

Next-Generation Drug Delivery via 3D Printed Polymers: From Material Science to Regulatory Translation

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Abstract

The use of 3D printing technology in the pharmaceutical sector has revolutionized the production of intricate and personalized drug delivery systems. The following review covers the history, materials, and 3D printing technologies, with emphasis on the role of polymers in drug development. It explains how 3D printing enables the creation of individualized dosing forms tailored to the unique patient, from the geriatric to the paediatric patient, from the boundaries of the traditional manufacturing processes. The review extensively details the various 3D printing processes, including fused deposition modelling (FDM), binder jetting, stereolithography (SLA), selective laser sintering (SLS), and semi-solid extrusion (SSE), and explains the regulatory regimes which enable their use in the clinical and industrial setting. Furthermore, the use of the technology in addressing public health challenges, from antimicrobial resistance to cancer treatment, is discussed in detail. The article concludes with regulatory adaptations and future directions for the integration of 3D printed pharmaceuticals into mainstream medicine.

Key words - Drug delivery, Polymers, 3D Printing, Regulatory, Technology

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1. Introduction

1.1 Evolution of 3D printing in pharmaceuticals

More than 30 years ago, three-dimensional (3D) printing was created to create 3D items from a computer design. This layer-by-layer procedure makes it possible to manufacture customized medications in a quick and affordable design cycle.⁽¹⁾The idea of personalized medicine, which entails adjusting medical care for each patient specifically, has gained popularity in recent years. Traditionally, medications are produced in vast quantities in a few distinct strengths, mostly utilizing processes developed over two hundred years ago. See [Figure1](#) Importantly, the chosen dosage schedules correspond to the amount needed for the "average" patient to get a safe and effective outcome. Rapid prototyping (RP), solid freeform technology, or additive manufacturing (AM) are

other names for the 3D printing (3DP) process, which is a new idea in the medical sector. 3DP is the "fabrication of objects via the deposition of materials using a print head, nozzle, or another printing technology." The American Society for Testing and Materials (ASTM) reports that⁽²⁾. Printing in three dimensions (3D) is revolutionizing the medical field. Three-dimensional printing is a platform technology that allows for the creation of complex things with fewer chemicals. The simplicity of the developing process offers it an advantage over traditional techniques. Each person requires a different dosage of therapy. The present conventional method, which is "one size fits all," may give way to a more customized one in the process of 3D printing. This paper's objective is to discuss various viewpoints on the choice of medicine, polymer, and technology for 3D printing.

This article also discusses regulatory issues and industrial possibilities in relation to clinical practice.(3)

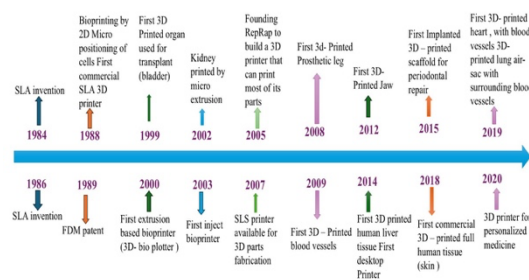


Figure 01 – Milestones in the evolution of 3D Printing and Bioprinting for medical and Pharmaceutical Application (1984-2020)

1.2 Importance of personalized dosage forms

The fundamental goal of personalized medicine is to provide patients with drugs that, if not particularly made for them as individuals, are more specifically made for them as members of a cohort of patients who share comparable genetic, physiological, or pathological characteristics. In contrast, most patients receive the same medication at the same dose and frequency as other patients under the current, widely used paradigm. Of course, there are several exceptions to this rule. Despite its many promises, the postgenomic age in which we are supposed to live has fallen short of expectations. It is anticipated that improved knowledge of pharmacogenetics and pharmacogenomics, as well as patient genetic profiling, particularly for clinical trial participants, will, The treatment of people and groups who are initially likely to respond to medicine and/or are unlikely to experience negative side effects from its administration will be supported by more useful data.(4) The study of personalized medicine is a modern and difficult field. The metabolizing enzymes, biomarkers, screening tests for metabolizing capacity in ethnic subgroups, or various external influencing variables on drug metabolism have been the subject of several recently published publications. It might be demonstrated that modified medication dosages are necessary to guarantee safe and effective treatment because of the impacts of both low and fast metabolizing capabilities. Individualized dosage and patient-adapted medication are also necessary for both pediatric and geriatric drug administration. formulations and methods of delivery.(5) Additionally, digoxin and preprohormone, two medications with narrow therapeutic windows, require careful dosage adaption, especially during the beginning dose titration periods. Appropriate dosage forms are desperately needed to choose and apply individual dosages and integrate basic knowledge of personalized medicine into routine medical practice. These formulations should, in

theory, be appropriate for all patient populations, from young infants to the elderly. (6)

In a hospital context, parenteral administration of a liquid medication formulation has frequently been associated with individual therapy. There are not many personalised therapy applications available on the market for pharmaceutical homecare. Examples include the use of child-appropriate dosing devices for growth hormone supplementation or insulin dose pens and pump systems for the treatment of diabetes. However, because parenteral medication formulations are limited to certain situations and are not well received by many patients, they do not fully cover the gap. The most crucial and often utilized application method is still oral medication administration. Thus, there is an immediate need for appropriate oral dosage forms that allow for customized dosing. The solid and liquid medication dosage forms that allow for individual dosing for oral administration are the main topic of this review. We provide information about oral treatment delivery systems that are either already on the market or have already been documented in patents or scholarly journals. We will elaborate and critically debate opportunities, problems, and more unmet requirements. The various methods are grouped and assessed based on their appropriateness, handling, stability, possibility for dosage change, cost of manufacturing or treatment, and application.(7)

1.3 Crucial role of polymers

Every material we use daily contains polymers, which are commonly used sophisticated materials. Because polymers are used in a wide range of fields in investigation, industry, and technology—from fundamental applications to biopolymers and therapeutic Polymer, their significance has been emphasized more recently. This editorial's primary goal is to highlight the practical applications of polymers in everyday life. We frequently hear the term "polymers," which is extremely important; life would be impossible without it. A broad class of materials called polymers, are utilized in many items and things that we use daily Polymers consist of several small molecules known as monomers that are linked to form long chains (8). People have a lengthy history of utilizing polymers, although they were mostly unaware of them up to the Second World War. The materials necessary to create the object essential for civilized existence were quite minimal. Cotton, wood, jute, and a few other agricultural items were used to manufacture apparel or textiles, while the bulk of structures were built using steel, glass, wood, stone, brick, and concrete(9)

Because they participate in essential life processes and provide fundamental structural components, organic polymers are essential to living creatures. For instance, polymers make up all the solid components of plants. These consist of diverse types

of resins, cellulose, and lignin. A polymer composed of molecules of sugar; cellulose is a polysaccharide. A Lignin is a complicated three-dimensional network of polymers. See [Figure2](#) Polymers of the simple hydrocarbon the isoprene make up wood resins. Another well-known isoprene polymer is rubber Proteins are amino acid polymers, whereas nucleic acids are nucleotide polymers. which are complex molecules made up of bases that include nitrogen, are two more significant examples of natural polymers, both phosphoric acid and sugars. In cells, genetic information is carried by nucleic acids. Glucose is the natural building block of starches, which are significant dietary energy sources obtained from plants.(10)

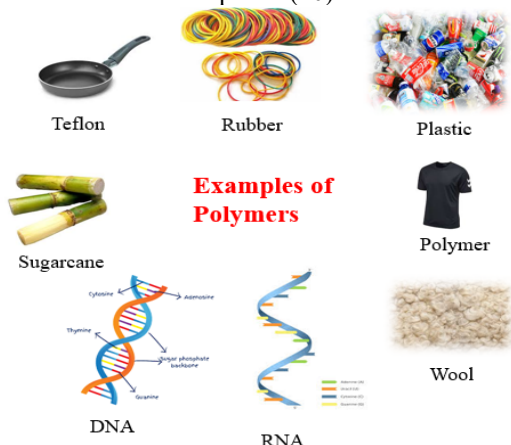


Figure 02 - Examples of Common Natural and Synthetic Polymers

1.4 Objectives and structure of the review

Researchers and pharmaceutical companies' interest in this technology has grown significantly. after the Spritam® (levetiracetam), a 3D-printed drug, received FDA approval in 2015.(11) (12). The formulation now possesses an extremely rapid disintegration feature that is hard to achieve with traditional tablet production technologies thanks to the Spritam® fabrication technology. Spritam® is made using binder jetting printing, which gives the tablet a high porosity and speeds up the drug's dissolution. Researchers have started looking at the benefits of other 3D printing methods. technology to generate formulations that were challenging to generate using traditional approaches. Additionally, as interest in personalized medicine has grown, this technology has emerged as a viable way to create tiny amounts of medications with the right dosage and release. The additive manufacturing process of 3D printing is founded on the idea that consecutive layers are deposited and solidified to create the digitally created 3D shape. Three primary Techniques for 3D printing, include nozzle-based deposition systems, printing-based inkjet technologies, and laser-based writing systems— have been studied for their potential to produce pharmaceutical formulations.(13).This review will go into great depth about these three systems. In

short, the laser-based writing system works by shining a laser on the layer of photosensitive liquid resin that must solidify. This process is repeated to solidify other layers, creating a three-dimensional structure. While inkjet printing creates a layer by spraying a liquid containing the medication and additives on a pre-selected location, the procedure is repeated to create consecutive layers that construct the three-dimensional shape.(14) .There are two forms of inkjet technology DOD stands for drop-on-demand. which jets droplet in in reaction to a signal that triggers and continuous inkjet printing (CIJ), which jets droplet continuously. Although this method produces Because the layers are thin, it takes a long time to produce a high-resolution print. The nozzle-based technology relies when pharmaceutical ingredients are extruded from a narrow nozzle, either by melting the material filaments (known as fused deposition modelling) or by applying pressure (known as Semisolid extrusion, or SSE, is another name for pressure-assisted micro syringes, or PAMs FDM (15)(16)(17) (18) (19)(20). Ref [Figure3](#)

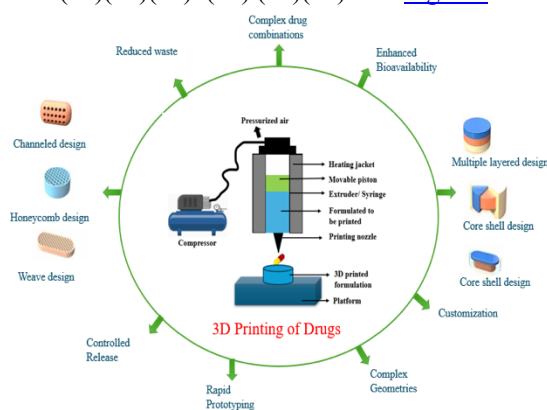


Figure 03 - Schematic Representation and Advantages of 3D Printing in Drug Formulation

Pharmaceutical dosages with dimensions and patterns that were challenging to create using conventional methods might now be prepared because of the development and adaptability of 3D printing. With the use of this technique, polypills containing many medications, each with a distinct dosage and release(21,22) might be produced to treat a particular condition. In addition to the 2015 Food and Drug Administration approval of Spritam®, FDA awarded Triastek approval for their Investigational New Drug Application (IND) for the 3D-printed medication T19, which is used to treat rheumatoid arthritis. This product's intricate internal geometry and design enable control and modification of the duration, onset time, and overall release profile (23). See [Figure4](#) To improve research efforts to consider individual differences in matters of gene, metabolism, and lifestyle, the precision medicine program was launched in the United States in 2015 with assistance from then-President Barack Obama. The options for applying precision medicine are incompatible. There is

already a unified medicine distributing approach. 3D printing is a viable approach of deploying precision medicine, since it can create tiny batches with exact dosing and release patterns(24)

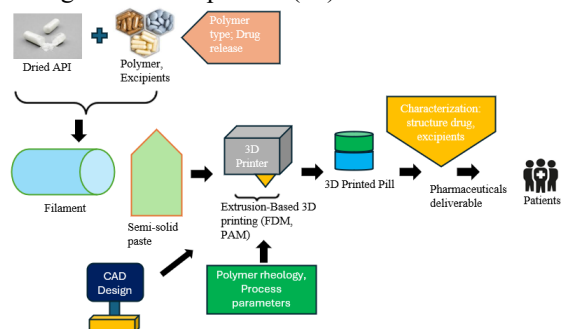


Figure 04- Polymers for Extrusion Based 3D Printing of Pharmaceuticals: A Material Process Perspective

2. 3D Printing Technologies in Pharmaceutical Applications

2.1 The Principle of BJ-3DP Technology

The main 3D printing method utilized to produce drugs is BJ-3DP (25). In Figure 5, the printing principle is displayed. To selectively join the powder, the roller first applies a thin powdery coating to the platform. Then, using the layer-by-layer printing concept, the platform is lowered, and the roller applies a powdered coating to the print head while adding droplets. And so on till the procedure is complete. Finally, the adhesive powder is removed, and the preparations are taken out, and postprocessing is done(26). The API and other excipients are found in the powder bed, whereas printing inks can only include the binder. API can also be sprayed as a solution or as a nanoparticle suspension onto the powder bed(26). Not only may APIs with strong water solubility be employed with the BJ-3DP technique, but pretreatment can also increase the solubility of intractable APIs; however, there aren't as many research on this topic. To improve the wettability and printability of clotrimazole, Kozakiewicz-Latała et al. (27) employed the hydrophobic API as a model medication and made a suspension with the hydrophilic excipients PVP and lactose in a specific ratio. This suspension was then spray-dried. Several 3DP Various techniques have been devised by changing the material's energy supply, source, and other mechanical features. Popular 3DP methods for printing include nozzle-based deposition systems, printing-based inkjet (IJ) systems, and laser-based writing systems. To the pharmaceutical industry. These systems may be further classified into numerous kinds based on energy, sources and materials employed.(14) (28)

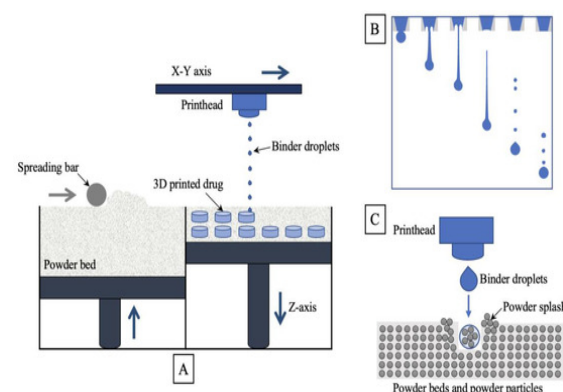


Figure 05 - Mechanism of Binder Jet 3D Printing (BJ-3DP) in Pharmaceutical Applications¹

2.2 Overview of Major Technologies

2.2.1 Fused Deposition Modelling (FDM) –

Simply melting the raw material and shaping it into new shapes is the fundamental idea behind the FDM manufacturing process. The substance is a roll of filament that is pushed by a drive wheel before being heated to semiliquid in a temperature-controlled nozzle head. The nozzle creates layer-by-layer structural parts by accurately extruding and guiding materials in very thin layers. This adheres to the layer's contours as defined by the software, often CAD, that has been added to the FDM work system (29). Fast production, cost effectiveness, accessibility, wide material adaptability, and the capacity to create complicated components make fused deposition modelling a popular additive manufacturing approach [28, 29]. Crump established Stratasys in 1989 after obtaining a patent for fused deposition modelling (FDM) in 1988. With the exception of the potential to generate complicated geometry (30), the first system contains all of the important core features of AM. FDM uses a variety of materials, however as previously said, PLA is the most popular material among home and business 3D printer users for the following reasons: Since polylactic acid (PLA) is a bioplastic, it is safe for the environment and does not pose a threat to the health of people or animals. Because Corn and other completely renewable materials are used to make PL. Sugarcane, wheat, or any other resource that contains a lot of carbohydrates, it is a green substance [31]. As a result, it is advised to utilize it to make packing containers, deli and food takeaway and cold drink cups. Ref Figure 6

¹ Figure 5 adapted from: Wang S, Chen X, Han X, Hong X, Li X, Zhang H, et al. A review of 3D printing technology in pharmaceuticals: technology

and applications, now and future. *Pharmaceutics*. 2023;15(2):416. Available from: <https://doi.org/10.3390/pharmaceutics15020416>

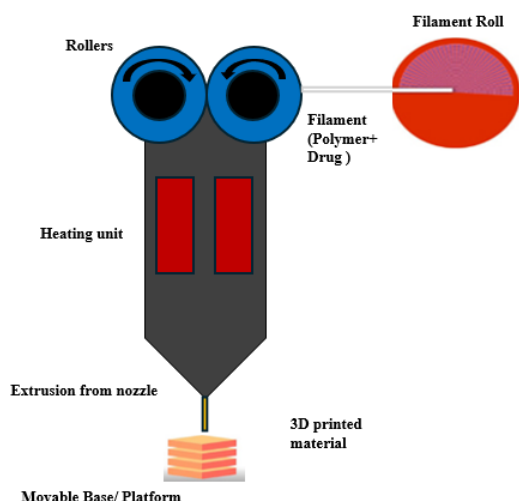


Figure 06- Schematic Diagram of Fused Deposition Modeling (FDM) for 3D Printed Pharmaceuticals

2.2.2 Inkjet Printing

Applications for inkjet printing technology include bioengineering, textile and flexible electronics, micromechanical and microfluidic devices, and printing microstructures in three dimensions (3D). Inkjet printheads were made possible by the invention of a recording device that resembles an inkjet and has a continuous inkjet head by William Thomson and Abbe Nollet in 1858. Fluid motion equations, DoD thermal inkjet (TIJ) printheads, and drop-on-demand (DoD) inkjet heads with the squeeze, bend, push, and shear deformation modes, employing a piezoelectric actuator, were introduced to further develop this technology. DOD inkjet and continuous inkjet (CIJ) are the two categories under which inkjet printing technology falls. In a CIJ system, charging electrode and an applied electric field cause a stream of droplets to be continually expelled. A catcher receives the uncharged raindrops. A voltage waveform in a DOD printing system can expel the droplet, taken from, and updated with knowledge of, the most recent printing technology. The inkjet printing technique categorization is displayed in Figure 7. (31) One well-known technique for printing pictures and text on porous materials is inkjet printing. It is being researched for printing optical and electrical devices, particularly those that contain biological elements, and has been employed as a free-form manufacturing method, technique for creating three-dimensional parts in recent years. Protein and nucleic acid arrays are also being produced using inkjet printers.

Numerous material issues that are not relevant to traditional image printing are brought up by the requirement for a flexible inkjet technique for free-

forming materials and multilayer devices. Printing organic transistors will need higher resolutions. To prevent device shorting, pinhole-free layers must also be able to be printed. It is necessary to print many layers that either combine or react to creating a single substance or produce distinct, unmixed layers. It will be customary practice to print on thick substrates instead of permeable one the range of printed materials is examined in this article, on as well as the problems that occur when the ink and substrate interact.(32)

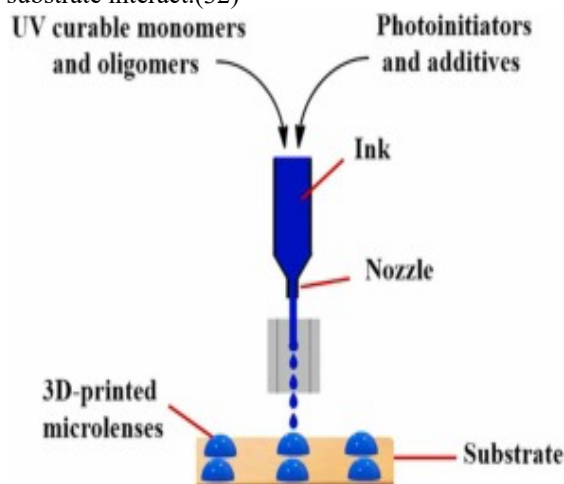


Figure 07- Mechanism of Inkjet-Based 3D Printing Using Photopolymerizable Inks²

2.2.3 Stereolithography (SLA)

In the 1970s, the first noteworthy work related to contemporary stereolithography AM systems appeared (33). A patent for a process that involves photochemical cross-linking or degradation, polymers to create three-dimensional objects was presented by Swainson(34). Then, Herbert presented a way for using photosensitive polymers to create solid things layer by layer. Nonetheless, most of Many people agree that CW Hull's work was the predecessor of current stereolithography.(35) His concept (Figure 8) states that ultraviolet (UV) light-curable photosensitive materials are utilized to create 3D things layer by layer. Stereolithography has advanced significantly to date, and several strategies have been created for stereolithography systems. Here, we concluded and divided the approaches that were described into four generations. Hull's work exemplifies the initial stages of first generation stereolithography, which creates 3D items by scanning liquid materials with a laser beam. The second-generation method, often referred to as Projection stereolithography, use photo mask technology to simultaneously cure each layer, removing the constraints of poor efficiency. In 2015, Tumbleston et al. developed the third generation of stereolithography (36). They

² Figure 7 adapted from: Magazine R, van Bochove B, Borandeh S, Seppälä J. 3D inkjet-printing of photo-crosslinkable resins for microlens fabrication.

Addit Manuf. 2021;41:102534. Available from: <https://doi.org/10.1016/j.addma.2021.102534>

developed a continuous liquid interface production (CLIP) method that enables a significantly greater print speed compared to earlier methods that produced components in minutes as opposed to hours. Volumetric stereolithography, which may be considered the fourth generation, was most recently reported to manufacture 3D things using the unit of sophisticated aperiodic 3D volumes on a temporal scale of seconds (37)

Figure 08 -Schematic Representation of Stereolithography (SLA) 3D Printing Process³

2.2.4 Selective Laser Sintering (SLS)

SLS is an important method in the rapidly growing field of additive manufacturing. It is a fast-prototyping approach that swiftly creates sophisticated components and geometry from a computer-aided design. (CAD) model. This is achieved by dissecting the model file into thin cross sections, usually with a thickness of less than 0.25 mm. A component construction is then constructed using these cross sections as layers. A feed-and-roller system is often used to distribute the build medium, which is typically extremely fine powder, onto a central platform. Following deposition, the powder is fused together using a laser to form the predefined layers' shapes. The process is continued until all of the model cross sections are done, after which the layer is lowered, and a new powder is added.(38) A high-power laser is used in the 3D printing process known as selective laser sintering (SLS) to bind or sinter each component into a solid mass. The initial layer of the solid 3D printed structure is formed by sintering the powder using a CO₂ laser (Figure 9). Using a roller, the fresh powder layer is deposited, increasing the thickness of the matching layer. Direct production of bio-ceramics with SLS is challenging due to the high-intensity laser's fast cooling and heating rates. But this technique is especially useful for creating composite scaffolds. Temperature, powder composition, and laser power are the key variables that need to be managed in this process. The only technique available for creating metal structures for dental implant fabrication is SLS. Because SLS produces better dimensional precision and does not need a support structure, it is better than stereolithography. (39)

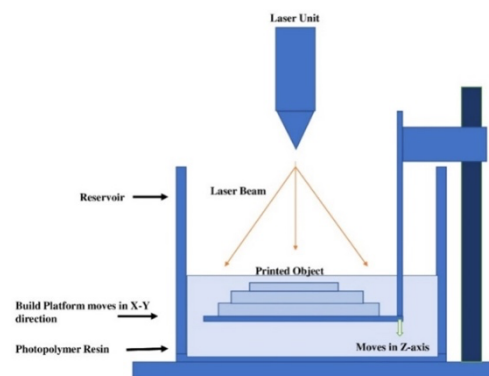


Figure 09 - Schematic diagram of the stereolithography (SLS) 3D printing process.⁴

2.2.5 Semi-solid Extrusion

Semi-solid extrusion (SSE) is a 3D printing technology that employs an extruder. It is commonly used for bioprinting and food printing. SSE is increasingly being investigated in the field of pharmaceuticals to develop solid dosage forms with qualities, such as chewable, fast-dissolving, or gastro-floating tablets, oral and topical films, polypills, and rectal suppositories, to name a few. SSE offers various advantages, including a reduced operating temperature, a decreased risk of drug instability, and a wide range of excipients (such as lipids, food additives, and natural or synthetic polymers) It may be used as feedstock to make gels or pastes for 3D printing. However, variables connected to formulation may affect the dose forms' characteristics. For example, the dose form's geometric shape, size of the dispersed components, and semi-solid rheological behavior, in addition to the printing process's characteristics, includes Printing speed, infill pattern, and number of layers. Because of its adaptability, SSE has developed into a potent instrument for creating novel dosage forms with therapeutic significance for certain populations, such as veterinary, pediatric, and elderly patients, customized medications. Ref Table 1, Figure 10 (40)

³ Figure 8 adapted from: How Stereolithography or SLA 3D Printing Works? [Internet]. Manufactur3D Magazine; [cited 2025 Jun 5]. Available from: https://manufactory3dmag.com/stereolithography-sla-3d-printing-works/#google_vignette

⁴ Figure 9 adapted from: Mustafa MA, Malik A, Javed E, Amjad A, Iqbal S, Mustafa E, et al. A Comparative Review of 3D Printing Technologies

and their Applications: A Systematic Review for Future of Medicine Fabrication. Int J Pharm Investig [Internet]. 2025 Feb 12 [cited 2025 Jun 5];15(2):313–24. Available from: <http://dx.doi.org/10.5530/ijpi.20250024>

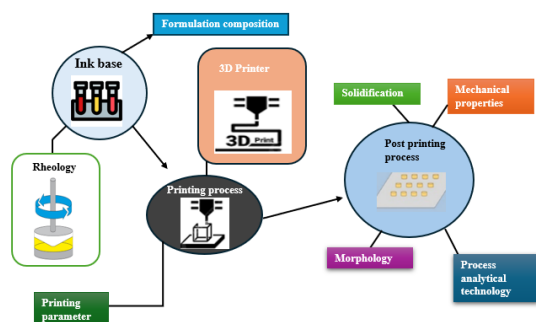


Figure 10 - Workflow of the 3D printing process using an ink-based formulation.

Table 1. Examples of Oral Dosage Forms Produced Using Different 3DP Technologies

3D printing technology	Formulation	Objective of the Study	Active Ingredient (API)	Excipients Used	Reference
Biodegradable jet printing	Structured drug tablets	Exploration of novel oral delivery systems	Methylene Blue, Alizarin Yellow)	Polycaprolactone (PCL), Polyethylene oxide (PEO)	(41)
	Rapid-dissolving tablets	To create fast-acting dosage forms	Paracetamol, Alizarin Yellow	SiO ₂ , mannitol, lactose, PVP K30, VP K30, lactose	(42)
	Cubic-shaped	Designing formulations with	Pseudoephedrine	Kollidon SR, HPMC	(43)

	tablets	near zero-order release			
	Erosion-controlled release tablets	Delayed release through matrix erosion	Chlorpheniramine Maleate, Fluorescein	Avicel PH301, Eudragit E-100, RLPO, or PVP with Tween 20	(44)
	Oral dispersible tablets	Rapidly disintegrating drug delivery development	Levetiracetam	MCC, glycerin, Tween 80, Povidone, sucralose	(45)
FD M	Caplets	Analysis of microstructure and drug release from PVA	Paracetamol or caffeine	Polyvinyl Alcohol (PVA)	(46)

		matri x			
	Sustai ned- releas e caplet s	Contr olled drug releas e over exten ded time	Budeson ide	PVA	(4 7)
	Modif ied releas e tablet s	Tailor ing drug releas e profil es	4-amino salicylic acid (ASA) or 5- ASA	PVA	(4 8)
	Bilay er tablet s	Creati ng dual- layere d sustai ned releas e tablet s	Hydroch lorothiaz ide	Inner: PVA+ mannit ol; Outer; polyla ctic acid (PLA)	(4 9)
	Dual- releas e tablet s	Devel oping tablet s with both imme diate and	Theophy lline	Eudrag it RL, RS, or E, hydr (HPC) SSL, TEC	(5 0)

		prolo nged releas e		or triaceti n	
	Exten ded- releas e tablet s	Long- acting drug releas e syste m	Predniso lone	PVA	(5 1)
	Orodi spersi ble films	Form ulatin g fast- dissol ving oral films	Aripipra zole	PVA	(5 2)
SSE	Bilay er tablet s (poly pill)	For treati ng respir atory disor ders with comb ined drugs	Guaifene sin	Polyac rylic acid (PAA), MCC, sodiu m starch glycol ate	(5 3)
	Comp lex multia ctive tablet s	Incor porati ng osmot ic pump and sustai	Nifedipi ne, Glipizid e, and Captopri l	HPMC	(5 4)

	(poly pill)	ned release in one unit			
	Cardiovascular polypill	Tablets with five APIs for heart-related conditions	Hydrochlorothiazide, Aspirin, Pravastatin, Atenolol, Ramipril	PEG 600, D-mannitol, cellulose acetate	(5 5)
SLS	Tablets	Tablet formation via laser sintering	Paracetamol	Kollicoat IR, Eudragit L, Candurin gold	(5 6)
	Implant devices	Fabrication of hormone-delivering implant	Progesterone	PCL	(5 7)
SLA	Modified-release	SLA-based personalized	Paracetamol or 4-ASA	PEGDA, PEG 300, photo	(5 8)

	tablets	release tablets		initiator	
	Drug-loaded hydrogels	Creating medicated hydrogel systems	Ibuprofen	PEGDA, PEG 300, photoinitiator, riboflavin, TEA	(5 9)
	Personalized facial mask	Anti-acne face mask using SLA printing	Salicylic acid	PEGDA, PEG 300, photoinitiator	(6 0)

3 Polymers in 3D-printed drug formulations.

To create three-dimensional (3D) materials are deposited layer by layer in a computer-controlled process based on a computerised model. It might be used in the pharmaceutical industry to give personalised and on-demand drugs, reducing side effects and unpleasant responses during drug treatment.(61). Using Arburex plastic free forming (APF), a direct granule fed thermal droplet-based three-dimensional printing method was recently developed for tablet manufacturing. The extremely controlled and adaptable material processing of APF, a new Thermal droplet deposition technique features two print heads. showed promise. Employing APF, Pharmaceutical materials that cannot be printed using existing commercial thermal 3D printing procedures can be processed to produce tablets with high quality, performance, and repeatability results.(62)

3.1 Key Requirements of Polymers for 3D Printing

Recent years have witnessed major advancements in polymer 3D (three-dimensional) printing, with several research areas now producing designed goods, particularly in the medical domain. Numerous medical fields that profit from the variety

of polymer material properties and processing techniques might benefit from polymer printing (63) Manufacturers have always been interested in polymer systems due to their special qualities, which include ductility, cheap cost, extended life, simplicity of processing, and light weight. However, the special qualities of the latter were always offset by the much lower modulus and strength that polymers provide when compared to metals and ceramics (64) According to the American Society for Testing and Materials (ASTM standards), the primary 3D printing processes for polymer materials include material extrusion (ME), vat photopolymerization (VP), powder bed fusion (PBF), material jetting (MJ), and others. Based on its own operating principle, each technology provides several alternatives for 3D printing. polymeric materials: the selection of a technology is mostly determined by the characteristics of the chosen polymers and the performance requirements of the intended products.(65) [69]

3.2 Classification of Polymers

Table 2. Classification of polymers used in 3D printing for pharmaceuticals

Polymer	Type	Melting Point (°C)	Solubility	Biodegradability	FDA Status	Ref
Polyvinyl Alcohol (PVA)	Synthetic	180–190	Water-soluble	Biodegradable (partial)	Approved	70
Hydroxypropyl Methylcellulose (HPMC)	Semisynthetic	No distinct melting	Water-soluble	Non-biodegradable	Approved	71
Polyethylene Glycol	Synthetic	50–60 (low)	Water-soluble	Biodegradable	Approved	72

1 (PEG)		MW)				
Polylactic Acid (PLA)	Synthetic	~150–160	Poor in water	Biodegradable	Approved	73
Poly(lactic-co-glycolic acid) (PLGA)	Synthetic	173–178	Poor in water	Biodegradable	Approved	74
Gelatin	Natural	Densities ~40–50	Water-soluble	Biodegradable	GRAS	75
Eudragit® RS/RL	Synthetic (Acrylic)	Varies by type	Insoluble in water	Non-biodegradable	Approved	76
Sodium Alginate	Natural	Decomposes before MP	Water-soluble	Biodegradable	GRAS	77

4 Formulation Design Strategies

4.1 Drug Incorporation Methods

Extrusion using hot melt the following are the basic stages active in developing dosage formulations utilizing continuous HME-3D printing Based on the benefits of combining the two technologies:

1) creating a dosage form and turning it into a printable format.

2) Processing raw materials (powders, particles, granules, or pastes).
 3) Creating hot-melted extruded filaments.
 4) Chilling the filaments.
 5) 3D printing; and
 6) removing the finished product, including any further drying, packaging, and refrigeration steps.

However, extruding the 3D-printable filaments and their disintegration of the weakly water-soluble APIs to molten polymeric excipients, as well as their combination to boost API bioavailability, are critical first stages in continuous pharmaceutical HME and 3D printing. (66) Since the 1980s, the plastic and pharmaceutical sectors have employed hot-melt extrusion (HME), a continuous production technique. Pellets, granules, films, implants, and ophthalmic and topical delivery systems are just a few of the pharmaceutical items that have been developed using the HME method as a continuous production technique during the past 20 years. Amorphous solid dispersions, cocrystals, taste masking, modified release dosage forms, floating dosage forms, abuse-deterrent formulations, and patient-centric 3D printed tablets are just a few examples of the products that have been developed and manufactured using HME. [Figure 11](#)

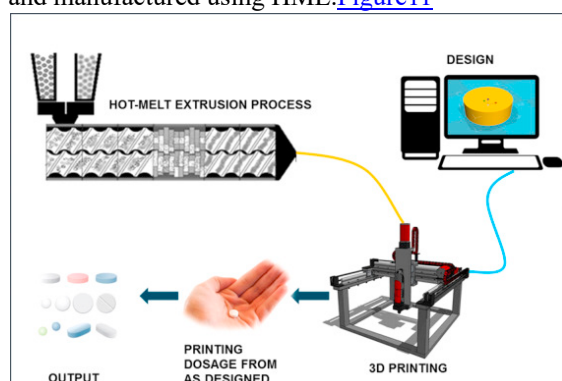


Figure 11- Schematic of the combination of HME and 3D process.⁵

HME provides several advantages for pharmaceutical product development, such as Continuous manufacturing with fewer processing steps, solvent-free techniques that minimise the need for additional drying stages, and very dense extrudates and granules improve the compressibility index of APIs with poor flow characteristics. Nevertheless, this technique's restricted use in the processing of thermolabile medicines is a significant disadvantage (67) Blending for filament production (FDM) and Fused filament fabrication (FFF) is a popular process because of its low cost, convenience of use, and compatibility with a wide range of shelf-stable material feedstocks. When printing using commodity polymers like ABS (acrylonitrile

butadiene styrene), PLA, and polyamides (like Nylons), FFF uses thermoplastic-based feedstocks. Companies like 3DXTech have recently created commercially accessible High-performance FFF feedstocks include the homopolymers polyetheretherketone (PEEK) and polyphenylene sulphide. Metal-filled polymers (such as stainless steel 316L, aluminum, and copper from Mark forged and the Virtual Foundry) and carbon-fiber reinforced thermoplastic (such as that manufactured by 3DXTech) are also available as feedstock.

It is envisaged that the creation of new "designer" or sophisticated functionality FFF-compatible materials would remain critical to the technology's future development and use (68) Inkjet system coating, Inkjet is a type of digital printing in which an electrical signal drives a jet device to release ink directly onto a substrate. The porosity and absorbency the coating layer's qualities are particularly needed by low viscosity and low surface tension of most inkjet inks. (69) Inkjet printing is a rapidly expanding printing industry that may be viewed as a group of distinct technologies rather than a single, uniform approach. Inkjet has shown promise in the printing of 3D, electronics, and biological materials. In addition to being utilized in home and business settings. While all forms of inkjet printing share some characteristics, there is a vast range in ink formulations, curing techniques, printing head configurations, and end applications. The design of each inkjet printing press has a direct influence on the final print quality. Each press has a unique droplet manufacturing technique (continuous and drop-on-demand (piezoelectric and thermal) that effects droplet size and ink characteristics. Ref [Table 3](#) (70)

[Table 03.](#) Examples of 3D-printed pharmaceutical formulations with details on the formulation type, polymers used, drug names, and 3D printing methods.

⁵ Figure 11 adapted from: Zhang J, Feng X, Patil H, Tiwari RV, Repka MA. Coupling 3D printing with hot-melt extrusion to produce controlled-release

tablets. Int J Pharm. 2017;519(1–2):186–197.

Available from:

<https://doi.org/10.1016/j.ijpharm.2016.12.049>

4.2 Dosage Form Types

Table 04. dosage forms created by 3D printing.

Formulation Type	Polymer Used	Drug Name	3D Printing Method
Immediate-release Tablet	PVA (Polyvinyl Alcohol)	Paracetamol	Fused Deposition Modeling (FDM)
Sustained-release Tablet	HPMC (Hydroxypropyl methylcellulose)	Metoprolol Succinate	FDM
Polypill	PVA + Eudragit RS100	Amlodipine, Simvastatin, Aspirin	FDM + Inkjet Printing
Buccal Film	HPMC + PEG	Rizatriptan	Solvent Casting + 3D Molding
Implant	PLGA (polylactic-co-glycolic acid)	Leuprolide Acetate.	Hot Melt Extrusion + 3D Shaping
Pediatric ODT	Gelatin + Mannitol	Loratadine	Semi-solid Extrusion
Geriatric Chewable Tablet	Gelucire + MCC	Donepezil	Direct Ink Writing

Dosage Form	Active Ingredient	Excipients	Ref.
Fused Deposition Modeling (FDM)			
Caplet	Acetaminophen mixed with caffeine	Polyvinyl Alcohol (PAA)	(71, 72)
Caplet	Budesonide	Polyvinyl alcohol (PVA) filament.	(73)
Capsule	Acetaminophen	PLA filament, hydroxypropyl cellulose (HPC), Polyethylene glycol 1500 (PEG 1500), PVA PEG copolymer, and brilliant blue	(74)
Tablet	5-Aminosalicylic Acid and 4-Aminosalicylic Acid	polyvinyl alcohol (PVA) filament	(75)
Tablet	Acetaminophen	PVA filament	(76)
Tablet	Fluorescein sodium	Polyvinyl alcohol (PVA) filament, 100% ethanol.	(77)

Implant	Fluorescein, sodium	Vinyl acetate made from ethylene	(78)
T-shaped intraluminal systems	Gamma indomethacin	Ethyl vinyl acetate	(78)
Pressure-Assisted Syringe			
Bilayer tablet	Guaifenesin	Hydroxypropyl methylcellulose (HPMC)poly (glycolic acid), microcrystalline cellulose (MCC) sodium starch glycolate	(79)
Tablet “polypill”	Aspirin, Hydrochlorothiazide, Atenolol, Pravastatin sodium, Ramipril	Polyvinylpyrrolidone (PVP)lactose D mannitol sodium starch glycolate HPMC, cellulose acetate, PEG 6000, solvents	(80)
Tablet “polypill”	Glipizide, Nifedipine	HPMC, sodium chloride, D-	(81)

		mannitol, crospovidone sodium, MCC, cellulose acetate, PEG 6000, solvent acetate, PEG 6000, acetone, and DMSO	
Tablet	Theophylline	Ammonia methacrylate copolymers type A and B, HPC, triethyl citrate	(82)
Drop on Solid Deposition			
Implant	Levofloxacin	Poly (D, L-lactic acid), methanol, acetone, and pure water	(83)
Implant	Rifampin, Isoniazid	Poly(D,L-lactic acid), methanol, acetone, and pure water	(84)
Tablet	Chlorpheniramine Maleate	MCC, basic butylated methacrylate copolymer, ammonium methacrylate copolymer type A	(85)

Tablet	Diclofenac sodium	MCC, spray dried lactose, methacrylic acid-methyl methacrylate copolymer, ammonium methacrylate copolymer A, solvents	(85)
ODT	Acetaminophen	Colloid silicon dioxide, PVP K30, lactose, mannitol, xylitol, and aspartame	(86)
ODT	Levetiracetam	Colloidal silicon dioxide, dibasic calcium phosphate, MCC, polysorbate 20, povidone, sucrose, HPMC, flavouring agents	(87)
Drop on Drop Deposition			
Mucosa l thin films	Cetirizine hydrochloride, diphenhydramine hydrochloride	Basic butylated methacrylate copolymer in ethanol.	(88)

	e, and Ibuprofen		
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1. Pharmaceutical Applications

5.1 Personalized Medicine

Because they make it possible to use a patient's genetic information, personalized medications are growing in popularity and can lead to better drug designs with fewer adverse effects. It is possible to mix many dosages into a single dosage form that is appropriate for the patient's demographics. Personalized medicine Using 3D printing technology is a modern way to therapy based on the patient's genes. (89) Overcoming biological hurdles for complex therapeutic compounds, creating systems capable of rapid, selective, and cue-responsive biomolecule release in tissues, and achieving targeted administration. Some of the issues with medication delivery include single-cell or cell-compartment resolution. As dynamic delivery systems that offer sustained, complicated biologics, overcome biological barriers, and adapt to the environmental signals, cell treatments have shown promise in reducing the frequency of doses and the requirement for medical interventions. (90) A complex network of signaling channels controls every cell activity, and its efficacy depends on several interconnected stages. These processes—also referred to as signal transduction pathways—can be viewed as chemical messenger cascades that start a variety of interactions and feedback loops that eventually regulate cell division and activity. See [Figure 12](#) They consist of both intracellular and extracellular components. Cell surface stimulation may be the first step in molecular messages or signals(91).

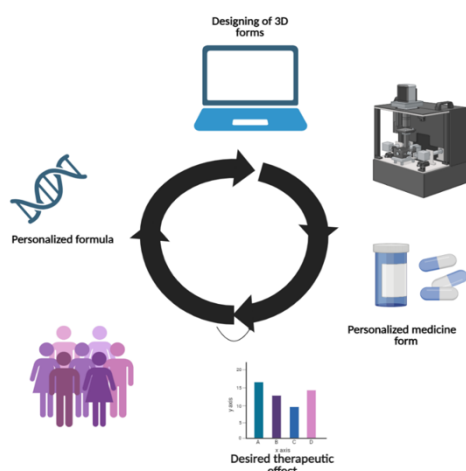


Figure 12- The cycle of personalised medication development using 3D printing.

5.2 Therapeutic Areas

Personalized medicine is based on the principle of giving "the right dose of the right drug for the right indication for the right patient at the right time." (92) Evidence-based, tailored therapy known as "personalised oncology" provides the appropriate

therapy to the relevant cancer patient at the appropriate time, improving outcomes and lowering medical expenses. (93) One of the most terrible illnesses that affects a lot of people worldwide is cancer. Chemotherapy remains a significant therapeutic option for several cancers, particularly for primary advanced and metastatic tumors, despite advancements in radiation and surgical therapies. However, cancer cells innate and acquired resistance to anticancer medications significantly reduces the effectiveness of chemotherapy (94) Cardiovascular (combination polypills) cardiovascular disease is a leading cause of mortality globally. Mortality and disability. In Asia, Europe, and the US, several guidelines for CVD prevention have been published. However, because of poor adherence to treatment drugs and a lack of prescribing owing to clinical inertia among healthcare practitioners, the recommendations' optimum pharmacological therapy is not being applied for all patients. (95)

Multiple pharmacological drugs that target the cardiovascular system may be present in polypills. While there is widespread agreement for the use of polypills in the secondary prevention of cardiovascular disease (CVD), there is greater debate around their use in the primary prevention of CVD. (96) Numerous earlier research have demonstrated the effectiveness of polypill therapy in preventing CVD. Polypills have been demonstrated to be more beneficial than standard treatment when used in conjunction with aspirin, statins, and antihypertensives. The main clinical trials intended to evaluate the impact of polypill methods for medication adherence and the prevention of CVD events are summarized in Table 1. Regarding polypills' impact on CVD primary and secondary prevention,

5.3 Infectious disease (AMR-specific antibiotics)

Antimicrobial resistance (AMR) poses a significant danger to public health globally. Greece has the highest rate of illnesses caused by antibiotic-resistant bacteria among EU/EEA nations. Hospital-acquired infections (HAIs) with limited treatment options (LTO) caused by resistant gram-negative bacteria are one of Greece's most serious AMR threats. Therefore, the purpose of this study was to determine the current AMR burden in Greece., as well as the advantages to the Greek healthcare system from minimizing AMR. to gram-negative infections. (97) Numerous studies have documented the factors contributing to the rise of AMR, such as self-medication, misuse of antibiotics, overprescription by practitioners, and public strong confidence in antibiotics, including non-prescription buying, restricted access to veterinary and extension services, the use of veterinary antibiotics for growth promotion and prophylaxis, and a lack of understanding about infection prevention and control (IPC) and antimicrobial usage (98) on order to lessen the impact of antimicrobial Tanzania

launched its first National Action Plan (NAP) on Antimicrobial Resistance (AMR) in 2017 to help the worldwide response. (99)

5.4 Geriatric and Paediatric Applications

Three-dimensional (3D) printing is revolutionising the pharmaceutical industry and clinical pharmacy, shifting the focus away from mass production and towards the creation of personalised, patient-specific medications(100). This technology enables the personalisation of oral dosage forms, giving exact control over size, shape, drug release patterns, and dose modifications, making it particularly helpful for populations with specialist medical needs, such as children and the elderly. (101) Enhancing The use of 3D printing into medicine formulation improves medication adherence and treatment efficacy in these vulnerable populations. While seniors may benefit from instant-dissolving tablets (IDTs), which reduce swallowing issues and boost bioavailability, paediatric children typically require chewable, flavoured, or quick dissolving pills to improve palatability and convenience of administration.(101). Furthermore, new excipients created especially for 3D printing become essential ingredients in creating age-appropriate pharmaceuticals that provide regulated release mechanisms and structural integrity. When selecting excipients or materials for 3D drug printing, it is important to consider the planned drug release profile (instant or prolonged release), the specific printing technology (extrusion, inkjet, or selective laser sintering), and the stability and compatibility of excipients with active pharmaceutical components(102). Furthermore, materials must be fulfilled. regulatory standards for toxicity and biocompatibility while also guaranteeing appropriate palatability and convenience of administration to encourage patient acceptability and compliance. Ref [Figure 13](#)

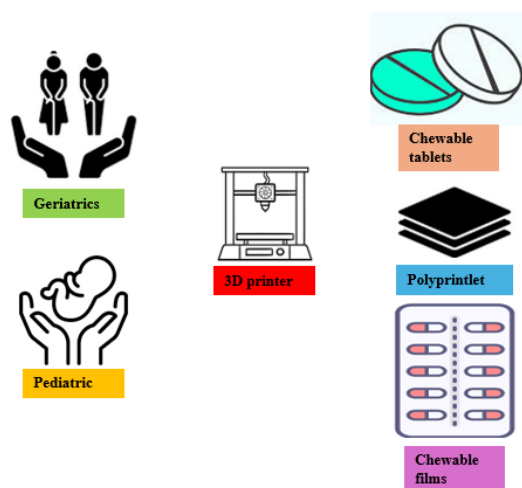


Figure 13 - The most often utilised 3D pharmacological forms among elderly and paediatric patients.

6. Regulatory considerations for the advancement of 3D printing

To correctly design complex structures with regulated Porosity and surface area, three-dimensional pharmaceutical printers need to be highly precise and have high resolution(103). This is essential for controlling dosage accuracy and medication release rates. Furthermore, pharmaceutical-grade materials that satisfy safety and effectiveness requirements, such as polymers and active medicinal components, must work with 3D printers (104). These substances shouldn't interact with the medication or change its characteristics (104). Throughout the printing process, equipment must remain sterile and avoid contamination; this includes using sterile materials and keeping the production area clean. (104). Expanding to bigger volumes can be difficult, even if 3D printing is perfect for small-scale manufacturing and prototyping. Technology must scale effectively without sacrificing the quality of the result. Additionally, with 3D printing, speed is frequently a limiting factor. Technical requirements define the capabilities and limitations of printers, materials, and methods, ensuring that every pharmaceutical batch not only meets stringent health requirements but also produces the intended therapeutic effects. For medications to be safe and effective, process control, material integrity, and design precision are crucial(105,106). To fully benefit from 3D printing, which will ultimately result in better patient-specific therapies and advances in drug administration, it will be crucial to enhance these technological requirements as the area of 3D pharmaceutical printing develops (107).

To guarantee uniformity and quality, every batch of printed pharmaceuticals must go through a thorough testing process (108). This includes confirming stability, dose accuracy, and drug release characteristics as well as validating the printing procedure. GMP standards include parameters for quality management, staff qualification, cleanliness, equipment verification, and process validation. must be followed by production facilities. Formula and design files are frequently transmitted digitally during the 3D printing process, therefore protecting the data from unwanted access and maintaining integrity at all times are essential. Keeping thorough records of the materials used, the production process, and the testing outcomes for every batch is also crucial. Addressing any quality concerns and, if required, handling recalls are made easier by this traceability(109).

6.1 3DP PM's Policy Implications

There are currently no international regulations or standards that explicitly define the function of 3D printing processes and offer a framework for their application in PM manufacturing. However, while searching for approaches to use 3D printing techniques to do this, chemists might consult

frameworks that describe how on-site extemporaneous synthesis of medications may be conducted. Therefore, we have described the worldwide compounding standards' regulatory frameworks in Table 2 and further discussed how they might be implemented In the context of 3D printing PM. Ref [Table5, Figure14](#) (110)

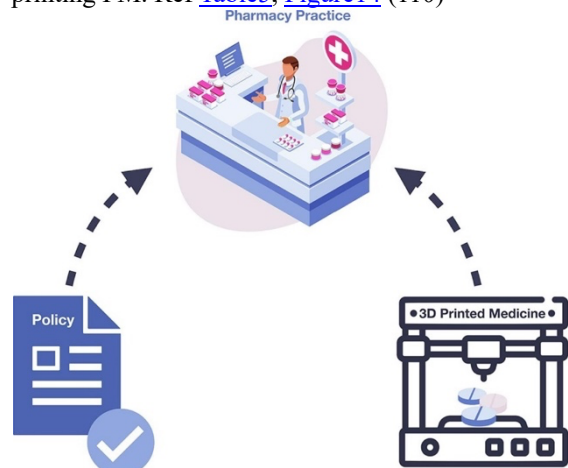


Figure 14 - Integration of 3D-printed medicines into pharmacy practice

Table 05. Overview of compounding exemptions and regulatory practices for 3D-printed pharmaceuticals in various countries.

No	Country	Criteria for exemption from mandatory governing agency approval	Ref
1	Australia	The prescription might serve as the instruction for compounding. Appropriate circumstances include unavailable commercial products, unsuitable commercial	(Pharmacy Board of Australia PBA, 2017)(111)

		products (e.g., allergies), and ethically approved research. Products are compounded using Reputable formulations having demonstrated quality, stability, safety, efficacy, and rationale. Developing a professional practice profile and demonstrating suitable training is necessary for compounding complex products such as Sterile preparations, hormones, cytotoxins, micro-dose dosage forms containing less than 25mg of API and modified-release formulations.	
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		Pharmacists must document the manufacture of compounded products.	
2	Europe	The physician must explain that the prescription is for an in-pharmacy preparation. Acceptable conditions include unavailable commercial products or allergies. Products should adhere to accepted quality assurance processes, such as the European Pharmacopoeia or national norms. Documentation is desirable but not required, except for stock preparation. Documentation comprises showing the necessity for	(Committee of Ministers COM, 2016)(112)

		pharmacy preparation, demonstrating that all substances fulfil applicable standards, keeping a record of the preparation procedure, and testing (if necessary).	
3	USA	Compounding must be noted on a valid prescription. Products must adhere to USP pharmacy compounding chapters. All components must be FDA authorised. The compounded drug cannot be a duplicate of commercially accessible medicines. The package does not include difficult-to-compound medications,	(US Food and Drug Administration FDA, 2016)(113)

		which are currently being developed with the Pharmacy Compounding Advisory Committee.	
4	Brazil	A chemist may prepare any lawful prescription. Compounding procedures adhere to the Brazilian Pharmacopoeia National Form or can be verified for quality, efficacy, and stability. Quality guarantee must be followed. Create documentation for processes, compounding orders, supplies, workstation conditions, storage techniques, personnel training, auditing,	(Brazil Ministry of Health BMOH, 2012)(114)

		inspections, and maintenance. Provide chemists with the essential subsidies to ensure product safety and efficiency, as well as hygienic and sanitary circumstances. Establish a quality control area.	
5	Canada	A patient-healthcare provider connection is essential. Outside of the pharmacy, no third-party resale of the medication is permitted. If commercial choices are unavailable or unacceptable for the patient, a pharmacist can construct a legal prescription.	(National Association of Pharmacy Regulatory Authorities NAPRA, 2018)(115)

		Prior to compounding, chemists must obtain sufficient orientation, training, and skills evaluation.	
6	United Kingdom	Prepare in accordance with the prescription. Keep records of temperature, moisture, personnel training, preparation techniques, and equipment/facility maintenance for audit purposes. Compounding formulas must be well documented, including methodology and source (e.g., British Pharmacopoeia or other reliable source).	(General Pharmaceutical Council (GPC), 2018)(116,117)

Criteria that exempted a compounded composition from obtaining permission from the relevant regulating pharmaceutical or manufactured goods agency were incorporated in all international

compounding frameworks. The criteria listed below aligned with every evaluated guideline: A trained pharmacy technician or pharmacist must prepare the product. and comply with the required quality evaluation form. guidelines, such as the United States Pharmacopoeia (USP), which stipulates that quality testing for medications made in the US must be verified. and the compounded formulation needs to be compatible with the medication, dosage, and form that the practitioner has recommended. A formal letter from the practitioner stating the need for compounding is also necessary in some situations, such as the US(117)

7. Future Outlook on 3D Printing in Pharmaceuticals

Because it allows for customized, on-demand medication manufacture 3D printing has the power to completely change the pharmaceutical production business. Patients with complicated treatment demands will benefit from future developments that support multi-drug formulations with unique release characteristics. Hospitals and pharmacies may use the technology as it develops, particularly for urgent or uncommon drugs. To manage the potential for customization of 3D-printed medications, Regulatory bodies, like the FDA, anticipated to implement adaptable and flexible approval processes. Key issues still exist, though, including scalability for scale manufacturing, dosage accuracy, printer resolution, and material compatibility. Hardware and pharmaceutical-grade material innovation will be needed to address issues. It is also necessary to consider ethical issues related to intellectual property and fair access. A new age of individualized, effective, and patient-centered medicine administration may be ushered in by 3D printing if industry, regulators, and academics continue to collaborate.

8. Conclusion

3D printing has been a game changer in the pharmaceutical industry, offering unmatched functionality in designing and producing tailored drug delivery systems. With the integration of patient-specific data and advanced polymer science, the technology enables precise control of dosage, release rates, and drug combinations in a single dose form. It offers solutions to age-old healthcare issues—e.g., patient non-adherence, polypharmacy, and age-related formulation needs—particularly in paediatric, geriatric, and chronically ill patient populations. Polymers are at the forefront of this revolution, which serve as the foundation of the creation of stable, biocompatible, and effective dosage forms. The multimodal nature of polymers has made it possible to create various 3D printing methods such as FDM, SLA, SLS, and SSE, each with its own applicability towards various drug delivery targets. Incorporation of these technologies into the pharmaceutical field not only enhances drug therapy response but also minimizes drug wastage

and enables on-demand manufacture in hospitals and rural regions. Nevertheless, in the midst of all this advancement, there remain enormous challenges—anything from technical challenges like low printer resolution and material limitations to more universal challenges like quality control, regulatory, and intellectual property concerns. Global regulatory harmonization plans, standard protocol testing systems, and robust GMP guidelines applicable to 3D-printed pharmaceuticals are all needed now. In the coming years, successful application of 3D printing in pharmaceutical development will depend on multi-stakeholder collaboration across academia, industry, healthcare practitioners, and regulatory agencies. With continued innovation and policy support, 3D printing is set to revolutionize the drug delivery future—forecasting a new era of precision, efficiency, and patient centered care.

CRediT authorship contribution statement.

Arunodaya B S Writing – review & editing, Writing – original draft, Visualization, Software, Resources, Project administration, Methodology, Conceptualization. **Gaganashree T V** Formal analysis, Data curation Investigation, Methodology, Conceptualization. **Chinmayee u Gowda** Software, editing– Investigation, **Shivadarshan J** - References and modification **G S Meghana** – Review and Validation.

Conflict of Interest

There is NO Conflict of Interest

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: I declare that I have no known competing financial interests or personal relationships that could have appeared to influence the work reported on this paper.

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Data availability

No data was used for the research described in the article

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