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# Review on 3D Printing Regulation in Pharmaceutical in India

**[1*]Rutuja Santosh Shewale, [2]Prajkta Vitthal Balakshe, [3]Dr. Atish B. Velhal and [4]Dr. Prakash Dilip Jadhav**

[1]Department of Regulatory Affairs, YSPM', Yashoda Technical Campus, Satara

[2]Associate Professor, Department of Regulatory Affairs, YSPM's, Yashoda Technical Campus,

[3]Professor at YSPM's, Faculty of Pharmacy, Yashoda Technical Campus, Satara- 415011

[4]Professor, Department of Pharmaceutics, Satara Yashoda Technical Campus, Faculty of Pharmacy, Wadhe, Satara-415011

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**KEYWORDS**

3DPrinting , Pharmaceutical regulation , Hot melt Extrusion , Computer – Aided Design , Drug solubility , patient – specific therapy , Buccal films , Drug-polymer interaction , Quality by Design , Regulatory Guidelines, Photopolymerization, Rapid prototyping, Inkjet Printing, Fused Deposition Modelling .

ABSTRACT:

Three-dimensional printing (3DP), also known as additive manufacturing (AM), is a revolutionary technology model changing pharmaceutical manufacturing, enabling personalized scalable construction of complex topic drug products in the lab to full fill customized patient prescriptions. This review outlines the history of 3DP, beginning with photopolymer printing in the 1960s and continuing through to the FDA approved 3D-printed tablet product, Spritam, in 2016. The information technologies—include the inkjet printing, stereolithography (SLA), and fused deposition modelling (FDM)/hot melt extrusion (HME)—are discussed, emphasizing their work capability in detail, along with incorporating their benefits tangibility enhancement and taste desensitization along with as well. There are requirements posed in recent research (i.e., warm property, polymer accessibility). Recent advances show promise that 3DP can prepare novel drug delivery systems composed of sophisticated architectures such as tablets with compositions of gradient.

## Introduction

3D printing technology is a modern and fast way to create physical objects by building them Layer by layer. In this process, different types of materials such as powders, filaments, pellets, or granules are used and assembled over another with the help of a 3D printer. This technology is also known to be “Additive manufacturing”, “Rapid prototyping” [1] and “Solid free-form technology”. (Rapid Prototyping is a fast way to turn a 3D Computer design (CAD) into a physical model, usually using 3D Printing. A 3D printer is a machine that makes physical 3D models and creates digital data, using a computer-aided design (CAD) file [1]. This technology is also called **Additive Manufacturing**, **Rapid Prototyping**, or **Solid Free-Form Technology** because the object is made by adding material step-by-step instead of cutting or removing material. A 3D printer is a machine that creates a real physical object from digital data. Suppose image Imagine a future where every medicine could be made using a **3D printer,** every day, whenever they are needed, no need to go to any pharmacy. It seems to be impossible, but now it is possible because today’s world is growing very fast with new technologies and innovations. **3D printing** and **pharmaceutical science:** 3D printing has huge potential in healthcare, especially for **personalised medicine**. [2] Modified medicine means giving treatment based on the specific needs of each patient instead of giving the same medicine to everyone[2] . 3D printing, medicines can be particularly designed for each person by changing:

- The **dose** (amount of drug),

Journal of Chemical Health Risks

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- The **shape** of the tablet, and
- The **drug release pattern** (how fast or slow the medicine works in the body).

Scientists have already shown that tablets can be made using 3D printing technology. These tablets can contain improved doses according to the diseased person's condition and medical needs.

The **drug regulatory authority** is the main government organisation responsible for making sure that medicines are **safe, effective, and of good quality**. Medicines are made by strict rules at every step to make sure they are safe, effective and of good quality. First stage is to research and idea, then manufacturing and monitoring the medicine after it is sold in the market.[4]

Pharmaceutical quality means making medicines according to **current Good Manufacturing Practices (cGMP)**. These rules are created by international regulatory organisations such as the **FDA**, **European Medicines Agency (EMA)**, and **International Council for Harmonisation (ICH)** to confirm medicines are consistently safe and reliable.

In the past, medicine was mainly checked for quality and tested only the **final finished product.** This method was also called as Quality by Test (QbT).

Traditional pharmaceutical manufacturing often faced problems because if the final batch failed testing, the entire production was wasted, resulting in loss of time and resources.

To overcome this issue, the concept of **Quality by Design (QbD)** was introduced. QbD focuses on building quality into the product from the beginning rather than testing it only at the end. It identifies risks during early development and uses scientific, risk-based methods and real-time monitoring to ensure the safety, effectiveness, and consistent quality of medicine. The approach progresses in manufacturing efficiency, decreases variations, and supports monitoring compliance. Modern technologies like continuous manufacturing and 3D printing are now gaining regulatory attention, but clear guidelines are still limited, especially for process optimisation and product standards. Therefore, detailed regulations are needed to define manufacturing steps, specifications, and testing methods.

3D printing is emerging as a revolutionary pharmaceutical technology, enabling flexible drug design, personalised medicines, and customised dosages, particularly beneficial for children, elderly patients, and rare disease cases. However, its widespread adoption requires stronger regulatory support and clear guidelines. The Modern technology used to continue manufacturing and 3D printing is now being noticed and careful important by regulatory authorities. Innovative technology like **continuous manufacturing** and **3D printing** is now recognised by regulatory authorities (as shown in Table 1).

| Innovative Technology | Regulatory Document | Regulatory Authority | Release Date |
|---|---|---|---|
| **AI(Artificial Intelligence** | Official Intelligence (AI) helps us to improve the quality, safety, and productivity of medicines by supporting every stage of the pharmaceutical pro cycle, from development to post – marketing monitoring. | EMA | 2023 |
| | Artificial Intelligence is also used in Drug Manufacturing: Discussion Paper. | FDA | 2023 |

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

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|---|---|---|---|
| **Continuous Manufacturing** | Q13 Continuous Manufacturing of Drug Substances and Drug Products | ICH | 2023 |
| | Emerging Technology use to Development Guidelines | FDA | 2021 |
| Advanced Manufacturing | Evaluation of Distributed and Point-of-Care Drug Production | FDA | 2022 |
| **Innovative Technology** | **Regulatory Document** | **Regulatory Authority** | **Release Date** |
| Nanomedicine | Drug Products are Involving Biological Products that Contain Nanomaterial's | FDA | 2022 |
| | Reflection of a Paper on Nanotechnology based on Medicinal Products | EMA | 2020 |
| Gene Therapy | Guideline on Good Clinical Practice specific to Advanced Therapy Medicinal Products | EMA | 2019 |
| | Considerations for the Design of Early Phase Clinical Trials of Cellular and Gene Therapy Products | FDA | 2015 |
| 3D Printing | Technical Considerations for Additively Manufactured Medical Devices | FDA | 2017 |
| | Medical Device Regulation (MDR) (EU) 2017/745 | EMA | 2017 |
| Personalized Medicine | Framework for Personalised Medicine Development | FDA | 2020 |
| Digital Health Technologies | Digital Health Innovation Action Plan | FDA | 2017 |
| Real-World Evidence (RWE) | Framework for FDA's Real-World Evidence Program | FDA | 2018 |

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

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|---|---|---|---|
| Pharmaceutical Quality (QbD) | ICH Q8 Pharmaceutical Development (Quality by Design) | ICH | 2009 |
| | ICH Q9 Quality Risk Management | ICH | 2005 |
| | ICH Q10 Pharmaceutical Quality System | ICH | 2008 |

**History of 3D Printing Technology**

3D printing is also called Three–dimensional printing (3DP) or **additive manufacturing (AM)**, it's a technology used to create 3D objects by using material by using layer by layer. The design of an object or 3D

Object by creating or produced using computer software or medical images, such as MRI and CT scans.

Nowadays, 3D printing is used in every field, like **education, engineering, aviation, clothing, healthcare, and pharmaceuticals.**

**Early Development of 3D Printing**

**1960s:**

The first experiments with making 3D objects using light-sensitive materials (photopolymers) began at **Battelle Memorial Institute** in Ohio.

**1971:**

**Wyn Swainson** filed a patent for a technology using dual laser beams, called photochemical machining, which helped shape materials using light.

**1970s:**

**Dynell Electronics Corporation** developed an early method called solid photography, an important step toward modern 3D printing.

**1980:**

Japanese researcher **Hideo Kodama** introduced a rapid prototyping method using a single laser beam to harden thin layers of material one by one.

**1984:**

**Charles Hull** invented **stereo lithography (SLA)**, one of the first true 3D printing technologies. He later founded **3D Systems**, which produced the first commercial 3D printer.

**1987:** The world's first commercial stereolithography printer was launched by 3D Systems.

**Development in Pharmaceuticals**

**1990s:**

Scientists **Sachs and colleagues** developed a 3D printing method using **inkjet printing**, where a liquid binder was sprayed into powder layers to form solid structures. This method became important for pharmaceutical applications.

**2016:**

**Aprecia Pharmaceuticals** launched **Spritam (levetiracetam)**, the **first FDA-approved 3D-printed tablet**, used to treat epilepsy.

**Recent Growth and Importance**

- The global 3D printing market was valued at **$9.9 billion in 2018** and is expected to grow rapidly due to demand for customised products.
- Medical and pharmaceutical 3D printing is growing quickly because it allows **personalised medicines** and patient-specific treatments.
- As many early patents expired, 3D printers became **more affordable and widely available**, increasing their use worldwide.

**What is 3D Printing Technology?**

3D printing of medicines is a process where 3D printing technology is used to create modified medications, allowing for personalised dosing, complex geometries, and rapid prototyping, enabling tailored treatments and novel 3D printing is pharmaceutical newly and advance technology use to make customized medicines it is based on patient requirements. Medicines are designed in different sizes, shape and drug release speeds using special 3D printing methods. It approaches use by

Journal of Chemical Health Risks
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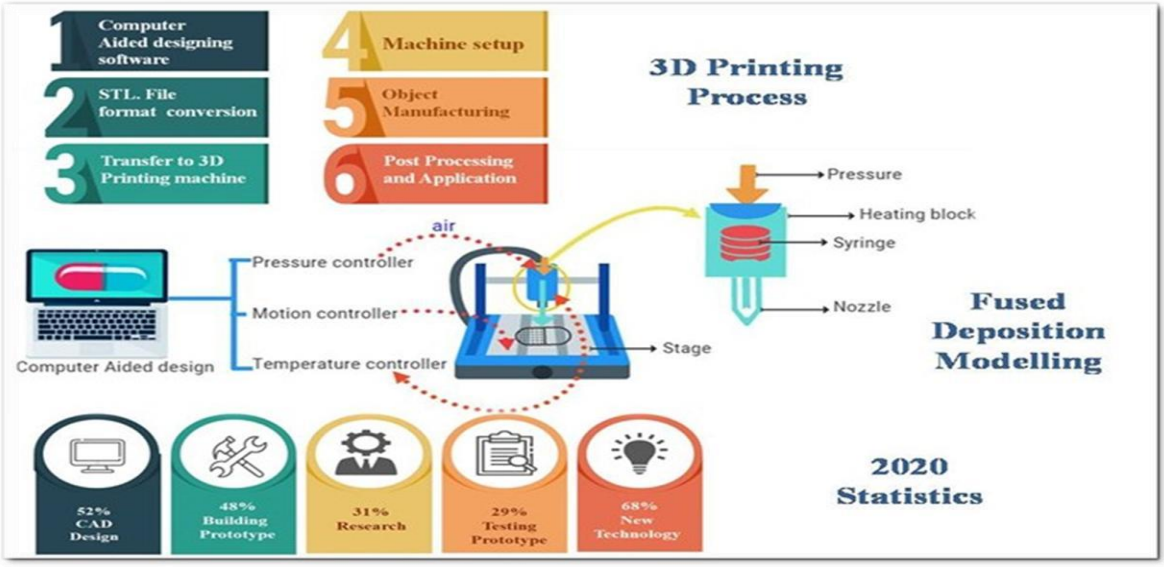
JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

layer-by-layer using technology as inkjet printing, stereolithography, and FDM.

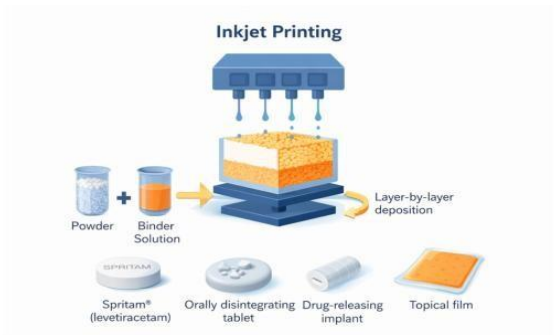



**Inkjet Printing (Simple Explanation)**

**Inkjet printing** is a 3D printing method used to make pharmaceutical products by spraying tiny drops of liquid (ink) onto a surface layer by layer. It is called a **"mask-less" or "tool-less"** method because it does not need special Molds or tools. The final shape is created by controlling the movement of the printer nozzles or the printing surface. This technique prints material using two main methods:

- **Continuous Inkjet Printing (CIJ):** Ink droplets are sprayed continuously.
- **Drop-on-Demand (DOD):** Ink droplets are released only when needed for precise printing.

**Stereo-Lithographic 3D Printing**




**Stereolithography (SLA)** is one of the **earliest and most commonly used 3D printing technologies**. It was developed to help engineers quickly create models and prototypes of their designs in an easy and efficient way. The basic idea of this technology started in the **1970s**. Japanese researcher **Dr. Hideo Kodama** first developed the modern layered method of stereolithography by using **UV (ultraviolet) light** to harden liquid materials called **photosensitive polymers**.

Later, in **1984**, **Charles (Chuck) W. Hull** improved this technology and patented the stereolithography process in **1986**. He also founded **3D Systems Inc.**, which helped make this technology commercially available.

**How Stereolithography Works**

- A container is filled with liquid resin (photosensitive polymer).
- A **UV laser light** shines on the liquid surface.
- The light hardens the liquid layer by layer.
- Each new layer is added on top of the previous one.
- Gradually, a solid **3D object** is formed.

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

This process is called **photopolymerization**, where light causes molecules to join together and become solid.

**Uses of Stereolithography**

- Creating prototypes and models
- Designing patterns and medical devices
- Pharmaceutical and healthcare applications

**Fused Deposition Modelling (FDM)**

**Fused Deposition Modelling (FDM)** is a 3D printing method. In this Method Drugs are mixed with the plastics material and pass to a small nozzle to form a tablet layer by layer. The success of printing depends on the **melting temperature** of the drug–polymer mixture and proper extrusion conditions.

Common thermoplastic polymers used include **polyvinyl alcohol (PVA)** and **polylactic acid (PLA)**, while **ABS** is less suitable for medical use because it is non-biodegradable. Printing performance is affected by factors such as feed rate, nozzle size, temperature, pressure, and thermal properties of materials. Studies showed that drug release can be controlled by changing **infill density** and tablet design. Thermally stable drugs (e.g., 5-ASA) can be printed successfully, while heat-sensitive drugs may degrade during printing. FDM allows production of tablets in different shapes (pyramid, sphere, torus) and enables **personalized drug doses** and controlled drug release.

This technique can also create **polypills** containing multiple drugs in one tablet with targeted release profiles. Compared to powder-based methods, FDM provides better resolution, strong mechanical properties, and complex designs. However, limitations include heat sensitivity of some drugs and the need to improve printing speed and quality for future clinical use.

**Comparison of Different 3D Printing Technologies in Pharmaceuticals**

| **Technology** | **Working Principle** | **Benefits** | **Drawbacks** | **Application Examples** |
|---|---|---|---|---|
| **Fused Deposition Modelling (FDM)** | Heating and extrusion of drug loaded thermoplastic filaments through a nozzle | - Cost-effective method - Compatible with many materials - good printing accuracy | - High temperature may damage heat sensitive drugs - Restricted to thermoplastic polymers | - Controlled drug release tablets<br>- Multi-drug (polypill) formulations |
| **Stereolithography (SLA)** | Solidification of liquid resin using light-induced photopolymerization | - High precision printing<br>- Smooth surface quality | - Limited material choices<br>- Possible toxicity of photo-curable resins | - Microneedle fabrication - Hydrogel systems for drug delivery |

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

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|---|---|---|---|---|
| **Selective Laser Sintering (SLS)** | Fusion of powder particles using laser energy | - No requirement of support structures - Suitable for various materials | - High energy consumption - Risk of heat related drug degradation | - Fast dissolving tablets<br>- Porous drug delivery structures |
| **Inkjet Printing** | Controlled deposition of tiny liquid droplets onto substrate | - Operates at room temperature - Accurate dose control | - Works mainly with low viscosity liquids - Risk of nozzle blockage | - Personalized medicines - Combination drug products |

**Hot Melt Extrusion (HME) Applications**

- Used for **solid dispersion preparation** to improve drug solubility.
- Manufacturing of **controlled release and sustained release tablets**.
- Preparation of **amorphous drug formulations**.
- Production of **drug-loaded filaments** for 3D printing (especially FDM printing).
- Taste masking of bitter drugs.
- Development of **personalized medicines** with specific drug doses.
- Used in preparation of **transdermal films and implants**.

**Advantages**

- **Solvent-free process** (environmentally friendly).
- Continuous and scalable manufacturing method.
- Improves **bioavailability** of poorly soluble drugs.
- Uniform drug distribution in polymer matrix.
- Reduced processing time.
- Suitable for **thermos labile drugs** with proper optimization.
- Easy integration with 3D printing technologies.

**Limitations**

- High processing temperature may degrade heat-sensitive drugs.
- Limited selection of suitable polymers.
- High equipment cost.
- Requires careful optimization of temperature and pressure.
- Possible drug-polymer incompatibility.
- Moisture sensitivity of some materials.

**Obstacles & Challenges**

Hot Melt Extrusion (HME) faces several challenges in pharmaceutical applications. The high processing temperature may degrade heat-sensitive drugs. There is also a limited selection of suitable polymers, making formulation development difficult. The equipment is costly and requires skilled operation and careful control of parameters like temperature and pressure. Additionally, issues such as drug–polymer incompatibility, moisture sensitivity, and possible stability problems during storage can affect product quality and performance.

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

Recent Approaches for 3DP in Design of Novel Drug Delivery Systems

Recent developments in 3D printing (3DP) have allowed the design of advanced drug delivery systems tailored to individual patient needs. Techniques such as fused deposition modelling (FDM), stereolithography, and inkjet printing are used to control drug dose, release pattern, and tablet geometry. These approaches help in producing personalized medicines, multi-drug tablets, and complex dosage forms that are difficult to manufacture using conventional methods.

Tablets with Rapid Onset of Action

3D printing enables the preparation of tablets that dissolve very quickly after administration. These tablets contain porous or highly structured designs that increase surface area, allowing faster drug release and rapid absorption. Such formulations are especially useful in emergency treatments, pain relief, and conditions where immediate therapeutic action is required.

3D-Printed Buccal Film

3D-printed buccal films are thin drug-loaded films placed inside the cheek for drug absorption through the buccal mucosa. This method avoids first-pass metabolism and improves drug bioavailability. 3D printing helps in controlling film thickness, drug dose, and release rate, making it suitable for personalized therapy.

Paediatric Printed Tablets

3D printing plays an important role in paediatric medicine by producing tablets with customized doses, shapes, colours, and flavours. This improves medication acceptance among children and reduces dosing errors. Personalized paediatric tablets ensure safe and effective treatment according to age and body weight.

**Hollow Structure Tablets**

Hollow tablets are specially designed using 3D printing to contain empty internal spaces. These structures help in controlling drug release and reducing tablet density. They can be used for floating drug delivery systems or sustained release formulations, improving therapeutic efficiency.

Nano Suspension

Nano suspensions consist of very small drug particles dispersed in a liquid medium. 3D printing can incorporate nano-sized drugs into dosage forms to enhance solubility and bioavailability, especially for poorly water-soluble drugs. This approach improves drug absorption and therapeutic performance.

**Advantages of 3D Printing in Pharmaceutical Sciences**

3D printing offers many advantages such as personalized drug dosing, reduced material wastage, and complex dosage form design. It allows production of multi-drug tablets, controlled drug release systems, and patient-specific medicines. The technology also supports rapid prototyping and flexible manufacturing.

Disadvantages and Critical Challenges

Despite its benefits, 3D printing has limitations such as high equipment cost, slow production speed, and limited availability of suitable printable materials. Regulatory guidelines are still developing, and maintaining consistent product quality remains a challenge. Skilled technical knowledge is also required.

Safety, Security, and Liability

Safety and security are important concerns in pharmaceutical 3D printing. There is a risk of incorrect dosing due to software or printing errors. Digital design files must be protected to prevent misuse or unauthorized production of medicines. Clear legal responsibility and regulatory frameworks are necessary to ensure patient safety.

Future Perspectives

**Emergence of 4D Printing and Smart Formulations**

4D printing is an advanced form of 3D printing where printed products can change shape or release drugs in response to environmental conditions such as temperature or pH. Smart formulations can provide controlled and responsive drug delivery.

**Integration of Artificial Intelligence (AI) and Machine Learning**

AI and machine learning can help optimize drug formulations, predict drug release behaviour, and

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JCHR (2026) 16(2), 3971-3980 | ISSN:2251-6727

improve printing accuracy. These technologies support faster drug development and better quality control.

**Decentralized Manufacturing and Digital Inventory**

In the future, medicines may be printed directly in hospitals or pharmacies using digital prescriptions. This decentralized manufacturing system can reduce storage needs, minimize drug wastage, and provide medicines on demand.

**Quality Control and Process Validation**

One of the major regulatory concerns is ensuring consistency and reproducibility. Unlike conventional tablet compression, 3D printing involves multiple process variables such as extrusion temperature, printing speed, layer thickness, and material viscosity.

Alzhrani et al. (1) stressed that regulatory agencies must define acceptable ranges for critical process parameters. Sah et al. (4) and Simon et al. (2) also suggested implementing Quality by Design (QbD) approaches to manage variability.

Additionally, Gokhare and Raut (8) explained various 3D printing processes, emphasizing that each technique—FDM, SLA, SLS—requires different regulatory considerations due to material and mechanical differences.

**Challenges in the Indian Context**

Several regulatory challenges remain:

1. Lack of specific regulatory guidelines for 3D-printed drugs
2. Need for harmonization with global standards
3. Intellectual property and patent issues
4. Validation of decentralized manufacturing (hospital-based printing)
5. Standardization of feedstock materials

Singh and Singh (10) and Simon et al. (2) emphasized that decentralized production models raise regulatory concerns about accountability and quality assurance.

**Future Perspectives**

India has the potential to become a global leader in personalized 3D-printed medicines.

However, regulatory authorities must:

- Develop dedicated guidelines for additive pharmaceutical manufacturing
- Integrate digital monitoring systems
- Encourage industry–academia collaboration
- Adopt harmonized global frameworks

Drawing lessons from global literature (1,2) and Indian review studies (5,6,9), India can establish a structured pathway for regulatory approval and commercialization.

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