COMMENTARY

Recent improvements in additive manufacturing methods used in the pharmaceutical industry

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ABSTRACT

Although the 3-dimensional Printing Method (3DP) was first invented in the 1980s, its use has significantly increased over the past 10 years, with the pharmaceutical industry playing a significant role in this development. Researchers from all over the world are working diligently to create novel pharmaceutical dosage forms, particularly customized ones that can meet the individual demands of the patient. These dosage forms aim to accommodate tailored medication, on-demand production, improved geometry, size, and dosage, as well as greater bioavailability of the drug active. With the advent of precision medicine in healthcare, the use of Additive Manufacturing (AM) technologies for the creation of oral dosage forms and polypills is now considered essential. This opens up new possibilities for the administration of drug combinations and formulations that are specifically suited to each patient's needs. The widespread commercialization and acceptance of AM techniques could potentially disrupt the current healthcare supply chain, but they also have the potential to reduce the amount of wasted medication that is produced by outdated and unneeded drugs.

INTRODUCTION

First of all, the pharmaceutical business is expanding quickly, and recent advancements have undoubtedly made it easier to produce novel dosage forms for targeted therapy. In spite of this, there are still just a few industrial facilities producing these pharmaceutical dosage forms, and they mostly use modified tablets as the traditional drug delivery method. The advent of 3-Dimensional Printing (3DP) technology has pushed the limits of research and the creation of novel dosage forms, particularly in the case of customized and altered tablets.

Although traditional dosage form manufacturing is designed for mass production, it has some drawbacks, including significant capital costs for major equipment acquisition, the need for a sizable operational area, a skilled and knowledgeable crew, and a lack of flexibility in dose adjustment. Additionally, because of the complex process and lack of flexibility, it is unable to realize personalized medicine. Despite being built for mass production, traditional dosage form manufacturing has numerous downsides, such as high capital expenditures for major equipment procurement, the requirement for a substantial operational area, a knowledgeable and skilled workforce, and a lack of flexibility in dose adjustment. Additionally, tailored medicine cannot be realized due to the difficult approach and lack of flexibility. In order to tailor the treatments for specific patients, about 3000 compounding pharmacies in the United States fill over 30 million prescriptions annually. Tablets are typically split using tablet splitters, hands, or knives, which results in varying doses due to uneven weight distribution after splitting. Tablet breaking might potentially have a significant impact on drug release characteristics, particularly for formulations with controlled or extended release. Additionally, the integrity of the tablet coating is directly impacted by its fractionation, which encourages early drug release. Conventional patient therapy with a conventional dose of a medication can occasionally result in trial-and-error, inadequate care, and an extension of the time needed to determine the ideal amount. This dramatically raises the patients' morbidity and mortality rates in addition to increasing the expense of their medical care. Individualizing the treatment plan can solve this issue and considerably lower the likelihood of Adverse Drug Reactions (ADRs). To provide better patient care and lower costs, the Personalized Medication (PM) has the potential to adapt the treatment regimen to deliver the best response with the highest margin of safety.

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Compounded preparations have a number of disadvantages, including a lack of quality control, unpredictable drug absorption through biological membranes, and an unknown stability characteristic, despite the importance of extemporaneous compounding of tailored medication. The pharmaceutical industry has adopted 3D Printing (3DP) or Additive Manufacturing (AM) as one of the most cutting-edge technologies as the production of drug delivery systems has increased significantly over the past ten years. A variety of methods are used in 3DP or AM technologies to build solid objects layer by layer. By employing Computer-Aided Design (CAD), which creates a computer-designed model that fabricates the desired product using layer by layer feed deposition, Additive Manufacturing (AM) makes it easier to create pharmaceutical dosage forms. Additionally, AM offers a cutting-edge platform to get around the drawbacks associated with the traditional "one-size-fits-all" idea. Electron Beam Melting (EBM), extrusion-based 3D printing, inkjet printing, Multijet Fusion (MJF), powder bed deposition, selective laser melting, Selective Laser Sintering (SLS), and Direct Metal Laser Sintering (SLM/DMLS), as well as Stereolithography, are the most frequently used 3DP technologies in pharmaceutical companies (SLA). Extrusion-based 3DP has shown enormous potential and interest among academics because to a variety of desirable properties such freedom with the design and polymers utilized, wide availability, and cheap operational costs. Based on differences in the process parameters and the kinds of polymers utilized, extrusion-based 3DP methods are categorized as Direct Powder Extrusion (DPE), Pressure-Assisted Microsyringe (PAM), and Fused Deposition Modeling (FDM). Utilizing a single-screw direct powder extruder 3D printer made for printing with Polylactic Acid (PLA) or Acrylonitrile Butadiene Styrene is known as the Direct Powder Extrusion (DPE) technique (ABS). Using this method, the material is added to the printer's hopper and pushed into the single-screw extruder using a little spatula. The extruder is positioned vertically to reduce air bubbles and promote the flow of powder into the screw. In addition, the issue of blending immiscible polymers is avoided by using pressure-assisted microsyringe to create hybrid film structures.

The chemical structure, morphology, mechanical qualities, and disintegration can all be identified using this method. Last but not least, Fused Deposition Modeling (FDM) is an additive or anabolic method that entails adding material to form components. The review's next section will briefly highlight the numerous 3DP-based technologies that come before the creation of customized dosage forms. There are several 3DP technologies, but not all of them can be used in the pharmaceutical manufacturing industry. The fabrication of intrauterine devices, implants, microparticles, printlets, orodispersible films, etc., which call for a high degree of quality, purity, and precision, can use these technologies, which may be promising technologies for the future. AM technologies have emerged as a possible remedy for the latter even in the COVID-19 pandemic, with the medical fraternity, healthcare experts, researchers, and investigators always working to minimize the infection incidence. These AM approaches help in monitoring and diagnosing the pandemic and case fatality rates in addition to speeding up the printing of medical devices and Personal Protective Equipment (PPE). By quickly making these 3DP dosage forms, PPE kits, medical devices, and theranostics accessible to healthcare practitioners around the world, these AM techniques therefore provided a helping hand inresolving the COVID-19 situation. However, the disadvantages of the latter include the absence of comprehensive rules, approvals, and difficulties with process design related to the 3DP technique. However, in a hospital or community pharmacy setting where these prescriptions are compounded on demand for special patient cohorts like geriatric, pediatric, or patients with special prescription requirements, like those allergic or intolerant to certain APIs or excipients, these technologies may be exempted from the regulatory restrictions (e.g. Lactose intolerance). These 3DP methods are also useful for producing customized dose formulations on demand in pre-clinical and clinical settings. Although these obstacles prevent these 3DP techniques from being widely used and accepted, resolving these problems will secure their application in the future.