

3-D Printing Technology in Pharmaceutical

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Abstract:

3D printing technology enables for layer-by-layer production of 3D objects of varied geometries. The capacity to construct sophisticated and complicated solid dosage forms, on-demand production, and cost-effectiveness benefits 3DP technologies over traditional manufacturing procedures. Also, in recent years, there has been an increased interest in using 3DP technology in pharmaceutical production and drug delivery systems. Despite the numerous potential medicinal and economic benefits of 3DP technology, significant technological and regulatory obstacles prevent its widespread use in pharmaceutical goods. To overcome present limits and provide patient-specific health care with on-demand personalised drugs in the future, 3DP approaches need constant invention and refinement. These procedures may generate pharmacological dosage forms, demonstrating the technology's viability in regular commercial production.

Keywords 3D printing · Dosage forms · Personalized medicine · Pharmaco-printing · Polypill

Introduction

Three-dimensional printing (TDP) is fabricating 3D items from digital models by fusing or depositing materials in stages. Process. It is also known as additive manufacturing. fast prototyping (Goole and Amighi. 3DP technology has existed since the late 1980s and utilized in engineering and non-medical manufacturing (automotive, (Alan et al. 2016), but quick 3DP technique improvements and the new biocompatible materials enable recent 3DP pharmaceutical uses Years. Following the first medicinal uses of 3DP, custom prostheses and dental implants 3DP technology has been utilized since the early 2000s. to directly print complicated 3D medical equipment custom-made medical gadgets A patient's anatomy (Maulvi et al. 2017). It may also minimize the likelihood of failure at medication development process, since this method may be used to create more predictable medicine Screening rigs (Peng et al., 2017).

Many inherent benefits over traditional technology, such as customizing and personalizing medications with specifically tailored dosages, fabrication of complicated solid dosage forms with high 3DP technologies in pharmaceutical production achieve high accuracy, precision, on-demand manufacture, and cost-effectiveness. recent years. Various medication delivery systems based on 3DP technology ORCs, microchips, implants pills, IR tablets, and MPR dosages Personalized dosage forms to prevent unneeded negative effects, to achieve customized release profiles, 3DP technology may be used to create individualized medicine delivery systems. Alhnan et al. Spritam® was FDA-approved in 2015 (Levetiracetam) is the first 3D-printed medicine. A new pharmacoprinting chapter (Norman et al., 2017). 3DP technologies suited for pharmaceutical manufacture will be reviewed and their applications to the creation of dosage forms, demonstrating the technology's economic viability.

3DP technologies applicable to pharmaceutical developments:

The energy source, material supply, and other mechanical characteristics of 3DP have been varied. Standard 3DP technologies for pharmaceutical applications include printing-based inkjet (IJ) systems, nozzle-based deposition systems, and laser-based writing systems (Murphy and Atala 2014). The sections that follow offer a short introduction to each 3DP technology.

Printing-based inkjet (IJ) system:

On-demand and continuous inkjet printing (CIJ) are two kinds of IJ systems (DOD). This method provides a constant stream of ink via a 50–80 μm orifice, whereas DOD produces droplets 10–50 μm in diameter and 1–70 pL in volume (Konta et al., 2017). Both IJ systems include a printing head that controls drop creation speed, size, interval, and fluid viscosity. The DOD system uses either a thermal or piezoelectric printer head (Goole and Amighi 2016). To print with thermal DOD, the ink is heated locally, forming bubbles that expel the ink. In piezoelectric DOD, a quick change in volume of a piezoelectric crystal produces an acoustic pulse sufficient for ink ejection (Gans-de et al., 2004). Thermal DOD is confined to volatile liquids, but piezoelectric DOD applies to all beverages (Goole and Amighi 2016). The thermal approach may achieve temperatures up to 300°C, which may degrade pharmaceuticals, but the piezoelectric DOD method can function at ambient temperature with less volatile and more biocompatible liquids.

Drop-on-drop deposition and drop-on solid deposition are two subcategories of DOD technology (Goole and Amighi 2016). To create a high-resolution 3D structure, the printer head ejects droplets onto each other. Direct writing IJ-printing produces tiny drug delivery systems with a droplet size of roughly 100 nm and layer thicknesses more minor than the droplet size owing to surface wetting, solvent evaporation, or shrinkage (Norman et al. 2017). The whole printed fluid composition should jet and solidify quickly (Norman et al., 2017). The viscosity and volatility of the printed fluid are also critical to avoid the coffee ring effect, fluid leakage, and nozzle clogging (Goole and Amighi 2016). The ideal viscosity is 8-14 cps (Sumerel et al. 2006). Loading capacity and stability of the product are also affected by pharmacological characteristics (Goole and Amighi 2016).

Drop-on-solid deposition seems more appropriate for pharmacoprinting a broader spectrum of pharmaceuticals, from chemical substances to biomolecules. Depending on the materials used, drop-on-solid deposition is also known as binder jetting, plaster printing, or powder bed 3DP. It is then lowered, and another powder layer is applied, repeating until a 3D structure is created (Goole and Amighi 2016).

The binder ink glues together the powder bed to form a 3D object (Gross et al., 2014). Layer thickness and spacing should be tuned for optimum layer adhesion. Its reactivity with the binder ink and topological properties influence the final product quality (Goole and Amighi 2016).

Nozzle-based deposition systems:

For example, insufficient hardness, a rough surface, and low drug loadings are disadvantages of the most frequent printing-based IJ approach (Dimitrov et al. 2006). Before dumping the binder solution over a powder bed, assemble the solid components and binders before 3D printing. A 3D object (Vaezi et al., 2013). This procedure is fused deposition modelling (FDM) and pressure-assisted microsyringes (PAM), procedure with or without material melting, respectively. FDM is a popular 3DP technology. Medicines, foods, and bioengineering (Alhijjaj et al. 2016). FDM stands for fused filament manufacturing. A method of melting a thermoplastic polymer is extruded via a high-temperature nozzle and layered onto a build tin (Goyanes et al. 2015a). An example of 1a shows FDM. The active pharmaceutical ingredient (API) and thermoplastic polymer are incubated in a specified solvent or melted at a given temperature before extrusion into the filament. FDM is a low-cost manufacturing technology that enables the manufacture of difficult-to-make pharmaceuticals. It is strong mechanically, with alternatives to change medication release rates (Konta et al., 2017). But it has several flaws that restrict its medicinal uses, such as high operating temperatures. Biodegradable thermoplastic polymers extrusion-friendly melt viscosity PAM is also a nozzle-based technology. In Extruded PAM, viscous, and semi-liquid materials aspirator (Goole and Amighi 2016). The syringe move like an IJ printer head, and the compressed air PAM technique produces microstructures of 5–10 μm . (Vozzi et al. 2003). It can design complicated drug delivery systems and compare them to other approaches since a constant flow at room temperature may be used. However, the use of solvents may cause safety and stability difficulties. steps (Goole and Amighi 2016) Konta et al. Microsyringe with Piston (PAM2)

PAM2 is a quick prototyping technique like PAM. Rather than a stepper motor than cranked air (Tirella et al. 2011).

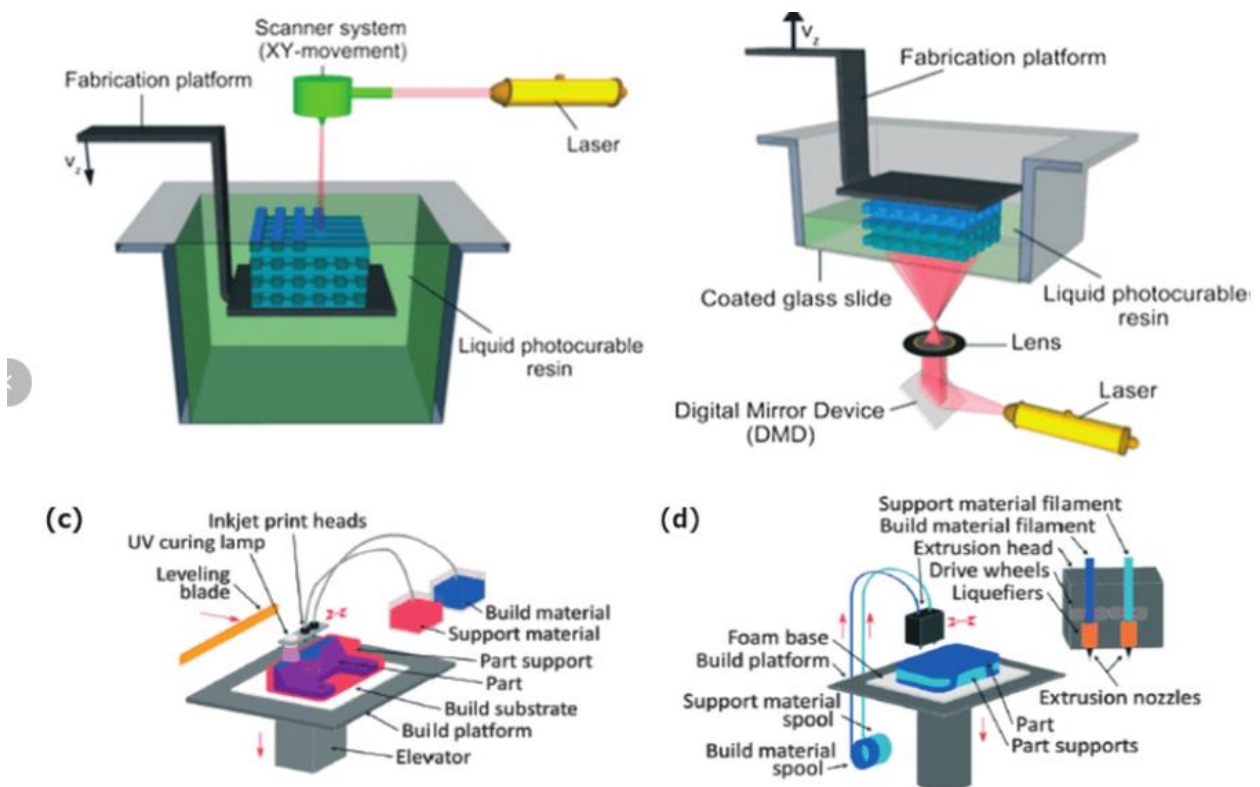


Fig 1: Graphical illustrations of 3DP processes. A FDM printer, B SLA printer, C DLP printer, D SLS printer

Laser-based writing systems:

Stereolithography (SLA) is the first commercially accessible laser-based solid freeform manufacturing process. SLA uses controlled solidification of a liquid resin to create 3D objects. polymerization (Chia and Wu 2015). A moveable platform is in the liquid photopolymer vessel. The lifting platform begins at the liquid photopolymer's surface, and once the laser is applied, the platform is lowered into a vessel to the new polymerized layer thickness (Fig. 1b). This iteration is made until a solid 3D object is produced. SLA high resolution permits complicated structure creation and reduces warmth during the printing process, making it ideal for thermo-labile meds (Konta et al., 2017). The photopolymer used is It should be a liquid that immediately solidifies. Ultraviolet (UV) light and must also be humanely authorised. Thus, a shortage of food FDA-approved photosensitive polymers and limited drug loading restrict the Despite its widespread use in pharmaceuticals, tissue engineering (Melchels et al. 2010). Digital DLP is a new 3DP method. Using liquid photopolymer resins and a laser beam to grow and solidify (Kim et al. 2016). The usage of a digital mirror gadget for curing one layer at a time, as seen in Fig. 1c. Because of the millions of mirrors, lowering layer production time by half (Gross et al. 2014). Thus, DLP provides quicker construction and simple adjusting of thickness. SLS employs a high-power laser as A way to sinter photopolymer powder (Fig. 1d). Using a laser to fuse powder photopolymer selectively lowers the platform supporting polymer to powder. Strength, chemoresistance, and rapid SLS technology have several benefits. SLS is comparable to direct metal laser sintering (DMLS). However, while DMLS is used on metal alloys, SLS is polymers, metals, and wares (Gross et al., 2014). e-beam melting (EBM) SLM and SLS are both comparable. Unlike sintering, both EBM and SLM layer-by-layer melting of metal powders process. SLM employs a laser beam's energy. Whereas EBM employs a high-power electron beam to fuse the powder particles void Higher throughput and more excellent a more homogenous thermal field than SLS, but less precision and surface quality (Bikas et al. 2016). EBM Used in drug-loaded implants (Bezuidenhout et al. 2015). Besides the 3DP technologies mentioned above, 3DP technologies include multi-jetting modelling, selective heat sintering, and laminated item production. Those 3DP techs are not presently utilised in pharmaceutical production; however, some may have future medicinal

uses. So, a big step forward in Material sciences and new materials will enable more widespread 3DP usage. Technologies.

Application of 3DP technology to pharmaceutical dosage forms

Table 1 shows that 3DP technologies like IJ, FDM, and SLS can now manufacture suitable medicinal dose forms. In this study, 3DP pharmaceutical applications are focused on oral solid dosage forms and transdermal delivery methods, which seem to be making more progress and are more appropriate for widespread usage.

Tablets:

Pharmaceutical goods are most often used orally. Tablets and capsules are common solid oral dose forms. The use of 3DP technology in pharmaceutical production has been widely studied. 3DP tablets fall into two categories: single API tablets and multi-API tablets. Examples of each type are provided in the following sections.

Table 1 Selective examples of pharmaceutical dosage forms fabricated by 3DP

Dosage form	3DP method	API
Tablets	Inkjet system	Acetaminophen
		Chlorpheniramine maleate
		Chlorpheniramine maleate, diclofenac
		Levetiracetam
		Pseudoephedrine HCl
	Laser assisted system Fused deposition	4-Aminosalicylic acid, paracetamol
		5-Aminosalicylic acid, 4-aminosalicylic acid
		5-Amino salicylic acid, theophylline, prednisolone
		Aspirin, hydrochlorothiazide, atenolol, pravastatin sodium and ramipril
		Captopril, nifedipine and glipizide
		Guaifenesin
		Paracetamol
		Prednisolone
		Theophylline
		Implant
Isoniazid and rifampicin		
Levofloxacin		
Levofloxacin and tobramycin		
Microneedles	Dacarbazine	
	Diclofenac	
	Insulin	
	Rhodamine	

Single API tablets:

Initially, 3DP was used to create basic IR tablets with a single API.

Many research used the FDM process to make IR tablets because of its ease of fabrication. Procedures. Single API IR tablet samples recent research (Goyanes et al. 2016a; Okwuosa et al. 2016; Sadia et al. Not just low-dosage versions but also highly drug-loaded dose forms 3DP technology FDM has been used to effectively manufacture thermoplastic polyurethane-based dosage forms containing 60% medication (Verstraete et al. 2018). Similarly, an IR tablet containing 80% paracetamol was made utilizing an extrusion-based method. 3D printer (Khaled et al. 2018). Besides IR pills, 3DP can make ER pills. Skowyra et al. ER pills made from prednisolone-loaded polyvinyl alcohol filaments with up to h (Skowyra et al. 2015). Another ER pill Alhijaj et al. (2016), utilizing polyethylene glycol, Tween 80, polyethylene oxide (Eudragit® EPO) or Soluplus®. When making tablets with 3DP, the choice of 3DP materials and processes the obtained tablets' physical characteristics, leading to varying medication release rates Formulation ratios Components modify the physical characteristics of tablets, affecting medication release. In, Wang et al. (2006) created three doses of controlled-release pseudoephedrine 3DP technology forms. On the other hand, changing the amount of Kollidon® SR and

hydroxypropylmethylcellulose (HPMC) with consistent manufacturing parameters (Wang et al. 2006). These formulas also revealed high association dissolution rates and clinical pharmacokinetics Distinctive doughnut-shaped multi-layered acetaminophen delivery devices the medication and release-delaying compounds used 3DP technique provides linear release of an aqueous drug (Yu et al. 2009). Besides, the immediate 3DP technology may be used for modified-release tablets. Using three LG, MG hypromellose acetate succinate and HG), the FDM produced enteric pills. How to make delayed-release pills an outer enteric coating (Goyanes et al., 2017). Also, 3D extrusion printing has the making gastro-floating pills (Li et al. 2018). Other 3DP approaches include SLA and IJ. Tablets (Kyobula et al. 2017; Wang et al. SLA, for example, utilizing polyethylene glycol diacrylate, diphenyl(2,4,6- (trimethylbenzoyl)phosphine oxide, and where the medication release profiles based on formulation components (Wang et al. Clark et al. (2017) recently produced a ropinirole hydrochloride tablet employing IJ and UV scalable, high-precision, and customizable IJ-based additive manufacturing to the pharmaceutical business (Clark et al. 2017). By integrating the geometrical capabilities of 3D printing with predictive computational methodologies, Kyobula et al. (2017) demonstrated that drug-loaded solid dosage forms with complicated geometries, such as honeycomb architecture, can be created using hot melt 3D IJ printing. Together, IJ and FDM techniques provide the greatest promise for producing oral solid dosage forms. However, the number of polymer excipients is restricted (Verstraete et al., 2018). Although polymeric excipients that affect drug release qualities are restricted, polymer blends may give an alternative solution. The degree of fusion between the printed strips during the FDM process may affect the drug release rate from the matrix (Alhijaj et al., 2016).

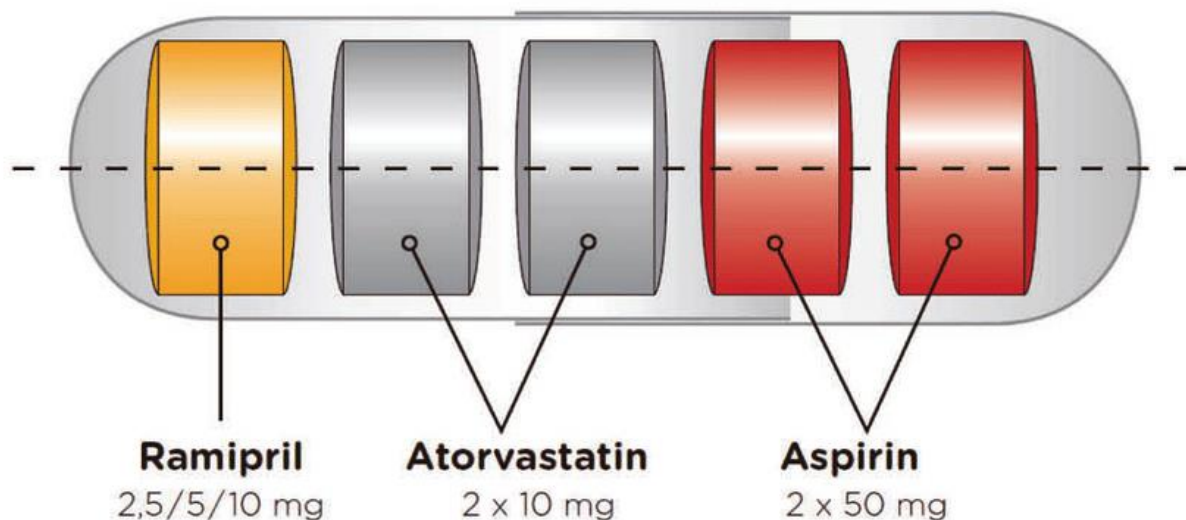


Fig 2: Schematic illustrations of polypills containing multiple active ingredients (APIs).

Multiple API tablets:

Numerous APIs have been effectively integrated into single-dose forms, principally tablets and capsules. Multivitamins with 50 distinct ingredients to sophisticated prescription dose forms with only two. Direct compression mix tableting may combine different APIs. However, not all APIs are compatible, and various APIs may need different release rates. Characteristics including particle sizes, densities, and other parameters affect API performance. Attaining content homogeneity, stability, and robust high-speed processing might be difficult or impossible. Formulators may use a range of strategies and excipients to attain these aims and address difficult situations. This webinar will cover: Techniques for integrating numerous APIs into a single dosage form Granulation Particle processing Direct compression TABLETING, MULTI- During the Q&A session, you may discuss your best approaches for integrating different APIs into a single dosage form. PharmJRS Summary: JRS Pharma is a renowned excipient company serving the worldwide health science market. Among our excipients are binders, disintegrants, lubricants, functional fillers, thickeners, stabilisers, carriers, and coatings. We provide superior technical assistance and biopharma services to meet our clients' demands and formulate issues.

Multiple APIs may be put into a single polypill to simplify complicated pharmaceutical regimens. Recent research has employed 3DP technology to create polypills with the controlled release (Khaled Sun and Soh

2015; et al. Khaled et al. (2015a) captopril, nifedipine, and glipizide polypill Treating patients using 3D extrusion-based printing diabetic, hypertensive. A polypill nifedipine sustained-release compartments and captopril osmotic pump chambers glipizide (Fig. 2a). After swallowing the tablet, it was immediately destroyed, resulting in compartments for captopril and sustained release. The captopril compartment displayed zero-order drug release based on the regulated osmotic release. Sustained-release compartments diffusion of nifedipine with glipizide gel layers (Khaled et al. 2015b). They applied. Using 3DP to create a polypill with four APIs (Khaled et al.) This polypill has two separate controlled release compartments: delayed-release and quick 2b) Simvastatin was in the quick-release compartment. The compartment had aspirin and HCTZ. The cellulose acetate shell is first extruded, followed by the APIs (ramipril, atenolol, pravastatin) and HPMC. Rapid HPMC hydration gels, allowing for prolonged medication release. In

Next, aspirin and HCTZ were extruded. To demonstrate quick medication release owing to the presence of a shattered (sodium starch glycolate). Patients with risk factors, including hypertension and dyslipidemia, may be treated with this medicine combination as a tablet. one pill at a time (Khaled et al. 2015a). To regulate more sophisticated release functions, Drug carrier templates (or moulds) come in several forms. It is possible to design multi-component tablets using sophisticated templates. Therefore, multi-action profile APIs are not only published in first or zero sequences but also more difficult. Sun and Soh (2015) unveiled a 3DP tablet fabrication technique to any desired release state. It is a surface-eroding surface-eroding polymer containing drug the medication and a protective layer of impermeable polymer (Fig. 3). The drug-containing surface-eroding polymer has a certain form. Permitting medication release as desired. Changing shape the drug-carrying surface-eroding polymer-drug release types profiles. Increasing release and pulse release are obtained, creating the drug-eroding polymer compartment. Releasing a medication with a pulse is a medication that must be coordinated with the patient's biological cycles. Reduced release be used when a significant dosage of medicine is required. To attack a subject quickly, then gradually to avoid toxicity. Because it modulates, It appears to promise to produce personalised medicine tablets with drug release profiles for complex drugs (Sun and Soh 2015). Goyanes et al. to create multi-drug devices with the particular design and drug release properties. 3D multi-nozzle printer used to build solid capsules containing acetaminophen caffeine Multi-layer design structures each layer containing a different medication, and a caplet placed in a two-compartment device inside a bigger caplet (DuoCaplet), a different medication They showed the distinctive Depending on the macrostructure of the devices. Drug release from multi-layer devices was independent of drug solubility. In

By choosing the drug's inclusion point and the device's properties, the DuoCaplet design might accomplish instant or delayed-release. the outer layer (Goyanes et al. 2015b). This study modified release oral dose forms. (caplets) of budesonide utilising FDM (Goyanes et al. 2015c). Wang et al. (2016) used the SLA how to make modified-release tablets with both This method may be used to create polypills that contain many different active ingredients and complicated drug release profiles. With fewer pills, better compliance, and individualised dose, polypills may aid patients. Although 3DP has numerous limitations in pharmaceutical production, it is an economical and efficient technique to make personalised tablets.

Conclusion

3DP approaches are divided into subgroups based on their functioning principles. 3DP technology allows for the creation of more complex pharmacological dosage forms and offers increased flexibility. Regulating does form shape and microstructure 3DP is also new and promising Patient compliance and pharmacological efficacy. Efficacy, side effects, and stability concerns of short-lived medicines, and finally lead on-demand patient-specific health care Medicines. Despite the various possible medical, Despite its many advantages and economic benefits, 3DP technology has certain technological limitations to product commercialization, such as choice pharmaco-technical difficulties of current 3DP technologies affecting the Final product quality, process capacity, and material stability. The regulatory changes and considerations for approving pharmaceutical items 3DP techniques created Constant innovation, and Rapidly advancing 3DP technology will overcome numerous technological and regulatory barriers. Apply to additional medication delivery systems and accelerate the patient-friendly clinical practice of future customizable dose forms.

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