress experienced by cancer patients (35). Therefore, topical therapies may address the shortcomings of traditional medical systems. Recently, a patch composed of 5-fluorouracil, polycaprolactone (PCL), and poly(lactic-co-glycolic) acid has been developed. This patch has been successfully positioned at the pancreatic cancer site, allowing for drug release over a duration of four weeks. Its precise geometry and release kinetics enhance the acceptability for patients (13).

CONCLUSION

The traditional one-size-fits-all approach to medication research and healthcare delivery could be completely transformed by this shift to personalized medicine. In summary, the potential of personalized medicine within the pharmaceutical industry is encouraging, with the ability to drive innovation, enhance treatment outcomes, and reshape healthcare systems globally. By adopting personalized medicine strategies and harnessing advanced technologies, pharmaceutical companies can lead this transformative movement in healthcare, ultimately resulting in improved treatments, better health outcomes, and increased value for patients and stakeholders.

In the current age, the demands of modern living have led individuals to increasingly depend on medications and nutraceuticals, often neglecting the importance of a nutritious diet. This trend has resulted in a rise in disease occurrences, thereby increasing reliance on various treatment regimens. Personalized medicine holds considerable promise for the design of formulations tailored to the specific needs and disease vulnerabilities of individual patients. The healthcare industry has observed significant growth in 3D printed formulations, employing techniques such as inkjet printing, nozzle-based printing, and stereolithography. The inkjet printing system allows for more precise formulation control, while Fused Deposition Modelling (FDM) achieves high dosing accuracy due to its superior resolution. In recent years, researchers have harnessed 3D printing technology to develop multiple dosage forms with minimal material loss. Cost-effective drug delivery devices, polypills, and transdermal drug delivery systems can now be produced with enhanced safety margins and shorter production times.

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