3D – PRINTED POLYPILLS FOR CHRONIC DISEASES MANAGEMENT: ADVANCING TOWARD PERSONALIZED PHARMACOTHERAPY

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ABSTRACT

Chronic diseases such as cardiovascular disorders, hypertension, diabetes mellitus and neurological conditions continue to represent a major global health burden, according to a significant proportion of morbidity and mortality worldwide. The long-term nature of these conditions necessitates continuous pharmacological intervention, often involving the administration of multiple medications simultaneously. This practice, commonly referred to as polypharmacy, frequently results in complex dosing regimens that can negatively impact patient adherence, ultimately reducing therapeutic effectiveness and increasing the risk of disease progression, adverse drug reaction and health care cost despite its advantages, the development of conventional polypills using traditional pharmaceutical manufacturing methods is associated with several limitations these include restricted flexibility in dose adjustment and difficulty in achieving physicochemical compatibility among different drugs. additionally, conventional manufacturing processes are primarily designed for mass production that limits their availability to the address individual patient needs. three-dimensional (3D) printing, also known as additive manufacturing, has emerged as a transformative technology in pharmaceutical. Innovative approaches involve the layer-by-layer fabrication of dosage form based on digital design models. and allowing preside control over the spatial arrangement of active ingredient or expedients. 3D printing enables the creation of complex and possible spelling mistake found. Structures that can accommodate multiples drugs within a single dosage unit to maintaining their stability and functionality. Various 3D printing techniques have been explored for pharmaceutical applications, including fused deposition modeling, ink jet printing, stereo lithography, selective laser sintering, and binder jetting. Each method offers distinct advantages and limitations in terms of resolution, material compatibility, processing conditions, and scalability. The choice of technique largely depends on the physicochemical properties of the drugs and recipients, as well as the desired characteristics of the final dosage form. A wide range of pharmaceutical-grade polymers, such as polyvinyl alcohol, Possible spelling mistake found. acid, polyethylene glycol, and Possible spelling mistake found. methyl cellulose, have been utilized to facilitate the printing process and modulate drug release behavior. From a pharmacokinetic and pharmacodynamic perspective, the design of 3D-printed polypills requires careful consideration of factors such as drug compatibility, dose optimization, and release kinetics. The spatial separation of drugs within the dosage form helps to minimize potential interactions and maintain stability. Additionally, the geometry and composition of the printed structure can be modified to enhance drug solubility and bioavailability. By enabling precise control over these parameters, 3D printing offers significant advantages in optimizing therapeutic performance. conclusion, 3D-printed polypills represent a significant advancement in pharmaceutical science, offering a novel and effective approach to addressing the challenges associated with chronic disease management. By combining multiple drugs into a single, customizable dosage form with controlled release properties, they have the potential to improve patient adherence, enhance therapeutic outcomes, and support the transition toward personalized medicine. Although several technical and regulatory challenges remain, continued research and technological advancements are expected to drive the successful integration of this innovative approach into mainstream healthcare.

INDEX TERMS: Additive manufacturing, personalized medicines, chronic diseases, pharmacokinetic, polypill, 3D printing.

1.INTRODUCTION

Chronic diseases such as cardiovascular disorders, diabetes, hypertension, and neurodegenerative conditions are among the leading causes of morbidity and mortality world-wide [32]. These diseases typically require long-term pharmacological management involving multiple medications, which can result in complex dosing schedules and poor patient adherence. Non-adherence not only reduces therapeutic effectiveness but also increases healthcare costs and the risk of complications [33].

1.1 Concept of Polypill:

The polypill concept involves combining two or more APIs into a single dosage form to address multiple therapeutic targets simultaneously. This approach simplifies medication regimens and enhances patient compliance, especially in individuals with multiple comorbidities [29].

1.2 Burden of Chronic Diseases:

The rising prevalence of chronic diseases is associated with aging populations, sedentary lifestyles, and unhealthy dietary habits. These conditions require continuous management and impose significant economic and social burdens. Polypharmacy is common, particularly in elderly patients, leading to increased risks of drug interactions and adverse effects [31,32].

1.3 Need for Combination Therapy:

Combination therapy is essential for managing multifactorial diseases. By targeting multiple biological pathways, it enhances therapeutic efficacy and reduces the likelihood of resistance. For example, cardiovascular diseases often require antihypertensives, statins, and antiplatelet agents administered concurrently [34,35].

1.4 Limitations of Conventional Dosage Forms:

Traditional dosage forms are designed for mass production and lack flexibility in dose adjustment. They also face challenges such as drug incompatibility, stability issues, and inability to provide controlled or sequential drug release [3,4].

1.5 Emergence of 3D Printing in Pharmaceuticals:

3D printing has introduced a new dimension in drug formulation by enabling the creation of complex dosage forms with precise control over structure and composition. This technology supports the development of personalized medicines tailored to individual patient needs [5,13].

2. POLYPILLS: CONCEPT AND EVOLUTION

2.1 Definition and Historical Background

The polypill was initially proposed as a preventive strategy for cardiovascular diseases, aiming to reduce risk factors through a single combination pill. This approach is designed to reduce the number of medications a patient must take separately, thereby improving treatment compliance, simplifying therapy and enhancing overall therapeutic effectiveness. [22]. Over time, the concept has expanded to include treatment of various chronic diseases. The foundation of the polypill approach originated from fixed-dose combination therapies that were introduced several decades ago. The modern concept of the polypill became widely recognized in 2003 when Nicholas Wald and Malcolm Law proposed the use of a combined cardiovascular prevention tablet. Their proposed formulation included cholesterol-lowering agents, antihypertensive drugs, aspirin and folic acid in a single pill. According to the research, such a formulation could significantly reduce the occurrence of cardiovascular complications in high-risk individuals [35].

2.2 Types of Polypills:

• **Fixed-dose combinations (FDCs):** They are pharmaceutical formulations that contain two or more active pharmaceutical ingredients combined in a single dosage form such as capsule, tablet, or suspension.

• **Layered tablets:** Are advanced pharmaceutical dosage forms of two or more distinct layers compressed into a single tablet unit. Each layer may contain different active pharmaceutical ingredients or excipients designed to perform specific functions [18-20].

• **Multi-compartment systems:** They are advanced drug delivery system platforms in which different active pharmaceutical ingredients are separated into individual compartments within a single dosage form.

• **Core-shell structures:** In which one of the material or drug-containing region, known as the core, surrounded by an outer protective layer called the shell [11,12].

2.3 Advantages of Polypill Strategy

Polypills reduce pill burden, improve adherence, enhance therapeutic outcomes, and lower healthcare costs. They are particularly beneficial in populations with limited access to healthcare [29].

2.4 Challenges in Polypill Development

Challenges include drug-drug interactions, chemical incompatibility, difficulty in achieving uniform distribution, and lack of dose flexibility [3,16].

3. OVERVIEW OF 3D PRINTING TECHNOLOGY IN PHARMACEUTICALS

3.1 Definition and Principles of 3D Printing

3D printing involves layer-by-layer deposition of materials based on digital designs. In pharmaceuticals, it enables precise placement of APIs and recipients [5].

3.2 Types of 3D Printing ways

- **FDM:** Uses thermoplastic polymers; cost-effective but heat-sensitive medicines may degrade [2,8].
- **Inkjet Printing:** High perfection; suitable for low- cure medicines [6].
- **SLA High resolution:** It uses photo polymers [13].
- **SLS Ray:** grounded greasepaint emulsion [14].
- **Binder Jetting**: Uses liquid binders for greasepaint connections [13].

3.3 Accoutrements Used in Pharmaceutical 3D Printing

Accoutrements must be biocompatible, stable, and printable. Common polymers include PLA, PVA, PEG, and HPMC [10].

3.4 Advantages over Conventional Manufacturing

- Customization of cure and release
- Rapid prototyping
- Reduced material destruction
- Complex shapes

Table 1. Comparative overview of 3D printing technologies, polymers/excipients, and their pharmaceutical relevance for polypills [14]

3D PRINTING TECHNOLOGIES	WORKING PRINCIPLE	POLYMER/ EXCIPIENT	LIMITATIONS	APPLICATIONS
Selective Laser Sintering	Uses a Laser to sinter powder particles layer by layer to form solid structures	Thermoplastic powders	Requires good powder flow, heat stress may affect drugs	Personalized tablets with modified release profiles
Inkjet Printing (Husky, Jet)	Sprays liquid binder onto powder layers to form structure	Lactose, Kollidon polymers	Weak mechanical strength; post-processing needed	Research formulations and proof-of-concept dosage forms
Fused Deposition Modeling	Extrudes melted polymer filament through a heated nozzle	PVA, plasticizers, colorants and APIs	Limited thermally stable drugs; slower mixing and reduced precision	Multi-layer tablets, sustained or immediate drug release

4. 3D PRINTED POLYPILLS

3D- published polypills combine multiple medicines into a single lozenge form with controlled spatial arrangement and release biographies [1].

4.1 Concept and Design Strategies: Designs include multilayered tablets, core- shell systems, and compartmentalized structures that insulate medicines and control release. The use of programmable printing parameters also allows modulation of porosity, density and dissolution characteristics. Such approaches improve therapeutic efficacy while maintaining structural integrity of the dosage form [19].

4.2 Multi-Drug Loading Approaches: APIs are incorporated into separate regions to help incompatibility and allow independent release control. Techniques such as co-extrusion and inkjet-based deposition ensure accurate placements of APIs with varying physiochemical properties. Additionally excipient selection plays a critical role in maintaining drug stability and ensuring uniform distribution throughout the formulation [25].

4.3 Controlled and Sequential Drug Release: Release biographies can be programmed as immediate, sustained, delayed, or pulsatile grounded on remedial conditions. For example, immediate-release layers can provide rapid onset, while sustained-release section maintain drug concentration over extended periods. Such control is particularly beneficial in managing chronic conditions requiring multi-phase treatment [7].

4.4 Personalization of remedy: 3D printing allows customization of medicine boluses according to case-specific parameters similar as age, weight, metabolism, and complaint inflexibility. Moreover digital health data can be integrated to design individualized treatment regimens, enhancing overall healthcare outcomes [21].

4.4 Case Studies and exploration Advances: Recent studies demonstrate successful fabrication of polypills for cardiovascular conditions and neurological diseases, showing advanced compliance and remedial issues. Furthermore, ongoing advancements in printable biomaterial and regulatory frameworks are accelerating the translation of this technology from laboratory to clinical practice [1,25].

5. APPLICATION IN CHRONIC DISEASES

3D- printed polypills have wide- ranging applications:

- **Cardiovascular conditions** - Ameliorate adherence and reduce threat factors. Enable fixed-dose combinations to manage multiple risk factors such as cholesterol and blood pressure simultaneously. Support tailored dosing to suit individual patient profiles and disease severity. To improve long-term adherence in patients requiring lifelong therapy [34].

- **Diabetes mellitus**- Enable sustained medicine release for glycemic control. Allow gradual and sustained drug release to maintain stable blood glucose levels. Facilitate combination therapy of antidiabetic agents in a single dosage form. Enable dose adjustment based on patient-specific glycemic requirements [28].

- **Hypertension-** Combine medicines with reciprocal mechanism and provide multi-drug formulations targeting different pathways involved in blood pressure regulation. Improve consistency in maintaining optimal blood pressure control and reduce pill burden for patients on combination antihypertensive therapy [34].

- **Neurological diseases-** Give controlled release for precise dosing, support controlled drug delivery for conditions requiring precise dosing such as epilepsy and Parkinson's disease. Allow customization of dosage forms for the patients with swallowing difficulties [25].

- **Contagious conditions-** Useful in long- term curatives and enables combination multiple antimicrobial agents in a single dosage form. Help in reducing the risk of drug resistance through consistent dosing and improve adherence in prolonged treatment regimens such as tuberculosis therapy.

- **Senior and Pediatric Care-** Offer cure inflexibility and ease of administration or provide flexible dosing tailored to age-specific requirements. Allow modification in shapes, size, and taste to enhance acceptability. Offer easy-to-administer dosage forms, improving patients comfort and compliance [29].

6. PHARMACOKINETIC AND PHARMACODYNAMIC CONSIDERATIONS

Understanding both pharmacokinetics and pharmacodynamics is essential for designing effective 3D-printed polypills. These parameters determine how drugs are absorbed, distributed, metabolized and eliminated, as well as their therapeutic effects [23].

6.1Drug Compatibility: Drug compatibility between APIs is pivotal to maintain stability and efficacity. Ensuring compatibility among multiple active pharmaceutical ingredients is critical to avoid degradation and loss of efficacy. Physical and chemical interaction between drugs and excipients must be carefully evaluated during formulation development. Analytical techniques such as thermal analysis and spectroscopy can be employed to assess stability and identify potential incompatibilities at an early stage [3].

6.2 Drug Optimization: Digital design enables precise cure adaptations acclimatized to individual cases. This approach supports precision medicine by tailoring treatments according to individual physiological and pathological conditions [7].

6.3 Medicine Release Kinetics: Release biographies are told by polymer type, figure, and publishing parameters. Mathematical models can further aid in understanding and controlling the kinetics of drugs delivering systems [13,36].

6.4 Bioavailability Improvement: 3D printing can ameliorate medicine solubility and immersion through optimized phrasings. This is particularly useful for poorly water-soluble drugs, leading to improved therapeutic outcomes [13].

7. ADVANTAGES OF 3D- PRINTED POLYPILLS

- **Enhanced patient compliance**: Simplifies medication schedules by combining multiple drugs into a simple dosage form and to minimizes missed doses through reduced dosing frequency. Improves ease of administration, especially for elderly and pediatric patients [40].

- **Individualized therapy:** They enables customization of drug combinations and dosages based on patient-specific needs. Allows flexible modification of therapy as per patient response and clinical condition. It supports tailored treatment according to genetic, metabolic or disease profiles [15-17].

- **Reduced tablet burden:** It reduces the complexity of treatment regimens, particularly in chronic diseases. They combine multiple medications into one unit, decreasing the number of pills taken daily. Improves convenience and adherence for patients on polypharmacy [30].

- **Advanced remedial issues:** Facilitates controlled and site-specific drug release for improved efficacy. Reduces the risk of drug interactions through precise formulation design and enables combination therapy with optimized pharmacokinetic profiles.

- **Long- term cost savings:** Decreases overall healthcare expenses by improving treatment adherence and outcomes. It reduces the hospitalization rates due to better disease management. They minimize manufacturing waste through precise, on-demand production techniques [36-38].

8. LIMITATIONS AND CHALLENGES

8.1 Technical Challenges: Maintaining reproducibility and precision in printing processes. Optimization of process parameters such as temperature, speed, and nozzle size is complex. Variability in printer performance in final dosage forms [16].

8.2 Stability Issues: Thermal degradation and chemical instability of drugs. Exposure to elevated temperatures during printing may reduce the drug potency [8].

8.3 Scale-up and Manufacturing Constraints: Difficulty in transitioning from laboratory to industrial production. Maintaining uniform quality during large-scale manufacturing is challenging. Integration with the conventional pharmaceutical production systems requires significant adaption [16].

8.4 Regulatory Challenges: Lack of established guidelines for personalized medicines. Absence of standardized evaluation criteria complicates product approval processes. Need for clear policies regarding quality assurance and validation of printed drugs [18].

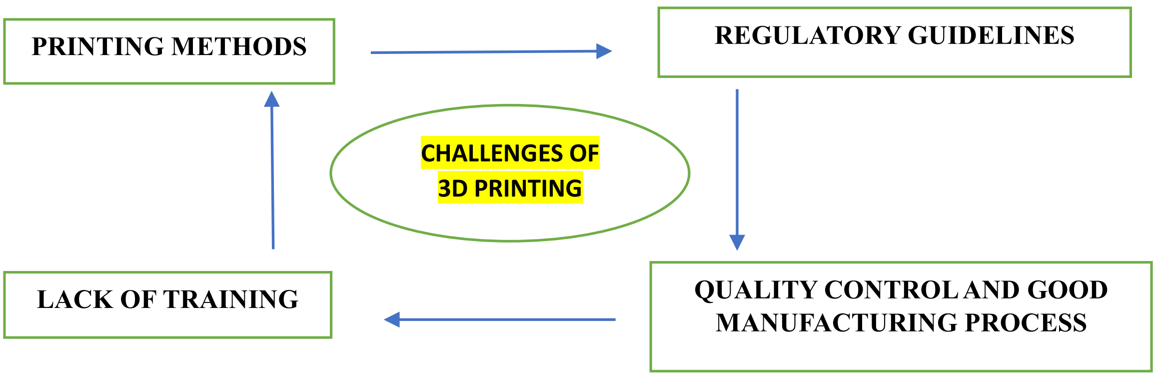

Figure 1. Challenges of 3D Printing [9]

9. REGULATORY PERSPECTIVES

Regulatory agencies are working to establish fabrics for 3D-printed medicines [18].
Crucial considerations include:

- Quality control and confirmation or development of standardized guidelines for validation and reproducibility of printed dosage forms.
- Batch description for substantiated medicines. Need for clear protocols to ensure consistency in patient- specific drug product [37].
- Establishment of regulatory pathways for decentralized or point-of-care manufacturing.
- Approval pathways for novel dosage forms. Harmonization of international regulatory requirements to support global adoption.
- Implementing of robust documentation and traceability systems throughout production.
- Continuous monitoring and post-marketing surveillance to ensure the long-term safety.
- Example: Approval of SRITAM as the first 3D- printed drugs [38,39].

10. FUTURE PERSPECTIVES AND INNOVATIONS

Future advancements include:

- Integration of artificial intelligence in drug design and development of multi-drug formulations with controlled and sequential release profiles. Advancements in bioprinting for personalized tissue and organ-based therapies [26].

- On-demand manufacturing in hospitals and adoption of portable and user-friendly 3D printers for clinical and remote setting. Expansion of personalized medicine tailored to individual genetic and metabolic profile [27].

- Smart polypills responsive to physiological conditions. Improvement in printing speed and scalability to support industrial-level production.

- Use of advanced polymers and novel excipients to enhance drug stability and metabolic profiles [24].

11.CONCLUSION

3D-printed polypills represent a transformative advancement in pharmaceutical technology, offering a practical result to the challenges of habitual complaint operation. By combining multiple medicines into a single, customizable dosage form, they ameliorate patient adherence, enhance therapeutic issues, and support substantiated drug. Although challenges remain, continued exploration and technological advancements are anticipated to drive their adoption in clinical practice. Furthermore, the ability to spatially separate drugs within a single dosage unit minimizes incompatibility issues and enhances formulation stability. The technology also supports the creation of complex geometries that enable sequential or site-specific drug release, ultimately improving therapeutic efficiency. These advantages position 3D-printed polypills as a promising tool in the advancement of personalized medicine, where treatments are designed according to individual patient characteristics and clinical needs. However, despite these benefits, several challenges must be addressed before widespread clinical implementation can be achieved. Issues related to manufacturing scalability, reproducibility, material selection, and long-term stability remain critical concerns. In addition, the current regulatory landscape requires further development to accommodate the unique aspects of additive manufacturing and personalized drug products. In summary, 3D-printed polypills offer a transformative solution for modern healthcare by combining innovation in drug delivery with patient-centric treatment strategies. Continued research, technological refinement, and regulatory support will be essential to fully realize their potential and facilitate their integration into routine clinical practice.

ACKNOWLEDGEMENT

The authors would like to express their sincere gratitude to the Institute of Pharmacy and Paramedical Sciences, Dr Bhim Rao Ambedkar University, Agra for providing the necessary facilities and academic support to carry out this review work. The authors are also thankful for the faculty members and guide for their valuable suggestions, encouragement, and continuous support during the preparation of this manuscript.

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