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PATIENT-CENTRIC PHARMACEUTICAL MANUFACTURING USING 3D PRINTING TECHNOLOGIES

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ABSTRACT

Three-dimensional (3D) printing, also called as additive manufacturing, is a transformative technology that utilizes computer-aided design (CAD) software and digital programming to create three-dimensional objects through the precise layer-by-layer deposition or solidification of materials. In pharmaceutical applications, medicinal substances are planned in a three-dimensional format using CAD systems and converted into machine-readable files. These files define the external geometry of the dosage form, which is then digitally separated into printable layers and manufactured sequentially by the printer.

1. INTRODUCTION

Drug delivery refers to the technology and formulation strategies designed to carry pharmacologically active compounds within the body safely and effectively. Therapeutic efficiency can be significantly enhanced by controlling the drug release profile, which directly influences pharmacokinetics. However, interspecies and interindividual variability remain a major challenge in clinical practice [1]. Approach in genome analysis has further highlighted the need for dosage forms that can be tailored not only in dose but also in release pattern, size, shape, and other physical features.

2. HISTORY

In parallel, another major 3D printing technology, **Fused Deposition Modeling(FDM)**, was patented in 1989 by Scott Crump. In this technique, thermoplastic polymer filaments are heated to a semi-molten state and extruded through a heated nozzle. The material is then deposited layer by layer onto a build platform, where it solidifies to form a three-dimensional object [2].

In the pharmaceutical field, inkjet printing technology has also been applied for drug manufacturing.

3. Advantages of 3D-Printed Drug Dosages:

1. High drug-stuff capacity
2. Accurate and precise dosing
3. Decrease material wastage and cost
4. Fitting for difficult-to-formulate drugs
5. Controlled and advanced drug release profiles

4.DISADVANTAGES:

1.Nozzle blockage or interruption can affect the final product structure.
2.Powder clogging can hinder uniform and consistent material deposition.
3.Printer parameters influence print quality, product performance, and overall cost.

5.LIMITATIONS:

1. Printed dosage forms may have low mechanical strength.
2. Production is slower than conventional mass manufacturing.
3. Limited polymers are both printable and pharmaceutically acceptable.
4. Drug–excipient incompatibility may occur.
5. Ink viscosity must be within a narrow range for proper printing.
6. Reproducibility and process validation can be challenging [3].

6. TECHNIQUES IN 3D PRINTING:

1: Inkjet Printing:

In this method, ink is deposited onto a substrate either through continuous inkjet printing or drop-on-demand printing, enabling high-resolution deign formation.

2: Thermal Inkjet Printing

This technique has been broadly used in the fabrication of drug-loaded biodegradable microspheres, drug-loaded liposomes, patterning and coating of microelectrode arrays, and loading of drug-eluting stents.

3: Hot Melt Extrusion (HME):

Hot melt extrusion is a procedure in which polymers and drugs are melted and mixed under elevated temperature and pressure to achieve uniform blending. It is a continual manufacturing method require feeding, heating, mixing, and shaping of material

5.4: Extrusion 3D Printing

Technique has been used to fabricate tablets containing guaifenesin as an expectorant. Materials suitable for extrusion include molten polymers, suspensions, semi-solids, and pastes [4].

5.4.1: Semi-Solid Extrusion (SSE)

Semi-solid extrusion (SSE) is a 3D printing method an involve the extrusion of semi-solid materials, such as gels, pastes, or viscous polymeric formulations, through a nozzle in a layer-by-layer manner to fabricate pharmaceutical dosage forms.

5: Zip Dose technology:

Zip Dose® technology is the world's first and only FDA-approved commercial-scale 3D printing platform for pharmaceutical manufacturing. It utilizes digitally coded layering and zero-compression techniques to produce tablets with high drug loading and rapid disintegration, thereby overcoming swallowing difficulties.

6: Powder-Based 3D Printing:

Powder-based 3D printing utilizes a powder bed system in which thin layers of powder are spread sequentially and liquid binder droplets are selectively deposited using inkjet printers.

7: Fused Deposition Modelling (FDM) 3D Printing:

Fused deposition modelling is based on the layer-by-layer deposition of molten material according to a predefined digital model [5].

5.8: Selective Laser Sintering (SLS):

Selective laser sintering is a powder-based 3D printing technique in which a pre-designed object is fabricated directly from powdered material.

5.9: 3D Printer:

3D printing is an advanced tool used to develop optimized medications with tailored drug-release profiles, enhancing patient comfort and compliance [6].

7. TYPES:

1. ORAL DOSAGE FORMS

In most cases, oral dosage forms produced by 3D printing utilize conventional excipients that are already employed in established pharmaceutical manufacturing procedures. An exception is the fabrication of capsule shells, for which polyvinyl alcohol (PVA) is commonly used as an excipient, in contrast to traditional capsules that are typically made from gelatin.

1.2: EXTENDED RELEASE TABLE:

Overall, extended-release tablets represent the largest proportion of reported 3D-printed dosage forms. The broad availability of polymers and extensive pliability in software-controlled design parameters make 3D printing especially advantageous for ER formulation development [7].

1.3: PELLETS AND MINITABLETS**:**

According to the European Pharmacopoeia, pellets (also referred to as spheroids) are classified as granules and are defined as spherical units with diameters typically ranging from 200 to 2800 μm.

1.4: CAPSULE:

According to the European Pharmacopoeia, capsules are single-dose, solid pharmaceutical dosage forms that are primarily intended for oral administration. Capsules are classified into hard and soft types [232]

1.5: FILMS:

While the European Pharmacopoeia (Ph. Eur.) refers to orodispersble films (ODFs) and mucoadhesive buccal films only within the context of preparations for use in the oral cavity, the United States Pharmacopeia (USP) divided films as an independent pharmaceutical dosage form. In addition to buccal films, sublingual films are specifically designed to promote systemic drug absorption through the oral mucosa [8].

Based on these definitions, films discussed in this review are categorized as follows:
(1) Oral films (local): films applied in the oral cavity to achieve a localized therapeutic effect;
(2) Oral films (GIT): films intended for drug absorption via the gastrointestinal tract that do not meet the criteria for ODFs; and
(3) Buccal/sublingual films: mucoadhesive films designed to enable prolonged systemic drug absorption through the buccal or sublingual mucosa.

1.6: ORAL FILMS:

Cellulose derivatives are the most commonly used film-forming polymers for the fabrication of films intended for swallowing. These polymers have been processed using material extrusion with fused extrusion (MEX-FE) or printed as hydrogel-based systems via semi-solid extrusion (MEX-SE).

1.7: ORO DISPERSIBLE FIMS:

In the dried state, films typically contain a plasticizer in addition to the drug and the cellulose derivative Furthermore, combinations with other gelling and thickening agents have been investigated to modify mechanical properties, printability, and disintegration actions [9].

1.8: BUCCAL FILMS:

Buccal films typically contain hydrophilic polymers that form hydrogels upon react with saliva and adhere to the oral mucosa Accordingly, material extrusion–based 3D printing using semi-solid extrusion (MEX-SE) of polymeric hydrogels has been the most commonly applied technique for the fabrication of buccal films in recent years.

1.9: OTHER ORAL DOSAG FORMS:

1.9.1: GASTRO RENTENTIVE DOSAGE FROMS:

Gastroretentive dosage forms (GRDFs) are make to remain buoyant by floating on the surface of gastric fluids. In addition to buoyancy, key parameters used to characterize GRDFs include the duration of floating, the floating onset time (i.e., the lag time before the floating mechanism is activated), and the drug-release kinetics [10].

1.9.2: CHEWABLES

The formulations investigated contained hydrophilic and lipophilic components. The effects of three excipients on breaking strength, friability, and drug release were evaluated. Subsequently, the influence of varying amounts of sweeteners was assessed. Different dose strengths were achieved by designing child-friendly geometries of varying sizes and shapes.

1.9.3: DENTAL

In contrast, 3D printing offers a transformative approach to the design and fabrication of dental devices, enabling a high degree of customization, more efficient production workflows, and the potential integration of drug-delivery functions directly into the device.

1.9.4: OTHER MISCELLANEOUS

As previously described for chewable formulations, hydrogels can also be simi for peroral drug delivery [11].

2.PARENTRAL DOSAGE FORMS

According to the United States Pharmacopeia (USP), parenteral dosage forms include injections and implants that are administered through an external body barrier (such as the skin) to deliver drug substances directly into the body.

Although ophthalmic dosage forms are generally discussed separately, intravitreal preparations are classified under parenteral dosage forms.

For implantable dosage forms, shape individualization is highly important because:

- Geometric factors such as surface-area-to-volume ratio affect the rate of drug release.
- The implant must be designed to fit the specific anatomical site of implantation for proper function and patient comfort [12].

3. CUTANEOUS DOSAGE FORMS:

Many dosage forms applied to the skin are designed either for:

- Systemic drug delivery (e.g., transdermal delivery into systemic circulation),
- Local delivery to specific layers of the skin, or
- Protective or keratolytic effects on the skin surface.

Some medicated patches may resemble transdermal patches in structure, but they are specifically intended for localized drug delivery without significant systemic absorption [12].

3.1. Non-gelled patches

Non-gelled, drug-releasing patches produced by 3D printing are typically flat and flexible structures. Some studies report printing the patch directly onto a backing layer, onto packaging materials or directly onto the printer build plate by selecting appropriate polymeric matrices, drug release could be extended from several hours up to several days [13].

3.2. Gel-based patches

Gel-based patches consist of hydrophilic polymer networks that form three-dimensional structures capable of absorbing and retaining water or water-miscible fluids. Due to their soft, adhesive nature, they readily attach to the skin and are widely used in wound management, burn therapy, and situations where a moist environment promotes healing.

To achieve sufficient mechanical strength, most printed hydrogels require crosslinking, either by UV exposure or by adding chemical crosslinking agents.

4.Ophthalmic

According to the European Pharmacopoeia (Ph. Eur.), ophthalmic dosage forms include eye drops, eye lotions, semi-solid eye preparations, and ophthalmic inserts. However, these conventional formulations often suffer from short durations of action, requiring frequent administration to maintain therapeutic drug levels [14].

5.Vaginal dosage forms

Vaginal dosage forms traditionally include semi-solid preparations, vaginal rings, inserts, ovules, suppositories, as well as tablets or capsules. These formulations are commonly used for the local treatment of infections, hormone replacement therapy, and contraception.

The primary objective of the identified studies was to develop vaginal dosage forms capable of providing prolonged drug release, thereby improving patient compliance and therapeutic efficacy.

6. Intravesical dosage forms:

Intravesical dosage forms are drug preparations designed for direct delivery into the urinary bladder. They are mainly used to manage conditions such as interstitial cystitis, bladder cancer, and urinary tract infections [15].

Traditional treatment methods include systemic drug therapy or transurethral instillation using a catheter. Systemic administration can lead to a higher incidence of side effects, while transurethral delivery often suffers

from short drug retention time because of regular bladder emptying [16].

7. Rectal dosage forms:

According to the European Pharmacopoeia (Ph. Eur.), rectal preparations include liquid, semi-solid, and solid dosage forms used for both local and systemic drug delivery [17].

Among these, suppositories are the most widely studied rectal dosage form in pharmaceutical 3D printing. They are especially useful for patients who cannot take oral medications or who need localized treatment in the rectal area [18].

8. Conclusion and outlook:

This review systematically evaluated PubMed-indexed studies published between 2019 and March 2024 on the 3D printing of pharmaceutical dosage forms. Out of more than 500 publications identified, most concentrated on oral (peroral) dosage forms. However, research also covered solid formulations for various other administration routes, including parenteral, cutaneous, vaginal, rectal, intravesical, ophthalmic, and dental uses.

8. APPLICATIONS:

Applications of 3D Printing in Pharmaceuticals and Healthcare:

8.1Broad industrial applications

Utilized in industrial design, aerospace, architecture, medical engineering, tissue engineering, and pharmaceuticals [19].

8.2 Advancement of pharmaceutical product development

8.3 Healthcare and device fabrication

8.4. Personalized pharmaceutical dosage forms

9. CHALLENGES:

Challenges in 3D Printing Technology:

1. Early developmental stage
    - Limited large-scale industrial and clinical implementation has been achieved so far.
2. Versatility and standardization issues
    - Ensuring consistent and versatile application across different dosage forms and drug delivery systems remains challenging.
3. Selection of suitable excipients
    - Many conventional pharmaceutical excipients are not suitable for 3D printing due to inadequate thermal, mechanical, or rheological properties.
4. Post-processing and post-treatment requirements
    - Printed dosage forms often require additional processes such as drying, curing, or sintering.

10. FUTURE DIRECTION AND PERSPECTIVE [20]

Future Prospects of 3D Printing in Pharmaceuticals:

1. Transformation of pharmaceutical manufacturing:
    - Expected to significantly change drug development, production, and distribution processes.
2. Advancement in 3D printing technology:
    - Development of high-precision, cost-effective printers.
    - Ability to process a wider range of pharmaceutical materials.
3. Expansion of printable materials:
    - Ongoing research into new polymers and excipients compatible with 3D printing.
    - Increased compatibility with a broader range of APIs.
4. Multi-drug and combination dosage forms:
    - Independent control of drug release profiles for each API.
    - Improved therapy for patients with chronic and complex conditions.
5. Advanced drug delivery systems:
    - Development of tissue-targeted and stimuli-responsive drug delivery systems.
    - Enhanced precision in personalized drug therapy.

11. CONCLUSION:

Over the last decade, the use of 3D printing in pharmaceutical drug delivery has advanced considerably. This growth has been largely supported by the increased availability of affordable 3D printers, which has expanded access to the technology and stimulated research. A major advantage of 3D printing is its ability to create complex, customizable dosage-form structures, allowing precise control over drug release patterns-something often challenging with traditional manufacturing methods. In addition, the technology enables the development of mathematical and mechanistic models that link formulation design with drug-release actions supporting the rational and efficient production of dosage forms with predetermined performance.This review systematically examined PubMed-indexed studies published between 2019 and March 2024 on pharmaceutical 3D printing. Among more than 500 identified articles, most focused on oral dosage forms. However, research also included formulations for various other administration routes, such as parenteral, cutaneous, vaginal, rectal, intravesical, ophthalmic, and dental applications, utilizing a broad range of 3D printing technologies.

12. AUTHOR CONTRIBUTIONS

All authors contributed equally.

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13. DECLARATION OF COMPETING INTEREST

The authors have no conflicts of interest to declare.

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