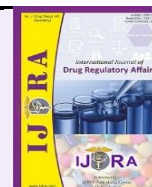


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Review Article

**Pharmaceutical 3D Printing: A Promising Technology for creating customized Medications**

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Abstract

Three-dimensional printing (3DP) enables the development of diverse geometries through computer aided design using different techniques and materials for desired applications such as pharmaceutical drug delivery system. Now a days 3D PRINTING technology has caught the attention of medical devices industry and pharmaceutical industry due to its applications on various platform in health care industry. Although this technology has been around for quite some time, it is currently of significant public interest, especially following the approval of 3-D printed tablets and other medical devices. Additionally, the introduction of the USFDA's guidance on technical aspects related to devices utilizing additive manufacturing, which includes 3-dimensional (3D) printing, has sparked numerous considerations about this technology that are essential for the effective delivery of the intended product. It emerges as one of the most influential and impactful tools utilized for the accurate production of advanced dosage forms, tissue engineering, and disease modeling.

Conclusion: 3D printing is emerging as a transformative technology in the pharmaceutical and medical device industries, enabling precise fabrication of advanced drug delivery systems, tissue engineering solutions, and disease models. With growing regulatory support and proven applications, it holds significant potential to shape the future of personalized healthcare.

Keywords: 3D printing, computer-aided design, manufacturing process, Novel drug delivery, Customized Medications

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1. Introduction

Challenges in the mass production of dosage forms and limitations in the availability of different types of dosage forms have all restricted the traditional pharmaceutical manufacturing process, (1) An increased attention is being received by personalized medicines and the dose of the drug to be administered due to their elevated chances of adverse effects. During the manufacturing of pharmaceuticals for the population, geriatrics and pediatrics have a high probability to exhibit adverse reactions. (2) 3DP technology has been available since the late 1980s and has been used in engineering and various non-medical manufacturing areas, including automotive, aerospace, and consumer goods industries, however, rapid advances in 3DP methods and the emergence of versatile biocompatible materials facilitate the pharmaceutical applications of 3DP technology in recent year. (3) Even though 3D printing holds great potential for the pharmaceutical industry, issues must be resolved before it can be widely used. To guarantee the safety and efficacy of 3D-printed drugs, regulatory considerations, quality control, and scalability are crucial factors that need careful consideration. Cooperation between pharmaceutical businesses, regulatory organizations, and technological

innovators is crucial to create standards and guidelines that uphold the greatest levels of patient care and product quality. (4-6)

1.1 Advantages (7-9)

- Precise and accurate dosing of potent drugs.
- Cost of production decreases because of minimal wastage.
- Narrow therapeutic window.
- Individual and personalized medication.
- Treatment can be customized to improve patient adherence in case of multi-drug therapy with multiple dosing regimen.
- 3D printers capture minimal space and are affordable.

1.2 Disadvantages

- In inkjet printers, ink having high precise viscosity can only be used.
- Ink formulation material should be self-binding but shouldn't bind to the other parts of the printer.
- Rate of drug release is affected when ink binds with printer materials.

- Printing of large objects is not possible.

2. Types of 3D Printing Technologies

2.1 Thermal Ink-Jet Printing (10-12)

In this printing technique, with the help of heat, the liquid ink is converted to the vapours and is forced to push the ink out of the nozzle or the orifice. Biodegradable drug loaded microspheres, liposomes, coating of microelectrode array and eluting stents loaded with drug

are prepared using this technique. Biologic films are also produced practically and efficiently by thermal inkjet printing. It is used in:

- Preparation of drug-loaded biodegradable microspheres
- Drug-loaded liposomes
- Patterning microelectrode arrays coating and loading drug eluting stents

THERMAL INK JET

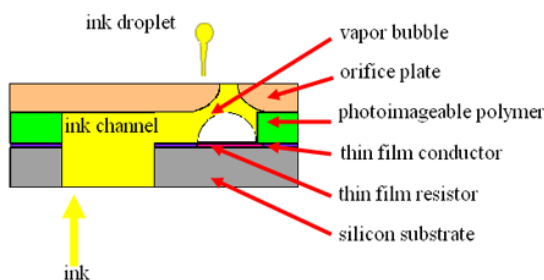


Figure 1. Thermal Ink-Jet Printing

2.2 Binder Jetting (13-15)

This is a prototype method for 3D printing that utilizes a liquid binder to bind powder into layers to create a solid 3D print. This method was initially developed in 1993 at MIT by Sachs and others (1993). Ceramics like alumina dipped in MgO, metals such as cobalt and copper, metal oxides including iron oxide, nickel oxide, and cobalt oxide, polymers like polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone (PCL), polyethylene oxide (PEO), and biomaterials such as poly-L-lactic acid, calcium phosphates, and calcium silicate are commonly utilized as binders. The perfect binder must be a low-viscosity substance that can swiftly take in droplets and readily detach from the nozzle. Typically, the binder is somewhat dried after every layer is printed. This will enhance the distribution to the subsequent layer,

eliminating surface moisture and may also lessen immersion. The procedure of applying the binder can similarly be observed in Zip M print, S print, and others. The fundamental steps of the binder spraying technique are outlined below with the sprayed binder.

- The binder is initially sprayed onto the inkjet printer's print head.
- A fresh layer of powder is subsequently rolled onto the current layer.
- Following layers are printed and attached to the layer before them.
- 3. Ultimately, the leftover powder from the lower strings ascends above the structures.

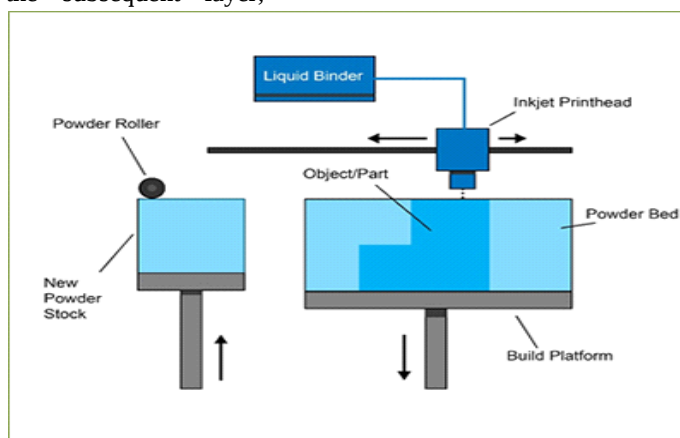


Figure 2. Binder Jetting

2.3 Stereolithography (SLA)

This 3D printing method entails transforming liquid resins into solid components through the photopolymerization procedure. The completed printed component is created with successive strata of the substance on the even plane

of a stereolithography machine. This method employs a UV light electron beam to initiate a chain reaction in every resin layer. (or also epoxy or acrylic), which can transform the original substance into polymer chains in the crystalline state. Different methods, like photocuring, can be utilized to mechanically enhance printed items. (16)

The printing procedure begins when the machine's work area is aligned with the resin storage compartment, maintaining a layer of separation between them. This layer is subsequently cured with UV light, and a new layer of fresh resin is applied over the prior layer so that the procedure continues until the final layer of object creation is triggered. In general, the printed component is cleaned with isopropyl alcohol to eliminate surface residues. Ultimately, the item the photocuring procedure is set up within a designated UV chamber. (17) For this procedure, the selection of resin needs to consider the suitable curing speed and its clearance by the FDA for utilized in medicinal products. (18) SLA technology is notable for facilitating the application of highly thin layers under the surface. This indicates that the method can accurately replicate submillimeter specifics of the created component, which offers enhanced quality and accuracy to the ultimate material Polylactic acid (PLA) and poly (vinyl alcohol) (PVA) are substitute polymers that have been

utilized in SLA technology. The findings indicated that the addition of various drugs (like aspirin and paracetamol) into the polymer matrix can directly affect the size of the printed pharmaceutical form. (19)

2.4 Printing-Based Inkjet Systems

In printing-based inkjet system, the ink is deposited on to the substrate mainly in two forms as listed below:

Continuous inkjet printing: In this type, due to the counter mechanisms the drops are continuously driven as needed thereby expelled only when necessary. this method continuous flow of ink is desired during the process. The processing occurs in such a manner that the vibration in the piezoelectric crystals helps in releasing the liquid continuously. The droplet obtained are charged electrostatically and thus, directed towards the substrate. It is mainly useful in printing of packaging (Figure 3). (20)

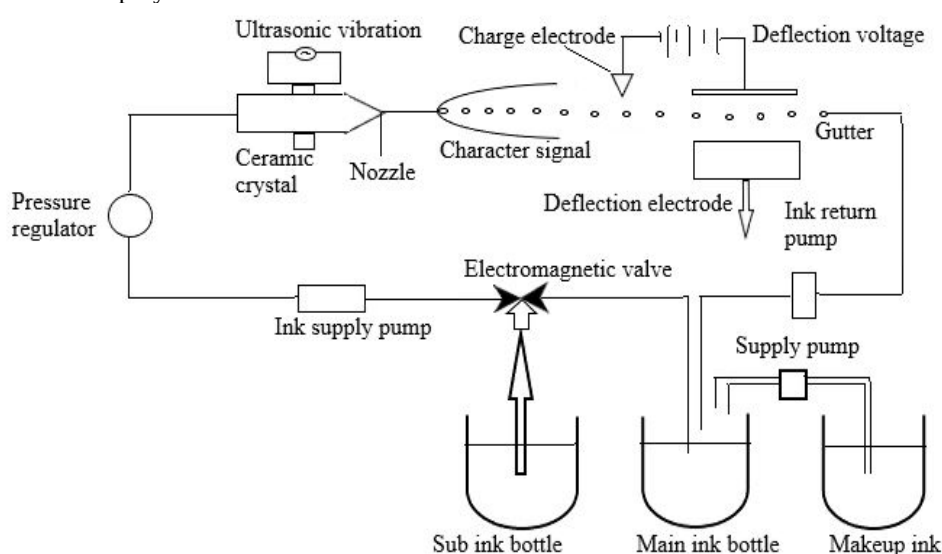


Figure 3. Continuous inkjet printing

2.5 Powder Based 3DP

The figure below describes the structure of this technique (Figure 4). In this method, the powder is evenly distributed

using a powder jet while the liquid binder is applied at the same time. Ultimately, the ink is applied to create a layered final result. It is a readily acceptable method to employ in the pharmaceutical sector. (20)

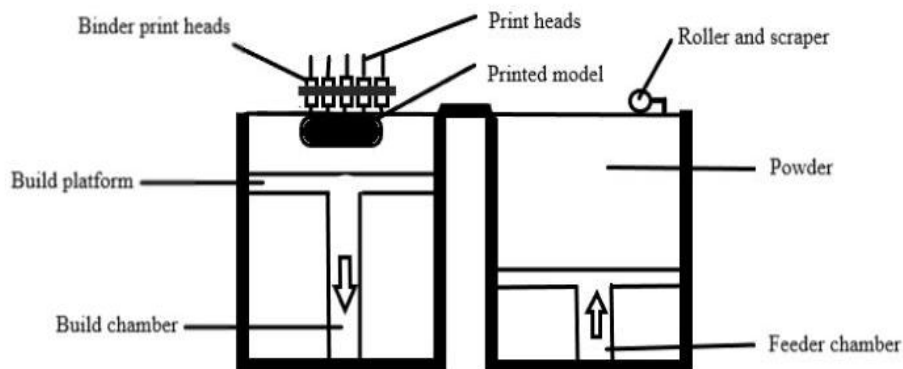


Figure 4. Powder Based 3DP

2.6 Digital light processing (21)

This functions similarly to stereolithography by employing photo-polymers. However, the distinction in this case is

based on the illumination source, which is primarily an arc lamp, integrated with a deformable mirror device or a liquid crystal display panel (Figure 5). It is a method that

offers superior resolution and is faster in execution compared to stereo-lithography.

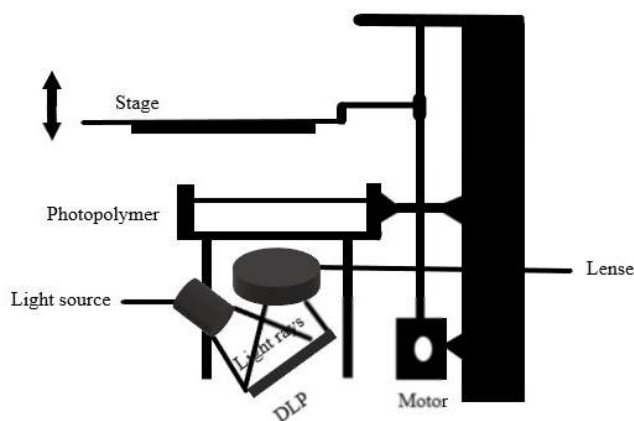


Figure 5. Digital light processing

2.7 Fused deposition modeling

The most frequently utilized kind of 3D printer in the creation of pharmaceutical products is FDM. FDM 3D printers operate on the principle of extruding thermoplastic filaments, which are constantly supplied through a nozzle head that is heated and melted just above its glass transition (T_g) temperature. The hot-melt extrusion technique is utilized to incorporate active pharmaceutical ingredients (API) into thermoplastic polymeric filaments, where the drug along with other polymers and excipients is extruded through a nozzle under heat and pressure, producing filaments suitable for FDM printers. Solid polymer filaments can be employed to create a geometrically structured drug delivery system featuring customizable release profiles, drug-releasing devices, and scaffolds through the FDM process. (22-25)

2.8 Semi-solid extrusion

Semi-solid extrusion (SSE) is another technology under the material extrusion umbrella. SSE utilizes a syringe-like mechanism to deposit a gel or paste in successive layers rather than extruding a filament or powder to form the 3D object. An advantage of this technique compared to FDM and DPE is the lower temperature required for printing, which makes SSE more adequate for thermolabile drugs. This technology has been employed to prepare rapid

release tablets and gastro-floating tablets, as well as polyfills with compartmentalized drugs to obtain both immediate and sustained release profile, and or dispersible films. (Moreover, utilizing SSE, it was possible to produce lipid-based dosage forms with various geometries, intended for oral administration or rectal use in the form of suppositories. (26-31)

2.9 Extrusion 3D printing (32-36)

As per the ASTM International standards organization, extrusion refers to a particular 3D printing technique in which material is precisely released through a nozzle or opening. Extrusion, also referred to as Fused Deposition Modeling, is the most prevalent and straightforward technique in 3D printing. It is used in almost every environment. The main printing material is plastic filament. The filament is heated, and melted in the printing head of the 3D printer. Extrusion is an “additive” technology commonly used for the modeling, prototyping, and production applications. An object is formed by depositing material in layers; a coil unwinds a plastic filament or metal wire, providing the material needed to create a component. In this technique, material is extruded from the automated nozzle on to the substrate and it does not require any higher support material. (Fig no-6). (36)

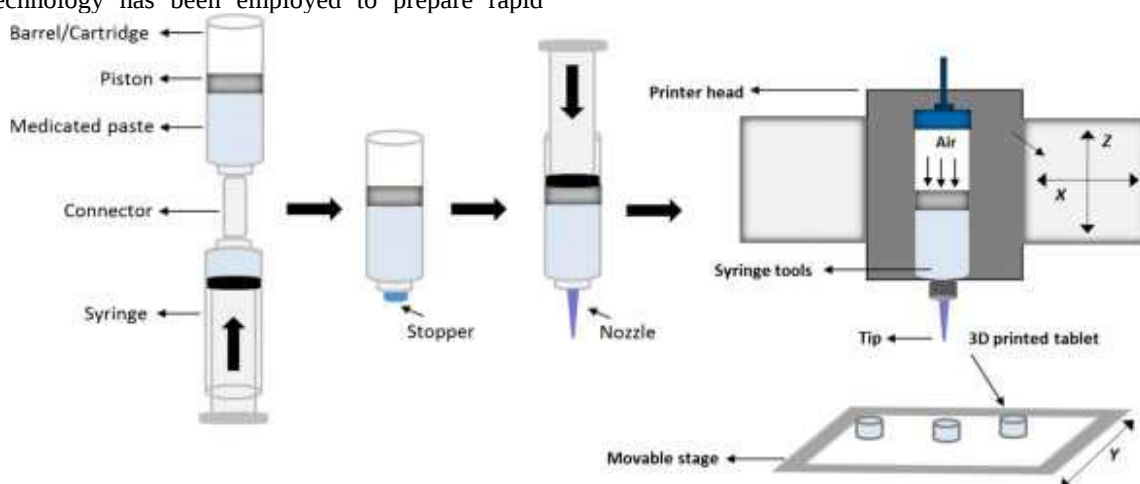


Figure 6. Extrusion 3D printing

2.10 Hot melt extrusion (HME)

Hot melt extrusion involves melting the polymer and drug at elevated temperatures while continuously applying pressure in the equipment for mixing. It is an ongoing manufacturing procedure that involves multiple activities like feeding, heating, mixing, and forming. In recent years, research has demonstrated that HME can enhance the solubility and bioavailability of drugs with poor solubility. (37)

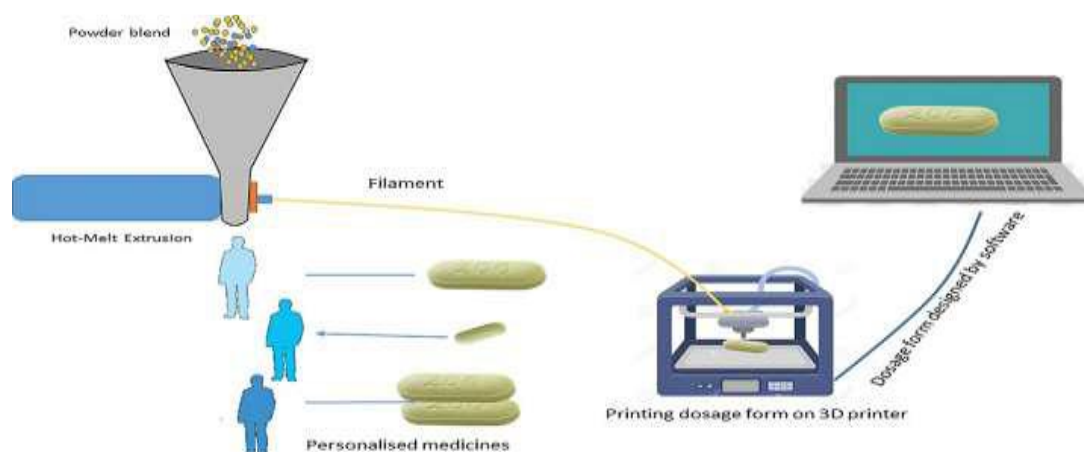


Figure 7. Hot melt extrusion

3. Current Challenges of 3D Printing of Medicines

Even with the benefits highlighted for 3D printing, there are several obstacles linked to this technology. The slow printing speed, the absence of quality control measures for printed systems produced at hospitals or pharmacy, or even the potential threat of cyber-attacks on the computer controlling the printing process, jeopardizing the formulation, are just some examples. (39)

Conversely, certain inquiries may arise regarding the printing process, such as, while conventional techniques can create a tablet in milliseconds, a 3D printer might need a couple of minutes to produce the medication. Whether 3D printing is appropriate for large-scale production; whether scaling up will be feasible; ways to avoid nozzle obstruction; whether the manufacturing pace will be sufficient to satisfy market demand; provided that the process is ready to replicate every unit dosage reliably and possesses adaptability; will the procedure be adhering to the requirements and verification outlined in Good Manufacturing Practice (GMP); if the the process might be effectively managed by the software or, potentially, if the software could be verified are some instances of inquiries that this technology prompts. (40-44)

3.1 Raw materials

The selection of APIs and excipients depend on their printability and physicochemical stability, in combination with the type of 3D printer to be used. Grasping the characteristics of raw materials and their influence on printability is crucial, aiding in a swift process system, helping to avoid or alleviate common processing issues, and anticipating the quality of the final product. Factors that could be influenced include printability of the raw materials, mass uniformity, content consistency, and resolution of the printed pharmaceutical product. The key

HME is utilized to create solid solutions/dispersions for drug delivery systems like pellets and granules, minimizing the processing steps in dosage form production and allowing for automation as a continuous process to enhance drug uniformity, enabling sustained, modified, and targeted release. Combining Hot melt extrusion (HME) with solid freeform fabrication (SFF) like Fluid deposition method (FDM) provides excellent opportunities for creating diverse drug delivery systems using 3D printing technology. (38)

elements that can affect the printability of raw materials are their mechanical strength and rheological characteristics. (45-46)

3.2 Process Validation

The validation plan and organization should ensure product quality, safety and efficacy all through its life cycle

Process validation may be performed according to ICH Q710, carried out under GMP, with data retained at the manufacturing site and available for inspection if not needed in the marketing authorization dossier. The validation scheme for the process should be included in the dossier, which encompasses the details of the manufacturing process, the tests to carry out and their acceptance criteria, an outline of any extra controls implemented, and the data that will be gathered. The rationale for the validation scheme must be provided in Common Technical Document (CTD) Module 3. Software needs to be validated for its intended usage based on an established procedure, as it plays a crucial role in maintaining a high degree of accuracy. As per the FDA's fundamental principles of software validation, software validation may take place during and at the end of the software development life cycle to guarantee that all the requirements have been achieved. (47-48)

3.3 Process Controls

The 3D printing process could be adjusted in a way that quality control is integrated into the manufacturing process itself. The quality systems should be able to take measurements at rate that is suitable to the specific type of printing and the length of the manufacturing process.

In research investigations, a phenomenon referred to as the First Layer Effect (FLE) has been observed, where the

initial layer laid on the build plate causes the fluid melt to spread laterally. Printing medicine combined with suitable online, in-line, or at-line assessment of essential quality attributes and effective feedback mechanisms can enhance production efficiency through real-time release testing. (49)

3D printing requires a reference trajectory, defined as a collection of points for the axes to follow in order to recreate the intended shape, yet currently, no printers exist with closed-loop process control to monitor material placement. To address this problem, sensors such as x-ray imaging, diffraction, and optical microscopy can be employed to observe the material positioning. (50-51)

3.4 Quality Assurance

Quality assurance could be a more challenging issue for 3D printing than it is for traditional methods of manufacturing. Even performing the proper quality controls through the printing process, variations in the final printed drug product can still appear (both intra-batch as well as inter-batch). Drug product specifications should follow the principles of the ICH Q611 guidelines. Additional quality attributes for the 3D printed manufactured drug product may apply, supplementing the typical quality attributes that are appropriate to the dosage form, like thickness, mass uniformity, water content and content uniformity. These methods should be performed according to the European Pharmacopoeia monographs. (52-53)

A Scanning Electron Microscopy (SEM) has been used to take images of the surface and cross-section of the printlets, giving visual information on the internal structure of the printed dosage forms. X-ray Powder Diffraction (XRPD) has been used to assess the physical properties of the crystallinity of the individual powder,

powder mixture, filament and the 3D printed final dosage form. (54)

4. Application of 3D Printing

3D printing has been used in medicine for a long time, from the manufacture of dental implants to prosthetics adapted for its use. Today, this technology is used in a wide range of fields, from tissue and organ production to various medical research related to drug discovery, delivery and dosage forms.

4.1 Complex Geometric Structures Fabricated by 3D printing

The 3D printing of medications offers the benefit of creating intricate external forms (Shape) and complicated internal geometries that can be utilized to regulate the rate of drug release, where in the GI tract the drug is released, the time of onset of release and the mode of release the internal structure vary from uniform, highly porous designs to diverse layered and compartmental arrangements created with various materials. Moreover, the allocation of API within these frameworks may be uneven or asymmetric, if preferred. These distinct features enable exceptional regulation of drug release and the possibility of enhancing a drug's pharmacokinetic characteristics to address a range of clinical and commercial needs. Fig. 7 presents illustrations of tablet designs that can be utilized to attain each of these release properties. All the instances can be utilized for both single ingredient medications and fixed dose combinations. These structures present significant opportunities that were unattainable with traditional dosage forms to meet clinical unmet needs. (55)

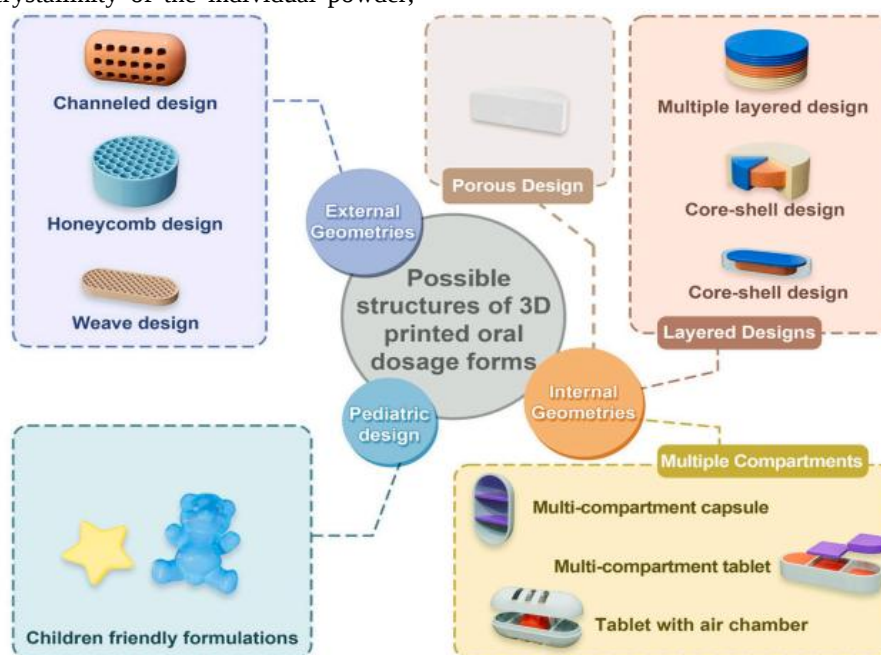


Figure 8. Possible Structures of 3D Printed Oral Dosage Forms

5. Conclusion

3D printing technology has become an important and promising asset for the pharmaceutical industry, leading to

customized medicine that prioritizes patient requirements. The ability of 3D printing to produce complex drug delivery systems, allowing multiple medications to be

released at different rates, has been demonstrated. Inkjet printing, laser systems, SLA, and nozzle deposition are among the most commonly utilized techniques in pharmaceutical manufacturing. Now a days many pharmaceutical Manufacturers using this technique have shown that the specific structure and shape they possess cannot be produced using the conventional manufacturing process. Researchers have dedicated the past decade to in-depth studies of various 3D printing methods to enhance printers, facilitating personalized medicine by simplifying the creation of novel and distinct dosage forms. This amazing technology makes it convenient to deliver many medications. Consequently, it is simple to create formulations with a variety of medications and release schedules. The pharmaceutical sector has started to focus more on 3D technology and is striving to develop unique formulations that start the production of personalized drugs by controlling the rate at which the substances are released. With more formulations on the market, it is anticipated that conventional pharmaceutical manufacturing would soon be replaced by more flexible 3D-printed items. Last but not least, the commercial success of the 3D printing technique will depend on the ability to accurately translate individual dose geometries as per patient requirements while considering the cost.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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