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THE STUDY OF 3D PRINTING ORAL SOLID DOSAGE FORM

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ABSTRACT

In the present study determine the various methods of 3D printing dosage forms. Additionally described the advantages and disadvantages of 3D printing dosage forms. In this study describes the benefits of 3D printing dosage forms over the other oral dosage forms.

KEYWORDS: 3D Printing, Techniques, dosage form, oral solid.

INTRODUCTION

The automated manufacturing of solid oral dosage forms began more than two hundred years ago.[1] The primary benefits of these dosage forms stem from their relatively simple and convenient production, along with strong patient adherence. Tablets, the key representative of the category, have seen advancements over the last decades with the introduction of techniques like film coating, double compression, andosmotic systems to facilitate controlled and targeted release. Nonetheless, in spite of technological progress, tablet manufacturing continues to rely on tableting machines whose design has not fundamentally altered for decades following the advent of automated tablet presses.[2] Traditional tableting methods continue to face obstacles, such as difficulties in the direct compression of powders and the consequent requirement for granulation. Another limitation of traditional tableting is the growing need for personalized therapies, which is expected to mark a major change in future healthcare.

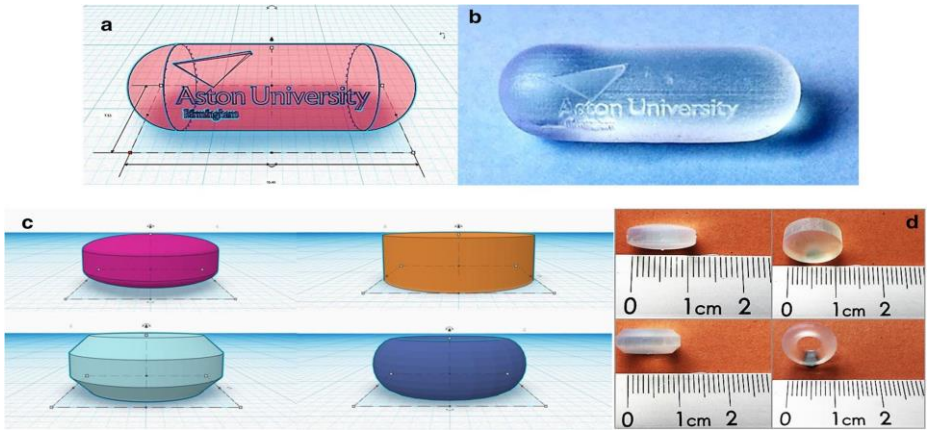


Fig. 1: a, c CAD models of drug delivery devices designed on Tinker cad (Autodesk Inc, USA) and b, d 3D printed prototypes based on the same.

TYPES OF ORAL DOSAGE FORM

Solid Powders: Formulations in solid doses made up of finely milled, micron-sized particles.

Tablets: Solid dosage medication, containing excipients or not.

Granules: Clusters of particles.

Capsules: Gelatine capsules serve to enclose medications.

Tablets: This tiny tablet includes excipients.

Lozenges: Solid formulations made from sugar and gum employed to address issues in the mouth and throat.

Suppositories: Solid dosage form containing medication that is inserted into body cavities aside from the mouth, including the rectum, nose, or ear.

Liquid Droughts: Oral liquid formulations that include one or multiple doses of a drug.

Elixirs: Liquid formulations for oral use that contain excipients and medications.

Emulsions: A water-containing mixture of fats and oils created with an emulsifier. Emulsifying agents cover oil particles to prevent them from merging when the interfacial tension between water and oil diminishes. Consequently, an emulsion forms.

Suspensions: For oral delivery, biphasic liquid formulations incorporate one or more active ingredients mixed in an appropriate medium. When agitated, it breaks down into a consistent suspension that is stable enough to provide the accurate dosage.

Gargles: Water-based solutions applied externally, concentrated for the treatment of throat infections.

Gels: Suspensions of medications in water utilized as antacids.

Lotions: External liquid formulations are typically applied without rubbing.

Liniments: External liquid preparations are typically applied through friction.

Mouth rinses: Like gargles, these rinses are utilized for maintaining oral hygiene and addressing oral infections.

Nasal drops: Liquid solutions applied with a dropper to address nasal infections and obstructions.

Remedies: Liquid medication suitable for internal or external use.

Syrups: Concentrated liquid medicines that are sweet, viscous, and can be made with or without sugar and medications.

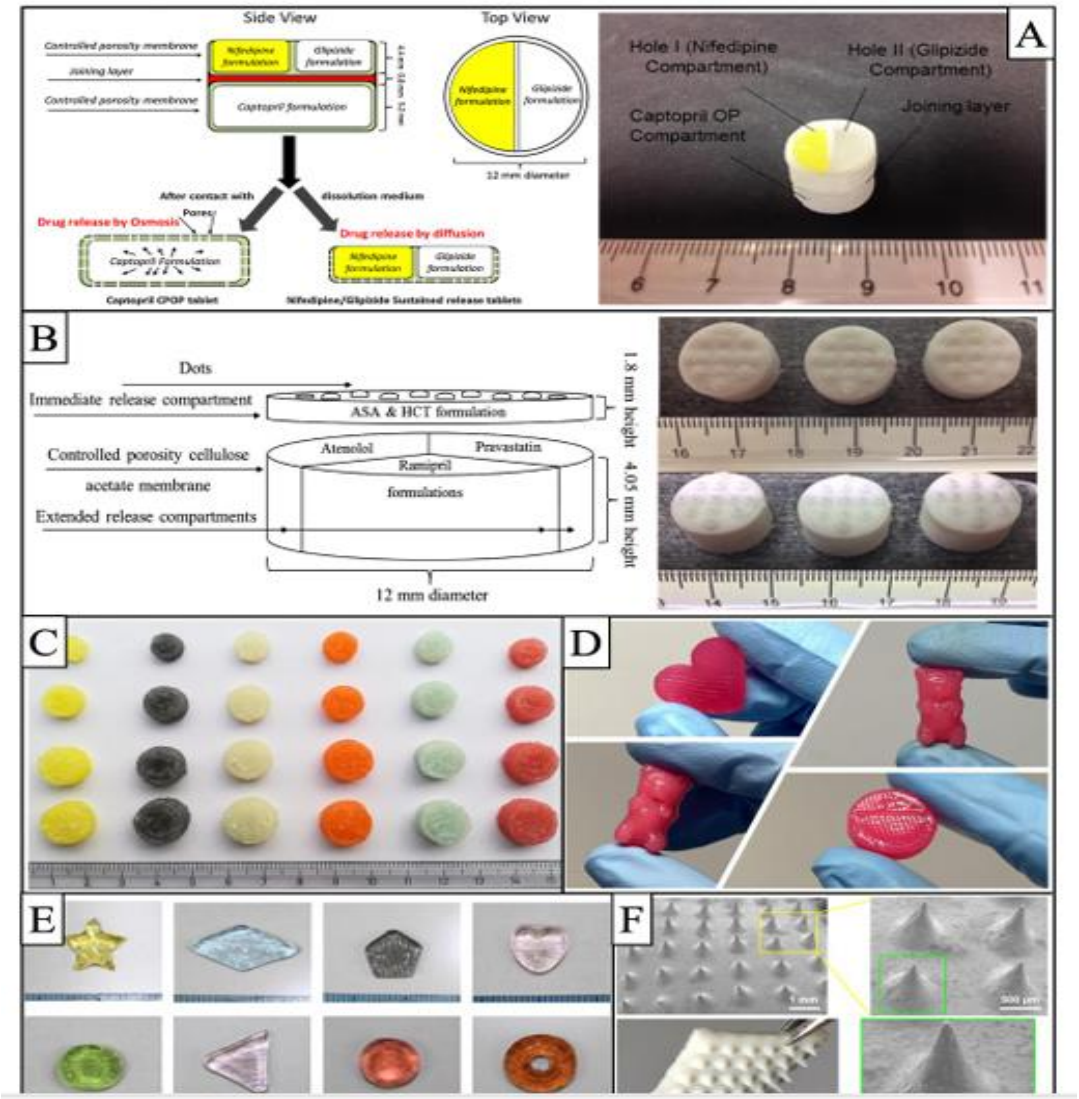


Figure No. 2: Images depict preparations from SSE technology: (A) Multi-active tablet with three APIs; (B) compounded tablet with five APIs; (C) flavoured chewable isoleucine tablets; (D, E) 3D-printed gummies; (F) 3D-printed microneedle; (G) 3D-printed films; (H) tacrolimus suppositories, showcasing various designs and formulations.

Methods of 3d printing dosage form

There are several types of 3D printing, which include:

- Stereolithography (SLA)
- Selective Laser Sintering (SLS)
- Fused Deposition Modelling (FDM)
- Digital Light Process (DLP)
- Multi Jet Fusion (MJF)
- PolyJet
- Direct Metal Laser Sintering (DMLS)
- Electron Beam Melting (EBM)

Choosing the appropriate 3D printing method for your application necessitates comprehending the strengths and limitations of each process and aligning those characteristics with your product development requirements. First, we will explore how 3D printing integrates into the product development cycle, followed by an examination of prevalent 3D printing technologies and their respective benefits.

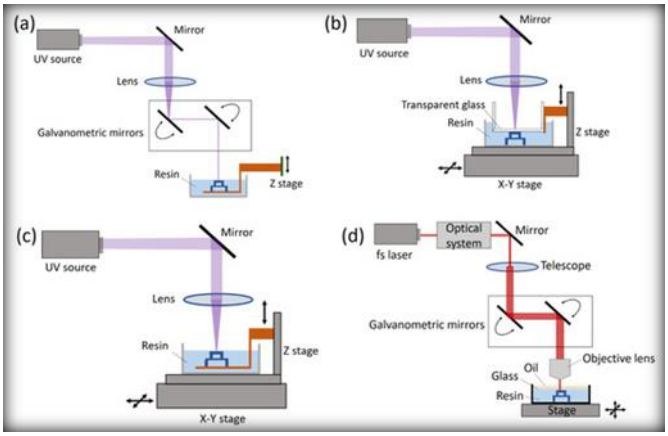


Figure No. 3: Scanning stereolithography processes. (a) Scanning stereolithography with dynamic light beam. (b) The constrain-surface system. (c) The free-surface system (d) A typical two-photon polymerization (2PP) system.

STEREOLITHOGRAPHY (SLA)

1. Photopolymerization of Resin:

SLA uses a liquid photopolymer resin that solidifies when exposed to a specific wavelength of light (usually UV laser).

2. Laser Scanning

A UV laser beam is directed onto the resin surface.

The laser traces the cross-sectional pattern of the CAD model.

3. Solidification

Wherever the laser strikes, the photopolymer undergoes free-radical polymerization, hardening that region.

Areas not exposed to the laser remain liquid.

4. Layer-by-Layer Curing

Once a layer is completed, the build platform moves down slightly (or resin recoats).

A new layer of resin covers the cured surface.

The laser again scans and cures the next layer, bonding it to the previous one.

5. Final Part Formation

This process repeats until the entire 3D object is built.

Uncured resin is drained or washed away.

PROCEDURE

START

↓

Pre-Formulation Studies

(Drug properties, excipient compatibility,

selection of photopolymer resin)

↓

Digital Design (CAD Model)

(Design tablet/implant geometry, porosity,

release profile → export as STL)

↓

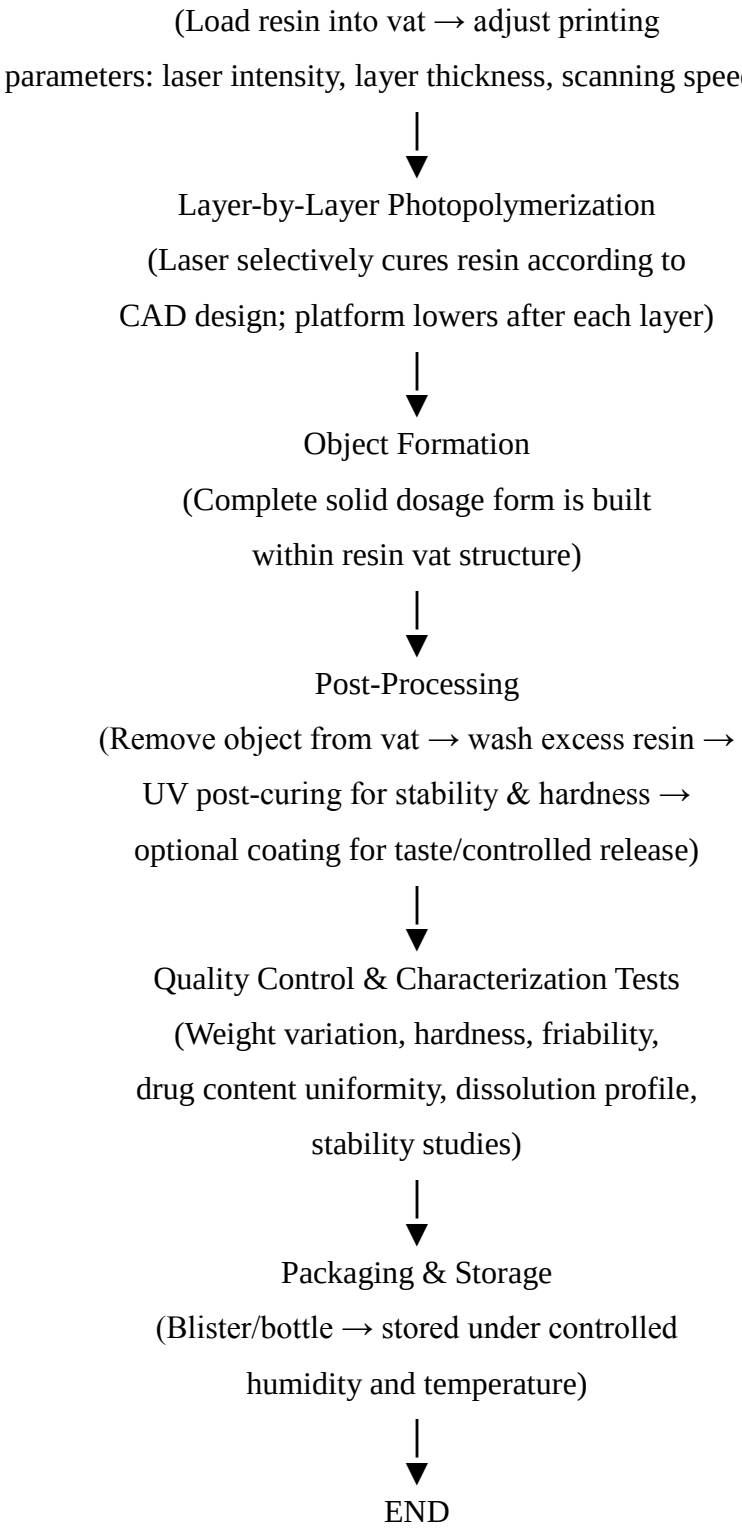
Preparation of Photopolymer Mixture

(Drug + photo-curable resin formulation,

homogenization to uniform mixture)

↓

SLA 3D Printing Setup



FUSED DEPOSITION MODELLING (FDM)

FDM technology is widely adopted in pharmaceuticals due to its straightforward tools, affordability, and durability. It employs computer-assisted design software to create 3D-printed items by layering molten material. The process involves forcing polymer filament containing the drug through a heated nozzle by two rollers. The printing head moves along

the X-Y axis under computer guidance, producing the product layer by layer. After completing a layer, the printing platform descends or the Z axis elevates by a thickness equal to one layer, enabling the printing of subsequent layers. This method allows for efficient and precise fabrication of pharmaceutical products.

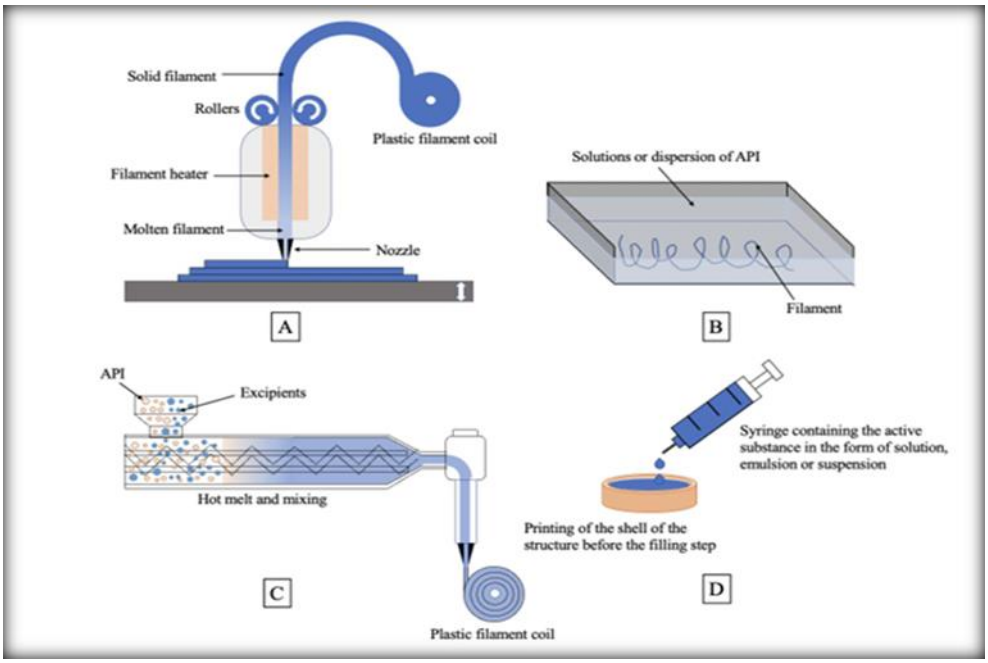


Figure No. 4: Schematic representation of FDM technology shows: (A) its printing principle; (B) drug-containing filament preparation via the dipping-melting method; (C) HME-FDM method for filament preparation; and (D) tablet preparation through filling.

Currently, three main methods for creating 3D tablets using FDM technology are identified: (1) Dipping-melting procedure, where filament is submerged in a solution with API, resulting in an API-infused filament for 3D printing. (2) HME-FDM, which integrates API with excipients during the filament production process, allowing the resulting filament to be used directly in 3D medication preparation. (3) Filling and shaping process, where an empty structure is printed, the API is added, and then the structure is completed; both operations may occur simultaneously or sequentially. These processes require significant filament durability and flexibility.

FDM technology is widely used for creating various pharmaceutical preparations. Initial research highlighted patient acceptance of 3D-printed, differently shaped and sized tablets, with findings showing preference for smaller, round tablets. Researchers like Jarmo et al.

utilized FDM to produce aripiprazole oral films, which showed enhanced dissolution rates. The technology also facilitates regulated release formulations; for example, Lim et al. created hollow scaffolds for steady drug release with zero-order kinetics. Goyanes and colleagues produced multilayer and double capsules using paracetamol and caffeine, demonstrating the capability of FDM in diverse applications. Additionally, FDM was explored for transdermal drug delivery, showcasing its versatility in pharmaceutical development.

PROCEDURE

START

↓

Pre-Formulation Studies

(Drug characterization, excipient selection, polymer choice, compatibility, dose fixing)

↓

Digital Design (CAD Model)

(Tablet/capsule geometry, infill density, porosity, release profile → design exported as STL file)

↓

Preparation of Drug–Polymer Filaments

(Hot-melt extrusion → drug + polymer + plasticizer blended and extruded into uniform filaments)

↓

FDM Setup

(Load filament into printer nozzle, adjust nozzle temperature, bed temperature, print speed, layer thickness, infill percentage)

↓

Layer-by-Layer Extrusion Process

(Heated nozzle melts filament → extrudes drug–polymer material → deposited layer-by-layer as per CAD design → each layer solidifies upon cooling)

↓

Object Formation

(Solid dosage form completed on build platform)

↓

Post-Processing

(Cooling of printed dosage form, optional coating for taste masking/controlled release, finishing)

↓

Quality Control & Characterization Tests

(Weight variation, hardness, friability, mechanical strength, drug content uniformity, disintegration, dissolution, stability studies)

↓

Packaging & Storage

(Blister packs/bottles, stored under controlled humidity and temperature)

↓

END

DIGITAL LIGHT PROCESS (DLP)

1. Light Projection

A digital micromirror device (DMD) or projector projects a pattern of UV/visible light onto the surface of a photopolymer resin.

Each pixel of light corresponds to a point in the layer being cured.

2. Photopolymerization Reaction

The light energy activates photo initiators in the resin.

This causes free-radical polymerization, solidifying the resin wherever the light is projected.

3. Layer Formation

Unlike laser-based SLA (which cures resin point-by-point), DLP cures an entire layer at once.

This makes the process faster and ensures high resolution (depending on projector pixel size).

4. Layer-by-Layer Printing

After one layer is cured, the build platform moves slightly upward (or downward).

Fresh resin flows over the cured layer.

The next layer is projected and cured. This repeats until the 3D object is complete.

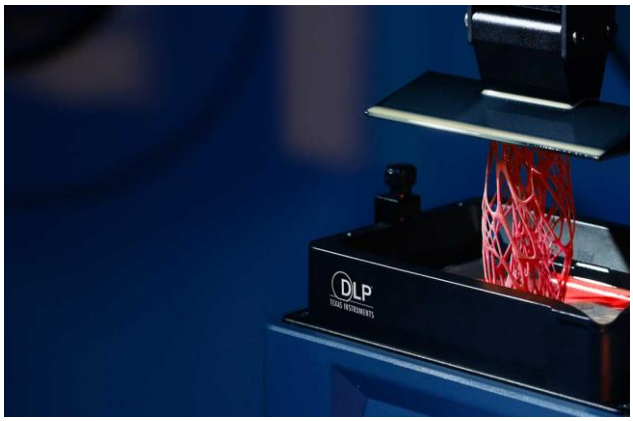


Figure No. 5: image of digital light process.

PROCEDURE OF DLP

START

▼

Pre-Formulation Studies

(Drug characterization, excipient selection,

choice of photo-curable resin, compatibility)

▼

Digital Design (CAD Model)

(Design dosage form geometry, infill density, porosity,

release profile → export as STL/OBJ file)

▼

Preparation of Drug–Resin Formulation

(Mix drug with biocompatible photopolymer resin,

homogenize to ensure uniform drug distribution)

▼

DLP Setup

(Resin loaded into vat → parameters set: light source

intensity, exposure time, layer thickness, build speed)

|

▼

Layer-by-Layer Photo-Polymerization Process

(Digital light projector flashes entire 2D cross-section

of each layer simultaneously → resin solidifies)

|

▼

Object Formation

(Dosage form-built layer-by-layer → remains attached to

build platform within resin vat)

|

▼

Post-Processing

(Remove object from resin vat → wash off excess resin →

UV post-curing to ensure mechanical strength →

optional coating for taste/controlled release)

|

▼

Quality Control & Characterization Tests

(Weight variation, hardness, friability, drug content,

disintegration, dissolution profile, stability studies)

|

▼

Packaging & Storage

(Blister packs or bottles → stored under controlled

humidity and temperature conditions)

|

▼

END

SELECTIVE LASER SINTERING (SLS)

Energy Source: A high-power laser is used as the heat source.

Material Base: Fine powder (thermoplastic polymers, metals, ceramics, or composites) is spread in thin layers on the build platform.

Selective Fusion

The laser beam, guided by CAD data, scans and sinters (fuses) powder particles only at the desired regions.

The powder absorbs the laser energy, and particles fuse together by solid-state sintering or partial melting.

Layer-by-Layer Process

Once a layer is fused, the platform lowers, and a new layer of powder is spread.

The laser sinters the new layer, bonding it to the previous one.

Self-Supporting System

The unsintered powder remains loose and acts as a natural support structure during printing.

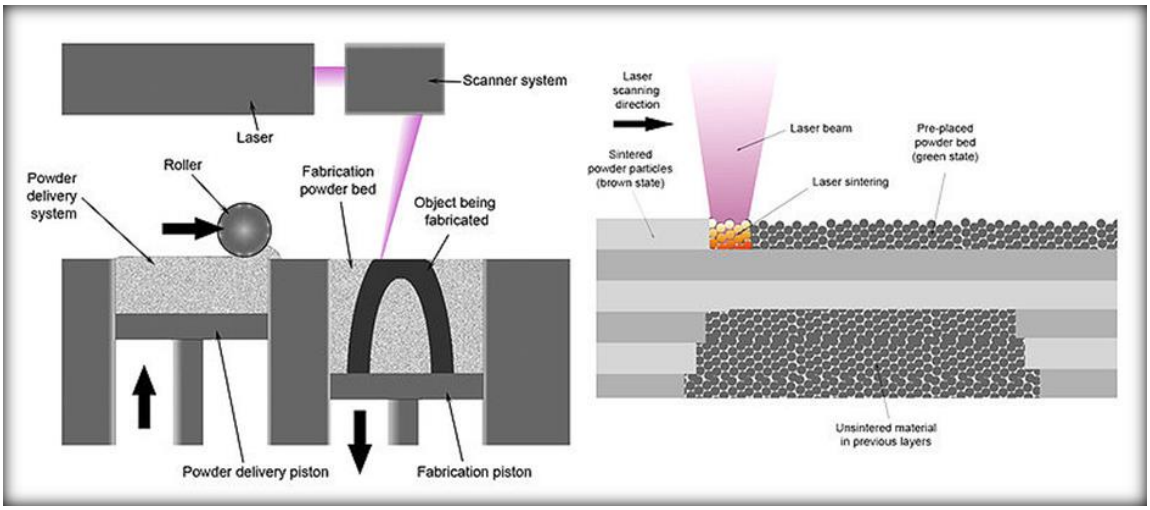


Figure No: 6.

PROCEDURE

START

↓

Pre-Formulation Studies

(Drug characterization, excipient selection,

polymer/carrier choice, compatibility studies)

↓

▼

Digital Design (CAD Model)

(Design dosage form geometry, porosity,
release profile → export as STL/OBJ)

▼

Preparation of Powder Blend/Feedstock

(Drug + polymer/binder + flow enhancers mixed,
particle size optimization for uniform layer)

▼

SLS Printing Setup

(Powder spread in thin layers over build platform,
printer calibrated for laser power, scan speed,
layer thickness, and bed temperature)

▼

Layer-by-Layer Laser Sintering Process

(Laser selectively fuses powder particles as per
CAD design; unfused powder supports structure)

▼

Object Formation

(Complete solid dosage form built inside
powder bed, surrounded by loose powder)

▼

Post-Processing

(Remove dosage forms from powder bed → clean off
excess powder → optional surface finishing or
coating for controlled/taste-masked release)

▼

Quality Control & Characterization Tests

(Weight variation, hardness, friability, mechanical
strength, drug content uniformity, dissolution,
stability studies)

▼

▼

Packaging & Storage

(Blister/bottle → stored under controlled

humidity & temperature conditions)

▼

END

FORMULATION

1) Target definition focuses on dose and uniformity (single/multi-API), release profiles (IR/MR/SR/pulsatile), mechanical needs (friability, hardness, disintegration), and patient factors (size/shape, taste, swallowability).

2) Selection of 3D-printing technology influences excipient choices, categorized as follows:

- FDM: Simple, low-cost, extrudable thermoplastic filament; heat exposure is a concern.
- SLS: Complex geometries using drug/polymer powders; requires flowable powders.
- SLA/DLP: High-resolution prints from photocurable resins; control of residual monomers is essential.
- Binder Jetting: Utilizes powdered drugs with binder liquid; needs post-processing.
- Material Jetting: Involves precise multi-material dosing but is complex.

3) Excipient toolkits

A) FDM employs hot-melt method with a thermoplastic matrix, featuring polymers like PVA/PLA, disintegrants, and stabilizers.

B) SLS uses a polymer/drug powder for laser fusion with performance-enhancing agents.

C) SLA/DLP involves photocurable resins with specific modifiers to control viscosity.

D) Binder Jetting incorporates lactose or mannitol, with a liquid binder and steps for post-processing.

4) Workflow: Define target product profile (TPP), select platform, conduct preformulation, choose excipients, and process development followed by design for release, printing small batches, characterization, iterative adjustments, stability assessments, and documentation.

5) Tailoring geometry affects release; strategies include porosity adjustments for rapid release or dense structures for sustained release.

6) Troubleshooting involves strategies for common issues like nozzle clogs or poor fusion across platforms.

7) Example formulations include FDM, SLS, and binder jetted prototypes for IR and SR applications.

8) Quality and regulatory considerations revolve around critical quality attributes (CQAs) and process parameters (CPPs), ensuring compliance and feasibility demonstrated by past FDA approvals.

ADVANTAGES

- Personalized dosing (patient-specific).
- Complex release profiles (immediate, sustained, pulsatile).
- On-demand production at hospitals/pharmacies.
- Polypills (multiple drugs in one tablet).
- Less waste & cost-effective for small batches.
- Better patient compliance (easy-to-swallow, flavored, customized).
- Rapid prototyping for faster drug development.

DISADVANTAGES

- High cost of equipment and materials.
- Slow production speed (not ideal for mass manufacturing).
- Regulatory challenges (lack of clear guidelines).
- Limited drug stability (heat/moisture during printing may degrade drugs).
- Technical expertise required (not easy to operate/standardize).
- Quality control issues (dose uniformity, reproducibility).
- Limited availability (still under research, not widely accessible).

FUTURE ASPECTS

- Personalized medicine benefits from 3D printing through tailored dosing and release profiles, producing customized medications based on individual patient requirements for better therapeutic outcomes.
- Special populations, such as pediatrics and geriatrics, gain from specialized formulations like chewable or instant-dissolving tablets which address unique needs. Novel forms like multi-layer tablets and oral films enhance flexibility and patient convenience.
- Advanced materials research focuses on biodegradable and biocompatible materials for safe printing, while innovative bioinks may facilitate tissue engineering. Integrating nanomaterials enhances drug delivery systems.

- 3D printing streamlines drug development with rapid prototyping, enabling decentralized manufacturing on-site, thus reducing costs and waste. Regulatory guidelines are vital for product safety, with AI technologies aiding in design optimization and quality control.
- Overcoming challenges like material limitations and scalability is essential for mass production. Technical improvements in printing resolution and speed, along with clinical studies, are crucial for validating 3D printed dosage forms in real-world settings, thus fostering acceptance by healthcare professionals and patients.

CONCLUSION

Researchers recognize 3D printing's potential for creating personalized solid dosage forms. FDA approved Spritam in 2015, enhancing quality and efficiency in pharmaceutical manufacturing tailored to individual patient needs.

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