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3D Printing of Medications: Customizing Dosages for Patients

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ABSTRACT

3D printing is revolutionizing pharmaceutical manufacturing by enabling the creation of customized medications tailored to individual patient needs. Traditional drug production follows a mass-manufacturing approach, which may not adequately address the diverse physiological responses of patients, particularly those with unique medical conditions. 3D printing allows for precise dosage customization, controlled drug release, and the development of multi-drug tablets, improving therapeutic outcomes and patient adherence. Despite its promising advantages, challenges such as regulatory compliance, material selection, and scalability remain. This paper examines the benefits, applications, regulatory considerations, and future directions of 3D printing in pharmaceutical manufacturing, highlighting its transformative potential in personalized medicine.

Keywords: 3D printing, personalized medicine, pharmaceutical manufacturing, customized dosage, drug delivery, regulatory challenges, bioavailability.

INTRODUCTION

3D printing is a disruptive technology that fabricates objects through an additive process, layer by layer, creating solid three-dimensional (3D) objects. In the era of Industry 4.0, 3D printers are seen as crucial for manufacturing complex, customizable products. However, adapting this technology to conventional pharmacy operations is challenging, as pharmaceutical needs differ from other sectors. Nevertheless, 3D printing holds promise as a transformative manufacturing tool in the pharmaceutical industry, with potential for scientific and commercial success. It facilitates the fabrication of versatile and functionally graded oral dosage formulations, which can simultaneously release multiple drugs with specific profiles or modulate drug release over time. The industry has regarded pharmaceutical products and services as gateways to digital markets. With the advent of Industry 4.0, personalized drugs demand innovative production technologies. Research in drug targeting, combination therapies, and smart/nanomedicines is reshaping care provision and increasing therapy complexity, challenging traditional production methods. Drug manufacturers are facing intense competition, stringent regulations, and evolving market demands. They must achieve cost-effective, high-value healthcare quickly while improving productivity and flexibility. Integrating self-learning robotics, cyber-physical systems, Big Data, and Internet of Things technology is revolutionizing the conception, development, and delivery of pharmaceutical products [1].

Overview of 3D Printing Technology

3D Printing Technology: Advancements in digitization and technology have led to innovative manufacturing models, notably 3D printing, also known as additive manufacturing. Unlike conventional subtractive methods where material is removed, 3D printing adds material layer by layer to create objects. This technique utilizes various raw materials, including polymers, metals, ceramics, paper, and biological tissue, enabling the construction of complex structures that usually require costly infrastructure. The technology's growing presence has made numerous object files readily available for printing, highlighting the digital era's transformational impact on manufacturing. Modern 3D printing facilitates the direct transfer of digital data to the print head, eliminating the need for manual processes in manufacture or design. It encompasses controlled material deposition and prototype fabrication, enabling

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doctors to produce precise patient-specific models before surgery. Commercially, it accelerates time-to-market, allowing designers to directly print prototypes in hours using preferred materials. With the rise in demand, various industrial 3D printing methods, such as fused deposition modeling, selective laser sintering, and stereolithography, have emerged. Furthermore, varactor systems can deliver powder to lower layers, fusing it into desired patterns with focused thermal energy, while inkjet techniques are ideal for printing photopolymers [2].

Applications of 3D Printing In Medicine

D printing technology enables the creation of personalized solutions previously thought impossible. In pharmacy, it allows the on-demand production of custom dosages and forms of medication. This technology can enhance existing pills, preventing issues like overdose from broken tablets by producing tablets with properties that mitigate such risks. Multi-drug dosages or controlled-release tablets can be designed to be softer or breakable, thus improving patient adherence, as taking pills is often a disliked part of therapy. Patients may forget to take pills or may take incorrect doses at inappropriate times. In medicine, 3D printing can also create bio-models from medical images, anatomical models for surgical planning, and implants for joints. 3D imaging provides spatial information that aids in documenting lesions, patient education, and surgical preparation. To fully utilize 3D printing, it's crucial to identify specific cases where it can greatly enhance healthcare [3].

Current Challenges in Traditional Medication Manufacturing

Traditional medication manufacturing struggles with challenges that 3D printing can alleviate. Medications have typically been mass-produced in fixed dosages, which may not adequately address the needs of specific patient groups such as the elderly, children, or those with rare diseases. Specialized drug delivery systems, like modified-release or mucoadhesive systems, cannot be mass-manufactured effectively. This leads to difficulties in meeting individual patient needs under a "one-size-fits-all" approach. National Health Policies over recent decades emphasize personalized patient care to reduce adverse drug reactions, enhance drug efficacy, and minimize interactions. Besides personalizing treatment regimens, there is a focus on customizing drug delivery systems. Traditional production methods for modified-release dosages can be complex, often requiring many time-consuming steps and resulting in high rejection rates. Moreover, large-scale pharmaceutical production can lead to inaccuracies in dosing that might affect entire batches, often without immediate detection. Scaling up from preclinical to final product stages poses another significant challenge, as small-scale methods do not adequately predict larger batch behaviors. Additionally, stringent worldwide legislation mandates specific procedures for safe medication production, making the approval process lengthy and documentation-heavy, which delays market introduction. Ultimately, these restrictions hinder the adaptability of drug manufacturing systems to meet evolving patient needs. 3D printing technology presents a promising platform to address these issues and facilitate rapid exploration of innovative drug manufacturing solutions [4].

One-Size-Fits-All Approach

The 'one size fits all' medication model is inadequate for many patients, resulting in inconsistent treatment responses. This model presumes that average patients respond positively to treatments, neglecting individual differences and changing health statuses over time. Instead of merely substituting medications, a personalized approach emphasizes adjusting treatments based on individual needs and effectiveness. This method contrasts the ineffective "hit and hope" strategy, aiming for optimal drug therapy, often involving multiple medications or therapies. Recognizing the unique biochemical traits (polymorphisms) of patients is crucial. Prioritizing patient-specific factors, like life expectancy and overall health, is essential. Such individualized criteria allow for the identification of patient groups likely to benefit from similar treatment methods [5].

Advantages of 3D Printing in Medication Production

Medication production has advanced significantly due to 3D printing, allowing for layer-by-layer manufacturing with several advantages over traditional methods. This approach enhances the entire process from formulation development to customized dosages that meet patient needs. It could facilitate the accessible production of low-volume medicines for special patient groups overlooked by standard pharmaceutical mass production. Overall, 3D printing presents a promising pathway for personalized medicine, particularly in tailoring dosages for individuals. By integrating 3D printing with digitalization, there's potential for on-demand production of personalized dosage forms across tablets, capsules, films, and more. This review explores 3D printing as an emerging technology in pharmaceuticals, examining advanced formulations and the challenges associated with pharmaceutical 3D printing. This novel manufacturing method provides significant benefits such as easy prototyping and diverse dosage form

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production. Formulation parameters can be adjusted, and various 3D printing processes can be employed to enhance responsiveness to patient needs. Additionally, 3D printing facilitates the creation of complex geometries for controlled drug release and optimal formulation characteristics, and it supports other pharmaceutical manufacturing techniques, enhancing sophistication, quality, and productivity. The rapid prototyping capabilities of 3D printing can help identify optimal designs, reducing time and costs in the final product development [6, 7].

Personalized Dosages

The arrival of personalized dosages enabled by advancements in 3D printing is set to revolutionize medicine. Personalized medications can be tailored to individual needs based on unique physiology, optimizing therapeutic output. Each dosage can precisely control active ingredients, pill size, delivery method, and more, maximizing therapeutic efficacy. For instance, a personalized dosage of atenolol and hydrochlorothiazide was created for a 37-year-old male, considering his physiological parameters. Initial studies show proof of concept for patient personalization, indicating a need for further modeling and controlled research. Various studies currently explore integrating 3D printing in healthcare, emphasizing a shift towards patient-centered medicine. Medication adherence remains a concern, with up to 50% of patients struggling to follow prescriptions. Proper medication is effective only when taken accurately regarding drug type, timing, and dosage. However, traditional manufacturing constraints, particularly with laser-based 3D printing, hinder the production of true personalized medicine at low batch scales. Innovations like remote fabrication by coupling composers to printers could alleviate these issues. This approach suggests new possibilities in pharmaceutical manufacturing. Furthermore, personalized polymedication with diverse doses and release profiles can be 3D printed from a single composition setup, with output files suitable for multiple FLM printers. Despite challenges integrating stereolithography printers into 3D networks, aligners produced showed a 40% improvement in print accuracy. As pharmaceutical 3D printer options grow, this model may offer a cost-effective production method [8].

Improved Drug Release Profiles

The formulation of a drug product significantly impacts drug performance and patient adherence. The rate at which a drug is released is crucial. Tailoring this release rate can be important for specific patient needs; for example, rapid release can alleviate pain or prevent nausea, while sustained release may be preferred in other scenarios. 3D printing offers precise formulation control, allowing for optimal drug release tailored to performance. Various printing techniques enable the development of dosage forms with specialized release profiles. FDM printing utilizes a modulated nozzle to create Kontakt geometry that enhances drug release. Inkjet printing preserves the drug's release profile, regardless of tablet location. SLA printers with salmon-designed dosage forms surpass traditional geometries in targeted release. The intricate salmon and Kontakt geometries facilitate diverse release characteristics, enabling both immediate and sustained release from one dosage form. 3D printing's capability to develop multi-layered forms allows for sequencing drug releases, ideal for multi-drug regimens. Personalized printed regimens improve pharmacokinetics, enhancing medication effectiveness. Dosing accuracy and compliance can benefit from cascading release profiles. Smoothing-release designs reduce fluctuations in blood drug concentration, lowering adverse effects and improving quality of life. Enhanced blood concentration profiles contribute to better therapeutic outcomes. Crosshatch-printed tablets rapidly degrade, promoting swift drug release. Complex geometries help maintain therapeutic drug levels and provide biopharmaceutical advantages, including increased drug stability and bioavailability. Smoothing-release tablets delay gastric emptying of domperidone, validating predictions, while salmon-geometry tablets protect biologics, ensuring bioactive proteins remain intact until release [9].

Regulatory Considerations For 3D Printed Medications

The fast expansion of digital health and the introduction of 3D printed pharmaceuticals open a new era in 3D-printing-based personalized treatment. Nevertheless, this advancement should be tightly monitored by national and supranational regulatory agencies. Especially in the case of the comparably new 3D printed drug products, much attention should be immediately paid. The regulatory framework has to be set up or updated to guarantee that not only the safety and effectiveness but also the quality of the final product is sustained. The stringent demands will pose a challenge particularly for the micro-factories when selecting suitable equipment and feed materials/custom APIs for the production of medicines tailored to individual needs. The existing protocols and analytical methods, widely applied by the standard pharmaceutical industry, might turn out to be barely enough to conform to the necessary protocols and instead novel and more knowledge-intensive instructional tactics will have to be adopted. The two pioneering medical applications of 3D printing were the 3D printed radio-graphic anatomical

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models and the patient-matched titanium cranial-cranial maxillofacial implants. Since that time, national regulatory bodies have engaged with the scientific community, manufacturers, doctors, and other interested entities in a continuous dialogue on this topic. The cooperation aims to develop internal regulation as amended to the dynamically setting conditions, to discuss prominent issues, and to respond to raised concerns and requests for explanation. It has been underlined on several occasions that pharmaceutical companies keen to implement 3D printing should engage early on in the process with specialists: pre-clinical dialogues can be supportive in the establishment of an efficient course for the research, design, and testing strategy. However, the regulatory bodies also signal their constructive approach, e.g. customized drug approval utilizing progressive manufacturing setup [10, 11].

FDA Guidelines

As pharmaceuticals evolve towards personalized medicine, 3D printing of patient-specific dosages is becoming a common practice. This technology allows for a variety of oral dosage forms with customizable patterns and drug release capabilities, demonstrated through both prototypes and approved products. Despite potential cost-efficient methods for on-demand manufacture, challenges remain in terms of technology, regulation, and administration, necessitating a reevaluation of manufacturing standards, quality control, and patient safety. The FDA provides essential guidelines for developers and regulatory entities, influencing legal frameworks in the EU. Both the FDA and EU aim to support the pharmaceutical industry's implementation of 3D printing technologies, though the FDA's guidelines reflect unique considerations for patient safety during production. This article discusses the FDA's recommendations, highlighting crucial technical aspects for safety in 3D printed tablets, and presents recent FDA research on additive manufacturing, paving the way for expedited reviews of complex generic products [12, 13].

Materials Used In 3D Printing Pharmaceuticals

In recent decades, pharmaceutical dosage forms and their administration have changed considerably due to patient-specific needs, improved drug delivery systems, and the progression of disease states. Three-dimensional (3D) printing, often known as additive manufacturing or rapid prototyping, has witnessed significant and burgeoning research interest in the design and fabrication of dosage forms among researchers, academia, and industries utilizing medical applications. 3D printing enables the development of numerous forms of simple to complex geometries utilizing computer-aided design (CAD) and manifesting them as a physical formulation accurately within a short time. Pharmaceutical 3D printing is a game-changing technology that has emerged in the landscape of the pharmaceutical sector, permitting the production of personalized or complex-shaped formulations. The complexity of a dose makes an economic batch size function impractical, and 3D printing of a tablet could enable the combining of multiple drugs in a single dispersion program to make a dosage form with immediate, sustained, and delayed drug release possible. Three-dimensional printing of solid oral forms is a particularly promising way of enabling the development of personalized drug treatments and the better control of drug delivery. The pharmacologically active substances are generally blended with a whole range of pharmaceutical excipients, and the most popular form of drug delivery to the human body is oral solid dosages. Tablets, capsules, etc., are the usual forms of tablets, and capsules themselves consist of a number of pharmaceutical excipients like microcrystalline cellulose, pregelatinized starch, laponite, etc., which can alter the drug release dynamics. It can be implanted under the skin or in some part of the body where it is affected in small amounts over a long period of time. This polypill is designed to be very porous to ensure that it is absorbed slowly once implanted, although this device includes a number of risks incidental to its implantation, as in whole or part of the device. The cost of manufacturing this device is also very high because it must maintain a very high level of cleanliness and sterility [14, 15].

Polymers

The printing of medicines is seen as an innovative technology to allow the patient-friendly, on demand, flexible manufacturing of oral dosage forms. Pharmaceuticals can be manufactured by 3D printing using a range of polymers as printable materials. These materials can be printed as free-standing tablets, complex multi-material objects or as dual-drug reservoir systems. With the possibility of modifying the mechanical properties of the printed materials, polymers are versatile enough to substitute standard off-the-shelf drug delivery devices with tailor-made structures, adapted to the specific application. These drug delivery systems can be bioresorbable, eliminating the need for a second intervention to extract the system after the drug has been released. Polymers are frequently used either as drug delivery devices in the form of solid implants, fibres, micro- or nanoparticles or hydrogels. They can be bioresorbable and biocompatible, a crucial feature in many implant applications. The mechanical properties can be tailored

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to the required application by different crosslinking strategies, forming free-standing, mechanically strong solid objects. The unique opportunities to adapt the mechanical and drug release properties of the polymers to the drug formulation of interest makes it a highly versatile system for implant-based drug delivery. However, the release of the drug needs to be tuned accurately over many orders of magnitude to match the required dose and release kinetics. This is challenging since the drug release is governed by diffusion and often unstable mechanisms. Extraction of the drug has to be avoided, preserving the performance of the drug over many months or years. Common strategies to modify the release profile rely on the modification of the polymer properties, affecting the drug diffusion coefficient, by incorporating drug-loaded micro- or nanoparticles into the monomer or its copolymers or by tailoring the drug dose and the implant structure [16].

Hydrogels

Hydrogels are versatile polymeric network structures with high water content and exceptional biocompatibility. The unique properties of hydrogels can be used to develop drug delivery systems that swell upon exposure to various external triggers, releasing their cargo. In the domain of three-dimensional printing of pharmaceuticals, hydrogels have attracted significant attention as carriers or containers for drugs. The swelling properties of some hydrogels can be harnessed to produce dosage forms that conform to the shape of the target tissue after administration, thereby enhancing the efficacy and safety of the therapy. However, the application of hydrogels in 3D printing is challenging owing to suboptimal processing methods, layer fidelity due to poor mechanical properties, and a lack of approved excipients. Moreover, many hydrogels are swellable only in highly aqueous environments, limiting the integration of various drugs into hydrogel matrices. Nevertheless, this technology enables the transdermal and intestinal administration of diclofenac with improved bioavailability. The swelling characteristics of hydrogels have been exploited to create dosage forms tailored to the needs of a particular patient. Additionally, emerging research trends focus on enhancing the performance of hydrogels in 3D printing applications. Further, hydrogels play a pivotal role in tissue engineering and regenerative medicine [17].

Case Studies of 3D Printed Medications

Without beneficial technologies like 3D printing, it would be impossible for patients suffering from various diseases to access the exact dosages and drug combinations required for treatment. The technology behind these pharmaceutical advancements allows devices such as emergency rooms to print medication according to a specified dose, shape, and combinations of up to three pharmaceutical agents. This kept admitted patients medicated and able to rest calmly while waiting to be seen by a variety of different departments. Since these emergency room tablets are not mass-produced, they are more secure for the patient when compared to barcoding, as the sizes and shapes of each tablet can be customized against counterfeit drug manufacturers—acting as an unintentional visual authentication method. Additionally, these co-printed pharmaceutical agents and shape-defined tablets can be fine-tuned to suit a large variety of needs for chronic patient care, further discouraging the market for counterfeit medication. Production-based anti-counterfeit methods can be explored such as infusing marked text, logos, shapes, and geometries within the tablets. Quantifiable control points need to be identified and built into the workflow, and the practices and hardware for 3D printing need to be refined for optimal and speedy use [18, 19].

Spritam (Levetiracetam)

While many innovations have taken place in pharmaceutical sciences to comprise 3D printing technology, the production of 3D printed medications has brought numerous prospects to manufacturing customized solid dosage forms. One of the notable challenges of 3D printing has been to deal with an optimal excipient combination for a 3D printer, which has been recognized as the major challenge to meet standard medication post-printing in an acceptable appearance. An anti-epileptic drug that comes in a fast-dissolving oral preparation for epileptic patients with a complicated profile of restricted muscle functions. The technology emphasizes an OS strategy in drug endorsement as its capability for greater dosage accuracy eliminates other hitches linked to dosage variability, such as dosage accuracy in the scale of milligrams. Some neurological diseases, like epilepsy, need highly precise dosages to prevent perilous side effects. Blending controlled dosages and fast-disintegrating formulation in the same tablet is beyond the operational scope of conservative tablet production. 3D printing technology flawlessly amalgamates these features in patent compliant methods to manufacture medications with exceptional pharmacokinetics profiles as a reaction to specific restraining neural indications. A company has developed a 3D printer with the capability of accurate precise printability of various layers with patient-

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hyphenated prescription profile. The first case of scientific investigation, focused at measuring tablet characteristics e.g., size, mass, in-vitro disintegration period, revealed the existing challenges. Surprisingly, the printed single layer of a formulation was 67 times harder than the manually prepared composite. Technologies were primarily shielded by three dozens of patent memos. That's being imminently followed by comparable lawsuits against generic producers. On the other end, current guidelines on health products make production easier for companies with OS strategies planning since it is easier to dodge permission by printing only licensed materials due to drug compounding bottleneck. Collaboration needed further development with regulatory bodies to generate a balance between pharmaceutical establishments' monopolistic plans and the healthcare system as a whole. The case implies a broader focused verification of licensing pharmaceutical solids. It also encompasses progress in fundamental organic material R&D and a serious challenge of a multidisciplinary compound for the R&D market analysis concerning the remaining conceptual products [20, 15].

Future Directions and Emerging Technologies

In the relatively short time period since the first FDA approval for a 3D printed pharmaceutical product in 2015, researchers have gone from essentially exploring if and how 3D printing might be viable for pharmaceuticals to taking a more granular look at how the technology could be best optimized for a host of more nuanced applications. Research is underway to ensure the quality and safety of 3D printed dosage forms and further examines the technology to most effectively leverage it for applications like modified release formulations and the printing of numerous APIs in a single dosage form. The overarching goal of this area of work is to produce a comprehensive foundation for the safe and effective utilization of 3D printing in the pharmaceutical sector, which has great potential to benefit healthcare more broadly. This ongoing work is an exciting intersection of applied pharmacy, material science, and pharmacokinetics within the broader field of additive manufacturing, and as such is perhaps achieving the initial goal of such a research endeavor. Additional emerging technologies and practices of critical importance to the future of 3D printed pharmaceuticals. A number of these developments are currently underway or on the precipice of becoming mainstream, such as the maturation of continuous inkjet (CIJ) and semi-solid/inkjet platforms, individualized drug cocktails being printed and formulated in conjunction with macitentan and cabazitaxel. However, the potentially broader impact of the technology may not have overarching importance for the field until disease treatment strategy increasingly moves from the current focus on the chemical composition of drugs to the fabrication of functionally graded macro/microstructures, which might only come to pass in about a decade [21, 22].

Nanotechnology in Drug Delivery

Numerous studies have shed light on the promising intersection of nanotechnology and drug delivery, particularly within the context of 3D printed medications. One of the major focusing parameters is nanotechnology, leading to specific bioavailability improvement methods. A number of the most used preparation and technology methods for nano drug formulations are presented and their advantages into drug delivery according to many recent references are given. The other main parameter is the use of targeted approaches in drug delivery. Targeted drug delivery systems (DDS) can release the active pharmaceutical agents in a secure way, only to the area which is being diseased and hopefully, can further enhance drug efficiency. Moreover, the basic formulations, design, and interactions into the drug delivery system are explained in nano scale. The benefits and potential downsides of nano-sized drug carriers produced by 3D printing techniques in drug delivery materials are also discussed. The eminence of nanomaterials in regard to allowing controlled release profiles that can be aligned with the needs, disease state, and biochemical individuality of individual patents, is further explained. It is expected that in the following years, new studies providing a holistic understanding of how to combine different technologies in 3D printed pharmaceuticals may strongly emerge, improving patient care and advancing personalized medicine. The discussions reviewed the basis of, and the forces driving advances in the multidisciplinary approaches required to make 3D printed nanomedicines a clinical reality [23, 24].

CONCLUSION

The integration of 3D printing into pharmaceutical manufacturing marks a paradigm shift toward patient-centered medicine. By offering precise dosage customization, enhanced drug release profiles, and improved patient adherence, 3D printing has the potential to revolutionize drug therapy. However, regulatory frameworks must evolve to ensure safety, efficacy, and quality control in personalized drug production. The success of FDA-approved 3D-printed medications like Spritam underscores the viability of this technology, paving the way for future advancements. As research progresses, innovations in

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material science and nanotechnology will further enhance drug formulations, making personalized medication more accessible and effective in addressing diverse healthcare needs.

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