

Available online on 15.09.2025 at <http://jddtonline.info>

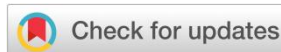
Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Copyright © 2025 The Author(s): This is an open-access article distributed under the terms of the CC BY-NC 4.0 which permits unrestricted use, distribution, and reproduction in any medium for non-commercial use provided the original author and source are credited



Open Access Full Text Article



Letter to Editor

Revolutionizing Personalized Medicine: 3D-Printed Drug Dosage Forms via Hot Melt Extrusion

Amit Kumar ^{*}, Pooja Arora

HRIT University, Ghaziabad, U.P., India

Article Info:



Article History:

Received 24 June 2025
Reviewed 03 August 2025
Accepted 27 August 2025
Published 15 Sep 2025

Cite this article as:

Kumar A, Arora P, Revolutionizing Personalized Medicine: 3D-Printed Drug Dosage Forms via Hot Melt Extrusion, Journal of Drug Delivery and Therapeutics. 2025; 15(9):1-2 DOI: <http://dx.doi.org/10.22270/jddt.v15i9.7357>

*For Correspondence:

Amit Kumar, HRIT University, Ghaziabad, U.P., India

Abstract

Recent advancements in pharmaceutical manufacturing are paving the way for highly personalized and on-demand therapies. This article discusses a novel approach that integrates Hot Melt Extrusion (HME) with 3D printing to produce drug dosage forms with customizable immediate- and modified-release profiles. By transforming APIs and polymers into drug-loaded filaments and then precisely printing them into dosage forms, this method addresses longstanding challenges, such as limited control over drug distribution and suboptimal solubility, while enhancing patient compliance. The innovative design not only promises tailored dosing regimens but also provides significant advantages in production efficiency and regulatory compliance.

Keywords: Personalized Medicine, Hot Melt Extrusion (HME), Solubility, Patient Compliance

Introduction

The pharmaceutical industry is shifting toward individualized therapy, where precise dosing and tailored drug release are critical. Traditional manufacturing techniques often lack the flexibility required to accommodate complex treatment regimens, particularly for chronic diseases that demand staggered drug delivery. Recent advancements in additive manufacturing, particularly fused deposition modeling (FDM) 3D printing, have facilitated the production of oral dosage forms with adjustable geometries and release profiles, therefore advancing the principles of precision medicine and patient-centered drug development.¹ In response, researchers are exploring the combined strengths of HME and additive manufacturing. HME's ability to process polymer-API blends into uniform filaments, when combined with the design freedom of 3D printing, opens up new avenues for creating dosage forms with spatially defined drug release zones. This technology holds promise for reducing manufacturing waste, lowering costs, and enabling on-demand production in clinical settings. Additionally, extrusion-based 3D printing platforms have demonstrated their ability to create polypills and multi-drug delivery systems, which can simplify complicated regimens and

enhance medication adherence in chronic disease management.²

Materials and Methods

The proposed system employs a two-step process. First, APIs—ranging from poorly soluble compounds to those with high solubility—are co-processed with tailored polymers using twin-screw HME. Polymers such as hydroxypropyl methylcellulose (HPMC) and pH-sensitive Eudragit variants are selected based on their ability to modulate immediate and sustained drug release. Plasticizers (e.g., triethyl citrate) are incorporated to optimize extrusion and filament flexibility. In the second phase, filaments are fed into a Fused Deposition Modeling (FDM) printer. Here, process parameters like nozzle temperature, layer height, and infill density are fine-tuned using a Design of Experiments (DoE) approach to achieve the desired dissolution kinetics. Post-print annealing further enhances the mechanical integrity, ensuring stable and reproducible drug release.

Key Innovations and Findings

A central innovation lies in the development of drug-loaded polymer filaments with an amorphous content exceeding 90%. This transformation from crystalline to

amorphous forms significantly increases drug dissolution rates—by up to five times in some cases. Recent advancements in amorphous solid dispersion (ASD) technology have enabled the stabilization of high drug loads in polymer matrices. This has greatly increased the dissolution rates and oral bioavailability of medications that don't dissolve well in water.³ Moreover, a systematic evaluation of printing parameters has led to the creation of dosage forms capable of releasing up to 80% of the drug load within the first half-hour, followed by a controlled, sustained release over several hours. Another novel element is the feasibility of incorporating multiple drugs within a single tablet, either through layered architectures or by spatial segregation. For example, co-printing antihypertensive and diuretic drugs enables synchronized therapeutic effects and may improve patient adherence. Successfully 3D-printed a singular “polypill” incorporating various antihypertensive agents within one floating tablet, each exhibiting a distinct sustained-release profile, highlighting how this approach can streamline complex drug regimes and improve compliance.⁴

Regulatory and Scalability Considerations

Beyond the technical achievements, scalable production and regulatory compliance remain key concerns. The implementation of Process Analytical Technology (PAT) during HME and printing enables real-time monitoring of critical quality attributes, including content uniformity and dissolution profiles. By aligning with guidelines from major regulatory bodies, the proposed technology has the potential to streamline approval processes—particularly for personalized dosages prepared in hospital settings. Recent advancements in process analytical technology (PAT) have facilitated real-time monitoring and control of important quality features during HME,⁵

Conclusion and Future Directions

This work demonstrates a promising strategy to transform pharmaceutical manufacturing. The integration of HME with 3D printing not only offers a platform for creating highly tailored drug delivery systems but also addresses critical manufacturing challenges. Future research will focus on correlating in vitro dissolution data with in vivo performance and further refining the process using artificial intelligence to predict optimal printing parameters. Preliminary investigations have utilized machine learning models to

accurately predict filament printability and appropriate HME/FDM process parameters, indicating that this optimization could significantly expedite the advancement of 3D-printed dosage forms.⁶ Ultimately, this technology could facilitate the transition to on-demand, patient-specific therapies, revolutionizing the production and administration of drugs.

By presenting distinct methodological advances and addressing regulatory challenges, this work contributes a significant leap toward personalized medicine.

Conflict of Interest: The authors declare no potential conflict of interest concerning the contents, authorship, and/or publication of this article.

Author Contributions: Both authors contributed equally to the preparation of the manuscript and its compilation.

Source of Support: Nil

Funding: No funding.

Informed Consent Statement: Not applicable.

Data Availability Statement: The data supporting this paper are available in the cited references.

Ethical approval: Not applicable.

References

1. Cailleaux S, Sanchez-Ballester NM, Gueche YA, Bataille B, Soulairel I. Fused Deposition Modeling (FDM), the new asset for the production of tailored medicines. *J Control Release*. 2021;330:821-841. <https://doi.org/10.1016/j.jconrel.2020.10.056>
2. Bandari S, Nyavanandi D, Dumpa N, Repka MA. Coupling hot melt extrusion and fused deposition modeling: Critical properties for successful performance. *Adv Drug Deliv Rev*. 2021;172:52-63. <https://doi.org/10.1016/j.addr.2021.02.006>
3. Alva C, Goetzinger E, Matić J, et al. Tailoring the release of highly loaded amorphous solid dispersions via additive manufacturing. *J Control Release*. 2025;382:113723. <https://doi.org/10.1016/j.jconrel.2025.113723>
4. Zgouro P, Katsamenis OL, Moschakis T, et al. A floating 3D printed polypill formulation for the coadministration and sustained release of antihypertensive drugs. *Int J Pharm*. 2024;655:124058. <https://doi.org/10.1016/j.ijpharm.2024.124058>
5. Wu S, Liu Y, Fan X, Shen Y, Qu H. Trends and new process analytical technologies in pharmaceutical manufacturing. *Int J Pharm*. 2025;682:125957. <https://doi.org/10.1016/j.ijpharm.2025.125957>
6. Ong JJ, Castro BM, Gaisford S, et al. Accelerating 3D printing of pharmaceutical products using machine learning. *Int J Pharm X*. 2022;4:100120. <https://doi.org/10.1016/j.ijpx.2022.100120>