REVIEW ARTICLE

Applications of 3D Printing Techniques in Pharmaceutical Dosage Forms

Nuha Mohammed Abdulkhaleq[1*], Mowafaq M. Ghareeb[2], Zainab M. Abdulkhaleq[3]

[1]*Department of Pharmaceutics, College of Pharmacy, Al-Mustafa University, Baghdad, Iraq*
[2]*Department of Pharmaceutics, College of Pharmacy, University of Baghdad, Baghdad, Iraq*
[3]*Department of pharmaceutical chemistry, College of Pharmacy, Al-Mustafa University, Baghdad, Iraq*

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ABSTRACT
Three-dimensional (3D) printing has evolved exponentially since the first technology was introduced in the early 1980s. 3D printing technologies are classified into various manufacturing techniques, also called Additive manufacturing, where all are based over formulation of three-dimensional objects layer: by: layer process according to the digitally designed structure. The main types of 3D printing technologies that have been used within pharmaceutical and biomedical field is classifiable into three groups: printing based on inkjet (IJ) systems, nozzle-based deposition systems (NBD), and system based on laser (SBL). From ten year ago (2015) when the FDA has been approved the 1ist 3D printed tablet, Spritam, extensive research into the role of 3D-printing in the pharmaceutical industry of various dosage forms and bioengineering has gone. 3D-printing is considered a potential tool and a key driving factor for the manufacturing of specialized dosage forms, prostheses, and devices. The involvement of 3D-printing in pharmaceutical applications will allow the formulation of sophisticated and complex solid dosage forms via many doses and drug release, adjusted to the individual needs, in a more cost-effective way than the conventional manufacturing processes. This article reviews the main 3D-printing technologies used in the pharmaceutical field, with their advantages, disadvantages, and their application with various dosage forms.
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INTRODUCTION

3D-printing also called additive-manufacturing, has recently been involved in various manufacturing disciplines including pharmaceutics. There are many 3D printing technologies discovered since the 1980s, all of them share the same principle of action which is the formulation of a 3D object in consecutive layers by deposition or solidification of the printing material based on the 3D design created via computer-aided-design (CAD) software.[1] The involvement of 3D printing in pharmaceutical manufacturing and medical applications has several advantages including (a) the possibility of producing different dosage forms tailored to individual needs with the required dose;[2] (b) incorporation of combining many medications into one dosage form as demonstrated by Pereira et al. where they successfully print a fixed-dose combination unit (polypill) containing four active ingredients, and this will enhance patient adherence and convenience,[3] (c) Formulation of complex design dosage forms with the possibility of modulating release profile based on the shape and density,[4,5] (d) 3D printing is considered a powerful tool in manufacturing of biomedical devices such as implants and prostheses that are designed and customized for individualized patients.[6,7]

Recently, Patient-centric treatment has received a lot of attention to development and studying the interindividual variability of patients from different backgrounds and the effect of pharmacogenetics and pharmacokinetic profile on selecting the optimized treatment for each patient.[6,8] 3D-printing is seen as revolutionary and powerful tool with a pharmaceutical industry that brings the possibility of manufacturing personalized medicine and customized devices based on patient's needs.[9–11] Nonetheless, 3D printing technologies available for pharmaceutical manufacturing have some drawbacks compared to traditional manufacturing techniques, especially in commercial large-scale production. In term of speed, 3D printing technologies are considered slow manufacturing techniques due to the time required to build a layer over layer, which limit their use in large scale production.[12] Also, the restricted accessibility of biocompatible and biodegradable printing materials appropriate for each type of printing technology still remains a barrier in the further development of dosage forms.[13] Various 3D-printing technologies have been employed in pharmaceutical research and the design of dosage forms, which can be categorized based on their mechanism of action and feeding materials into three categories including printing-based IJ systems, NBD , and SBL.[14] Each category is subdivided

**Author for Correspondence: pharmacyone94@gmail.com*

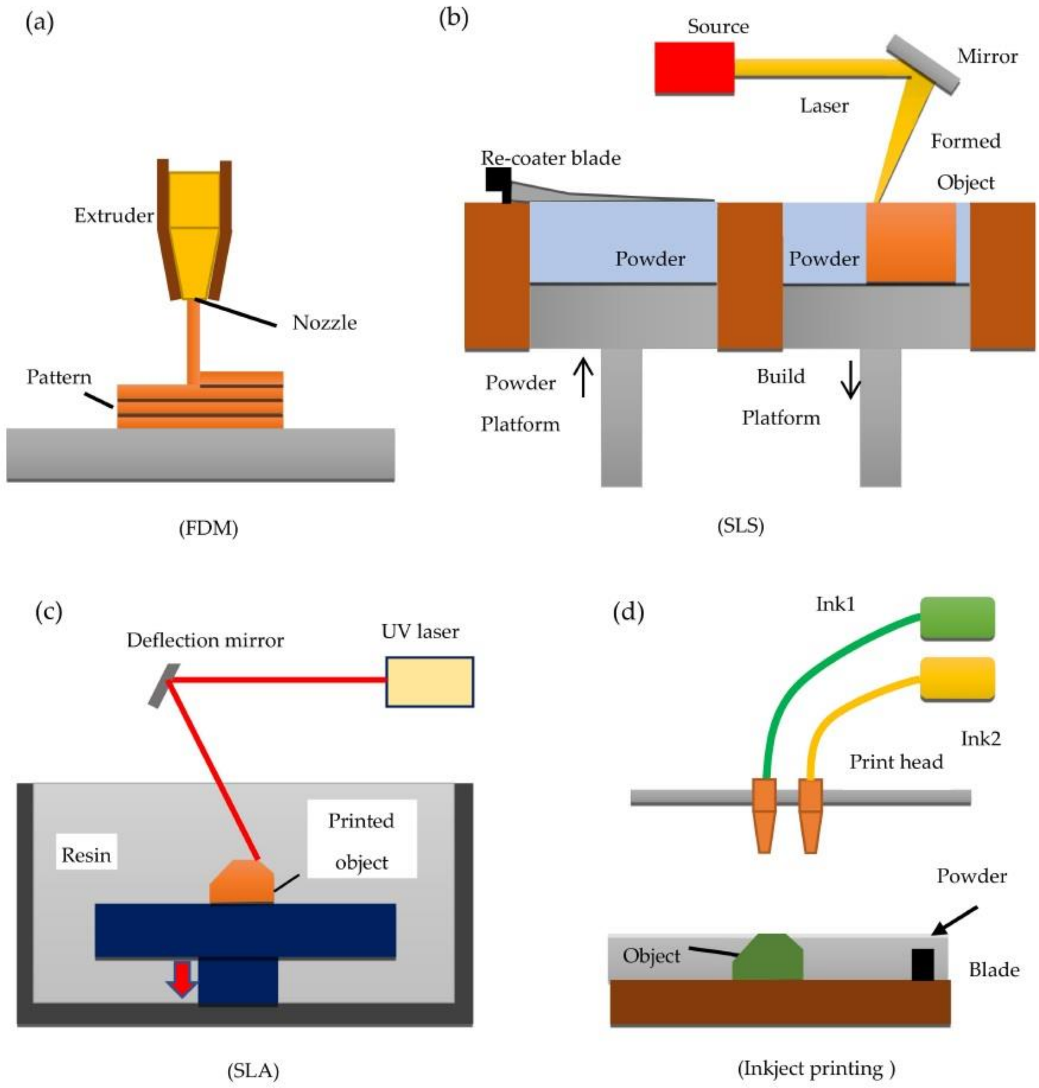

Figure 1. Schematic diagram of (a) FDM; (b) SLS; (c) SLA; (d) inkjet 3D printer. Adapted with permission from reference [41].

into several subtypes based on the material used and source of energy. One of the widespread technology used Fused deposition modeling is utilized in pharmaceutical research (FDM). which belongs to nozzle-based deposition systems, mainly because it's low cost, easy to use, the capability of printing complex designs, and availability of a broad range of materials compared to other technologies.[15]

FDM-printers are based on the thermoplastic filament extrusion through a heated nozzle head that's moving to create the 3D object in a layer-by-layer fashion.[16] It is possible to load drugs into the polymeric filaments by Hot Melt Extrusion (HME) where active ingredients and thermoplastic polymers are mixed and extruded through the application of heat and pressure to form homogeneous solid dispersion filament suitable for the FDM printers.[17] The usage of FDM 3D-printing in pharmaceutical research to design and formulate dosage forms suitable for individual cases as variable doses and strengths of actives pharmaceutical ingredients are needed within a dosage form. Furthermore, this approach may create customized complicated geometries and diverse shapes for the release of a single active medicinal ingredient, making it ideal for personalized medication therapy. The modification of the shape, size and drug release have an advantage in specific populations to increase their compliance.[18] For example, such printed pharmaceutical dosage forms can be useful in designing drugs for geriatric, pediatric, and patients having dysphagia.[19] When the age increase leads to increase polypharmacy (using more than one medicine) this leads to increase non-adherence, FDM 3D printing solved this problem by combining drugs for these patients in one tablet,[20] where Atenolol, Pravastatin, and Ramipril are combined in one tablet. Tablets with various release profiles were able to be formulated by FDM by choosing the suitable polymeric blend and modifying the design and infill percentage, e.g immediate-release[21,22], modified-release[23], zero-order release[24], and controlled release.[25] This paper describes the major techniques for 3D-printing drug delivery systems, in addition to their benefits and drawbacks, as well as uses of 3D-printing in the formulation of various dosage forms.

3D-printing techniques utilized in the formulation of pharmaceutical dosage forms

Inkjet printing (IJ)

Powder bed inkjet(IJ) 3D-printing technology has been broadly applied for building different types of highly porous three-dimensional objects[26]. The inkjet printer is based on the spraying of microdroplets consisting of the drug and other excipients via a nozzle then deposited on the solid platform based on the required design, as shown in Figure 1 (d). The advantage of inkjet printers include efficiency, precision, high resolution, high-speed manufacturing, multi-material printing, and economical, its limitation includes nozzle clogging, low friability, and hardness[27],[28].

Continuous inkjet

The continuous inkjet 3D printer is based on the application of a continuous stream of droplets (50–80 µm) under pressure via electrostatic plates to the substrate, forming the required structure, its advantages include high drop speed over extended distances, faster output, and no blockage of the nozzle, while its disadvantage includes a high degree of wasted ink, and restricted availability of solvent-based inks[27],[28].

Powder deposition technique

This method is also referred as a drop-on solid deposition because it uses spray drops from printer heads to deposit into solid materials in successive layers to generate solid free form. It is divided into two types: drops-on-bed and drops-on-powder deposition, based on binder fluid deposition on powdered materials, its advantage includes speed, average resolution, no support needed, and recyclable feed materials while its disadvantage includes a change in the mechanical properties and particle size of powder binding materials[29]. The materials that aren't sintered can also be easily separated from the support structures during the post-drying and polishing process. This is a less common approach in the pharmaceutical industry since the high heat energy emitted by laser beams might cause drug and excipient deterioration[30].

Pressure-assisted microsyringes (PAM)

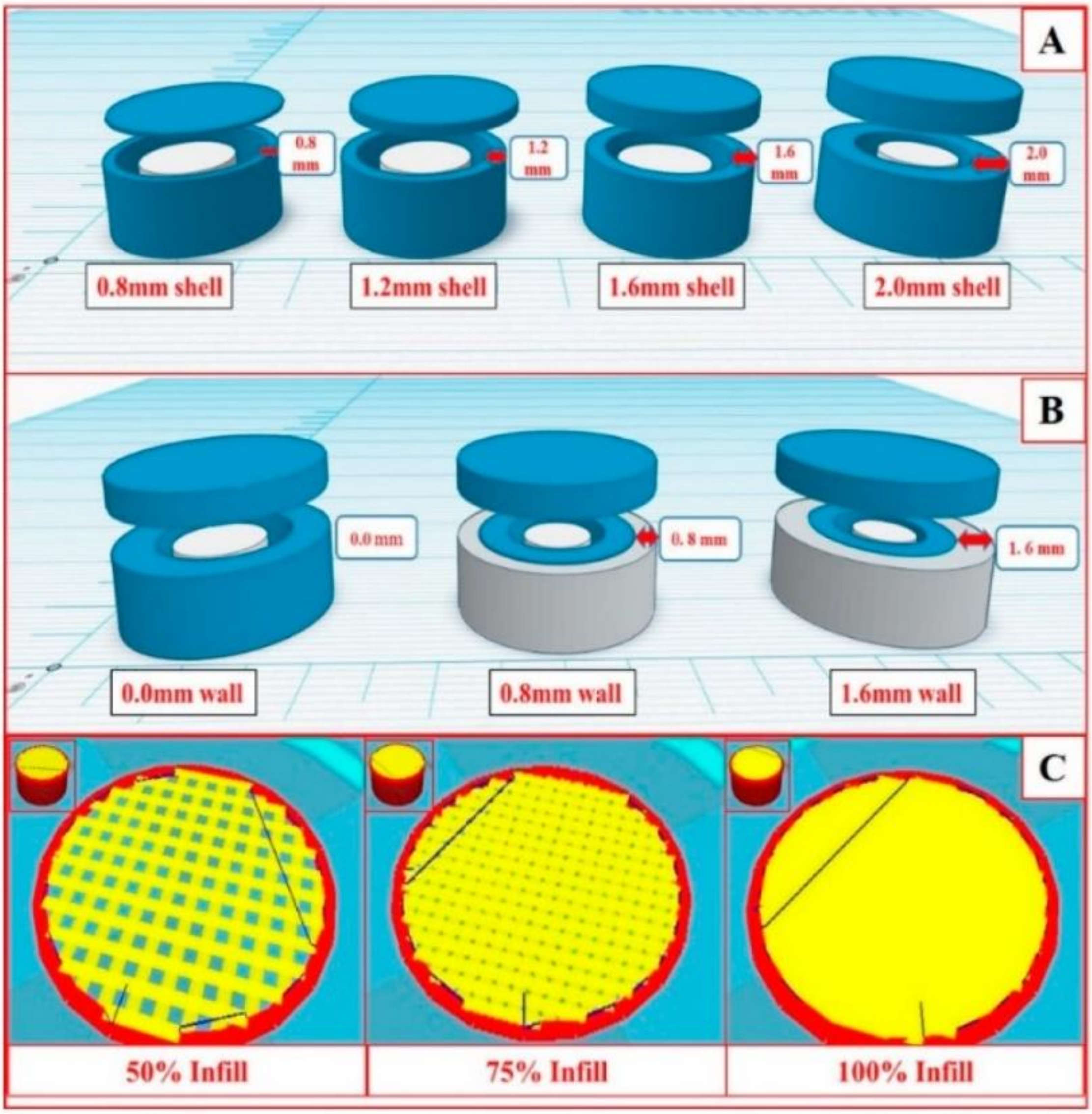

Figure 2. Graphical images of the floating tablets with different shell thickness (A), thickness of wall (B), infill density (C) Adapted with permission from reference [64]

The type of 3D printer belongs to the NBD system, which is depend on the extrusion of semisolid viscous material via a nozzle by the application of pressurized air in a cylinder. The advantages of semisolid materials extrusion include a high drug loading capacity, suitability for thermolabile drugs, faster printing speed, the process can be done at room temperature, and cost-effectiveness, but it has disadvantages such as the need for specific rheologic properties of the materials to be suitable for printing, cross-linking polymers are required, nozzle clogging is common, the resolution is inadequate in comparison to other technologies, the mechanical strength is low, and the resolution is restricted by the nozzle size[6,31].

Fused deposition modeling

The most common type of 3D-printer used in the formulation of pharmaceutical products is FDM. The extrusion of thermoplastic filaments, which are continually fed via a melted and heated the nozzle head just beyond its glass transition (Tg) temperature, is the basis of FDM 3D printers. As seen in Figure 1(a), the extruded (HME) material will be added layer-by-layer and cooled to formulate a 3D design. The hot-melt extrusion process is applied to load active pharmaceutical ingredients (API) into thermoplastic polymeric filaments, in which the medication and other polymers and excipients are extruded via a nozzle using heat and pressure, resulting in filaments appropriate for FDM printers[32]. Solid polymeric filaments can be utilized to print a geometrically designed drug delivery structure with adjustable release profiles, drug-eluting device, and scaffolds using the FDM process[33,34]. Its advantage includes compact equipment, Inexpensive, diverse, eco-friendly, readily available, non-contaminating raw materials, customized dosage forms, and ability to create complex designs, while its disadvantages include slow printing speed, lower resolution compared to other techniques, risk of drug and excipient degradation due to elevated temperature, limited availability of thermoplastic filaments[35].

Stereolithography

As depicted in Figure 1(c), stereolithography (SLA) is a laser-based 3D-printing process which uses resins with UV-sensitive to create layered prototypes, models, and patterns through photochemical reactions. The UV laser beam energy to which the oligomers and monomers are subjected determines the width of the dried layer [36]. The great resolution is one of the benefits of SLA technology. Fast, scalable 3D printing of stimuli-responsive hydrogels utilizing poly (N-isopropyl acrylamide) could help with a variety of pharmaceutical applications in the drug delivery system[37]. SLA printers have the advantage of high resolution and accuracy and minimal heat exposure, so thermolabile compounds can be used, but the main drawback is the limited availability of photocurable resins that's safe for pharmaceutical manufacturing[8].

Selective laser sintering

The selective laser sintering (SLS) is based on the emission of high power laser to sinter powder photopolymers, where the photopolymer is located on a platform that lowers when the first layer is cured to sinter the next layer until the 3D object is created, Figure 1 (b) shows a schematic diagram of the SLS printer. Its advantages include high resolution (30 µm), precision, faster fabrication, and no post-curing required while its disadvantage includes low efficacy, significant wastage of powder materials, expensive, limited availability of drug and excipients suitable for this process[38,39].

Digital light processing

The digital light processing technology is similar to SLA technology where liquid photocurable resin is objected to the laser beam to solidify and create the 3D object, but the difference is that in DLP a digital mirror apparatus is used which permits the curing of one layer at once. its advantage includes high speed, high resolution manufacturing while its main disadvantage is the toxicity of photosensitive resins[40]**.**

Application of 3D-printing in the production of pharmaceutical dosage forms

Oral dosage form

The FDM's potential usage in medicinal applications has been demonstrated through extensive investigation. This method successfully generated elegant 3D printed tablets, also known as printlets; a term that has been used to characterize 3D-printed oral dosage forms. Different from the ordinary manufacturing methods, the FDM is capable of formulating dosage forms with numerous sizes and geometries, where changing the shape or size will lead to different drug release profiles[4].

Goyanes A et al. conducted patient acceptance experiments and discovered that 3D printed tablets manufactured by FDM have various patient preferences, with different forms preferred to be ingested contrary to others, altering patient adherence to prescriptions.[42]. Furthermore, researchers found that the suitability and acceptability of the dosage form can be affected by the size and color of the dosage form, this can be important with a specific population such as geriatric and pediatric patients[42]. This technology has the flexibility allowing the production of printlets, where each shape has a different drug release profile, so providing more control over the drug profile[43].

Goyanes et al. have demonstrated that altering the geometrical structure of the printlets can change drug release characteristics in a variety of ways[4]. FDM printers were used to print five distinct shapes, including a sphere, pyramid, cylinder cube, and torus[4]. Another investigation discovered that the proportion of infill is another parameter impacting the release of drug profile[35]. By reducing the infill percent, which increases the surface area of the tablet and improves dissolution, an immediate release tablet was successfully manufactured through FDM printer, with more than 85 percent of the medicine released within 30 minutes[44]. HME has been widely studied in solubility enhancement through the formation of solid dispersion, and the incorporation of HME with FDM allows the formulation of dosage forms with improved solubility and hence bioavailability with the required dose and release profile[45–48]. Several techniques have been used in the formulation of solid dispersion for the purpose of solubility enhancement but HME is still one of the best techniques because it's a continuous process that does not require toxic

organic solvents and requires less time than other methods[49–51].
Another oral application was capsular devices made from hydroxyl propyl cellulose and coated with Eudragit® L 30 D 55 for pulsatile drug administration in the colon[52]. Additionally, successful oral formulations of immediate release and orodispersible 3D-printlets having carbamazepine-hydroxypropyl-beta-cyclodextrin complex have been reported with appropriate drug release and physical features[53]. DLP 3D printing technology was employed in another investigation to create sustained-release orally medicinal dose forms[54],[55].
Another application of 3D-printing in pharmaceutics is the manufacturing of films. Modified semisolid extrusion 3D printing method was utilized to prepare orodispersible films of benzamine hydrochloride[56]. The innovative technique adopted in the extrusion 3D printing technique significantly reduced the time of preparation in addition to augmented the mechanical characteristics of films[57].
The simplicity with which fast-dissolving oral films are administered promotes patient compliance, making them a viable alternative to traditional tablets, especially for special populations such as psychiatric, geriatric, pediatric, and cancer patients. The research showed that the FDM technology may be used to make single and multi-layered oral films[58],[59].
Okwuosa et al. investigated the use of FDM 3D technology to create liquid capsules made from Eudragit polymers, as well as the effect of capsular shell thickness and printing modes on the rate of drug release[60]. This dosage form design and formulation using 3D-printing will allow healthcare staff to produce modest amounts of liquid capsules, which will be especially advantageous to elderly and paediatric populations[61].

Gastro-retentive drug delivery system

The application of 3D printing was used to manufacture a novel form of gastro-retentive drug delivery system[62]. The candidate for gastro-floating delivery are drugs that affect the proximal part of the GIT, poorly soluble in the intestinal tract, or unstable in intestinal fluid. Floating tablets are designed to float on gastric contents surface until the drug is completely dissolved, and the passage into the duodenum will be avoided. FDM printer was utilized to formulate 3D dipyridamole tablets with a low-density internal structure, consequently, this design improved the rate of drug release and consequently improved the bioavailability and efficacy of the drug[63].
Qijun et al. have ultilized the extrusion-based 3D printer (MAMII) to formulate gastro-floating tablets of dipyridamole, the researchers created three-dimensional printed tablets with different infill percentages, which include 30%, 50%, 70%, and 100% infill[62].
Using FDM and HME together for 3D printing was to formulate floating tablets, where a core-shell with different infill percentages was formulated and used as a coat for Theophylline that has been directly compressed tablet, the coat of the tablet was manufactured using ethyl cellulose and hydroxypropyl cellulose-based filaments produced by HME method and printed with FDM printer, and the core of theophylline tablets was prepared by the direct compression method, as illustrated in figures A, B, and C.[64] Other uses of HME in combination with FDM 3D printing is the formulation of gastro-retentive delivery for medications such as itraconazole [48], amoxicillin [65], Pregabalin [66], and propranolol [67].

Colon-targeted drug delivery system

Colonic targeting is being considered as another innovative orally pharmacological application since it can be utilized to reduce drug doses and reduce systemic side effects. Using a covalent linkage of a drug with a carrier, the polymer having pH-dependent0solubility, erosion or swelling, the degradation of carriers by colonic enzymes, and the polymers having bioadhesive properties for targeted drug release are the most common methods for colonic targeting drug delivery. To prevent any potential drug release in the varied pH of the GIT, such drug delivery relies heavily on polymeric characteristics in addition to repeated coating. 3D printing technology can be utilized to generate multi-layered polymeric dosage forms capable of delivering drugs to the colonic target[68]. Colonic release is possible with a 3D-printed hollow tablet shell made of PVA filament with varying degrees of infill percentages [69],[70]. Khaled et al. exhibited the ability to create 3D printed tablets with varied medication release characteristics using three active components (captopril, nifedipine, and glipizide)[71].

Intrauterine drug delivery system

Vaginal rings are gynaecological drug delivery devices that supply a steady amount of medication over time. Personalized 3D-printed progesterone-loaded 'O', 'M', and 'Y' shaped vaginal rings were successfully printed using an FDM-printer, as demonstrated by Fu j et al[72] where the filaments were prepared by melting and mixing of the amorphous solid dispersion which contains the progesterone in combination with polymers PLA/PCL used at a ratio of 8:2 using Tween 80 as a plasticizer[72]. Genina et al. were able to create 3D printed T-shaped intrauterine devices and subcutaneous rods using Indomethacin as a model medication in another study[33].

Transdermal drug delivery system

The use of transdermal medication delivery has been shown to increase therapeutic efficacy and patient compliance[73]. The use of needles and microneedle arrays for transdermal drug delivery has been shown to boost the skin transport of different substances[74]. Different transdermal dose forms, such as microneedle transdermal patches, cream transdermal devices, and others, were designed using 3D printing technology[19], [32],[75]. Application of the coated microneedles, porous microneedle, and hollow microneedles array is used for pain-free rapid transdermal drug delivery. Ross et al. used Insulin polymeric coatings are applied to metal microneedles using inkjet printing technique for transdermal delivery[76]. It was proposed that biodegradable microneedles coated with amphotericin B might be made using a combination of piezoelectric inkjet printing, micro-stereolithography, and micro-molding[77]. SLA and other photopolymerization-based 3D printing technologies offer the potential to tailor the shape of the microneedle array to deliver medications at varied depths of skin penetration depending on the therapeutic intent and physicochemical properties of the actives[27]. In numerous research, digital light processing (DLP) technology was employed to create micromolds for the formulation of microneedles, and microneedle arrays made using the DLP technique were coated with various therapeutic compounds for diverse clinical uses[78]. Increasing the risk of infection-related with microarrays may be diminished by coating with zinc oxide and silver films with pulsed laser deposition due to the antimicrobial properties[78]. Biocompatible 3D printed electromagnetic microneedle has potential applications in the fields of drug delivery and bioengineering[79],[80]. Other applications of 3D-printing technology in the transdermal drug delivery were the coupling of HME-FDM and SLA echnique using various polymers for the design and manufacturing of personalized nose-shaped transdermal device containing salicylic acid[81].

CONCLUSION

The introduction of 3D-printing technologies into pharmaceutical manufacturing is still in its infancy and is likely to play a significant role in the development and formulation of new dosage forms. Patient-centric care and personalized dosing have gained wide attention recently, and the implication of 3D-printing will enhance the development of dosage forms and medical devices to meet these requirements. The significant increase in research and investigation in this field will lead to the development of new technologies and offers more safe and effective therapy for individualized persons. One of the main challenges in the application of 3D-printing in the pharmaceutical field is that the currently available technologies including inkjet printing, stereolithography, and nozzle based deposition technologies are designed for printing various materials that are not relevant to the pharmaceutical industry, and researchers are modifying the feedstock to be suitable for each technology, thus much research should focus on the development of new 3D-printing technologies designed specifically for pharmaceutical manufacturing and this will enhance the quality control and other regulatory guidelines of the resulted products and will bring this technology more into practice.

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