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Research Article

Development and Characterization of Pharmaceutical-Grade Eudragit® L100 Filaments for FDM 3D Printing of Solid Oral Dosage Forms

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Abstract

Fused Deposition Modeling (FDM) three-dimensional printing is an emerging technology in pharmaceutical technology, offering significant opportunities for treatment personalization and precise control of drug release profiles. However, one of the major technological limitations remains the availability of filaments specifically designed for pharmaceutical applications, as an alternative to conventional plastic polymers such as PLA or ABS. The present study aims to develop pharmaceutical-grade filaments suitable for FDM 3D printing using authorized excipients, and to evaluate their physicochemical and biopharmaceutical properties. Formulations based on Eudragit® L100, plasticized with glycerin or butyl phthalate, were prepared by extrusion using a semi-artisanal shaping process.

The resulting filaments were characterized in terms of appearance, hardness, mechanical resistance to breakage, and drug release profiles of two model compounds, methylene blue and ibuprofen, in simulated gastrointestinal media. The results demonstrate that Eudragit® L100 enables the production of filaments exhibiting a satisfactory balance between rigidity and flexibility, compatible with FDM 3D printing requirements. Release studies revealed a preferential drug release in simulated intestinal medium, confirming the pH-dependent behavior of the polymer. These findings demonstrate the feasibility of developing functional pharmaceutical filaments and highlight the potential of additive manufacturing for the production of personalized oral dosage forms.

Keywords: Pharmaceutical 3D printing; Fused Deposition Modeling (FDM); pharmaceutical filaments; Eudragit® L100; pH-dependent drug release.

1. INTRODUCTION

Conventional manufacturing methods for solid oral dosage forms rely on complex and highly standardized industrial processes, which often lack flexibility and limit the possibility of adapting medicines to individual patient needs¹. In recent years, three-dimensional (3D) printing has emerged as an innovative additive manufacturing technology with the potential to profoundly transform pharmaceutical formulation strategies, particularly in the context of personalized medicine and on-demand drug manufacturing²⁻⁴.

Among the different additive manufacturing techniques, fused deposition modeling (FDM) has attracted considerable attention for pharmaceutical applications due to its simplicity, low cost, and compatibility with a wide range of thermoplastic polymers⁵⁻⁷. FDM enables precise control over dosage, geometry, internal structure, and drug release profiles of solid oral dosage forms, thereby opening new perspectives for individualized therapies^{8,9}.

Despite notable advances and the commercialization of the first FDA-approved 3D-printed drug, levetiracetam (Spritam®), the widespread adoption of pharmaceutical 3D printing remains limited¹⁰.

One of the major barriers lies in the use of polymeric filaments initially developed for industrial or consumer applications, such as polylactic acid (PLA) or acrylonitrile-butadiene-styrene (ABS), which do not fully comply with pharmaceutical requirements in terms of biocompatibility, regulatory acceptance, and drug release performance^{7,11}. Consequently, the development of filaments exclusively formulated from pharmaceutical-grade excipients appears to be a crucial step for the successful translation of FDM 3D printing into pharmaceutical manufacturing^{6,8}. Among the polymers of interest, Eudragit® L100, an anionic methacrylic acid copolymer exhibiting pH-dependent solubility, is widely used for intestinal targeting of solid oral dosage forms^{12,13}. Its integration into printable filaments could enable the manufacture of delayed-release or site-specific oral dosage forms^{14,22,24,30}.

In this context, the present study aims to develop and characterize pharmaceutical-grade filaments based on Eudragit® L100, plasticized with suitable excipients, and to evaluate their physicochemical, mechanical, and biopharmaceutical properties for potential application in FDM 3D printing of solid oral dosage forms.

2. MATERIALS AND METHODS

2.1. Materials

The main polymer used for filament fabrication was Eudragit® L100 (Evonik Industries), an anionic acrylic polymer commonly employed in delayed-release and intestinal-targeted oral dosage forms. The selected plasticizers were glycerin and butyl phthalate, chosen for their ability to improve polymer flexibility and processability. Propylene glycol was used as an auxiliary plasticizing and homogenizing agent, while distilled water and wax served as the solvent and structuring agent, respectively. The model active pharmaceutical ingredients incorporated into the filaments were methylene blue, used as a water-soluble tracer, and ibuprofen, selected as a poorly soluble drug representative of non-steroidal anti-inflammatory drugs (NSAIDs). All excipients and active pharmaceutical ingredients used complied with the requirements of the European Pharmacopoeia. The experimental equipment included an analytical balance (ORMA, model BC), a mortar and pestle for powder homogenization, an electronic stirrer, graduated syringes used as an extrusion device, a durometer for hardness measurement, and a UV-visible spectrophotometer (Thermo Scientific™ Evolution 300) for the analysis of drug release profiles. All excipients and active pharmaceutical ingredients used in this study complied with the requirements of the European Pharmacopoeia and were selected based on their established use in pharmaceutical formulations and modified-release systems^{13,14}.

2.2. Selection and Optimization of Formulations

The selection and optimization of filament compositions were guided by the mechanical and rheological constraints imposed by fused deposition modeling, as previously described for pharmaceutical filaments intended for 3D printing^{5,6,15}.

An exploratory phase was conducted to identify compositions compatible with the mechanical and rheological constraints imposed by fused deposition modeling (FDM) 3D printing. Approximately forty formulations were evaluated by varying the nature of the polymer, the type of plasticizer, and their relative proportions. Selection criteria included filament continuity, absence of breakage during handling, sufficient flexibility, and adequate rigidity to ensure reliable feeding through an FDM 3D printing system. At the end of this preselection phase, two Eudragit® L100-based formulations were retained. The first formulation, plasticized with butyl phthalate, led to the production of a rigid filament (Filament A). The second formulation, plasticized with glycerin, resulted in more flexible filaments (Filaments B and C), suitable for continuous extrusion.

2.3. Filament Manufacturing Process

The filament manufacturing process was based on a semi-artisanal extrusion method, inspired by the principles of hot-melt extrusion used in FDM 3D printing.

The semi-artisanal extrusion process used in this study was inspired by the fundamental principles of hot-melt extrusion and fused filament fabrication commonly reported in pharmaceutical 3D printing research^{5,9,16}.

Initially, the solid excipients (Eudragit® L100, wax, and the active pharmaceutical ingredient) were accurately weighed and then homogenized by manual trituration in a mortar to ensure a uniform distribution of the API within the polymeric matrix. In a second step, the liquid components (glycerin or butyl phthalate, propylene glycol, and distilled water) were gradually added to the solid mixture under continuous stirring until a homogeneous and malleable paste was obtained. This paste was then loaded into graduated syringes that had previously had their needles removed. Extrusion was performed manually by applying constant pressure to the syringe plunger, allowing the formation of continuous filaments deposited onto glass or aluminum plates. The resulting filaments were air-dried at ambient temperature for 24 h to remove excess solvent and to stabilize their mechanical structure.

2.4. Physicomechanical Characterization of the Filaments

2.4.1. Visual Appearance Evaluation

The visual appearance of the filaments was assessed by direct inspection to characterize color, homogeneity, surface texture, and diameter regularity. This step enabled the detection of potential macroscopic defects likely to impair 3D printing quality.

2.4.2. Hardness Measurement

Filament hardness was determined using a durometer by measuring the load required to induce a measurable deformation of the filament. Measurements were performed at different time points after fabrication in order to evaluate the evolution of mechanical properties during storage.

2.4.3. Breakage Test

Mechanical resistance to breakage was assessed by a tensile test using a dual-range force sensor (Vernier). The filaments were subjected to increasing loads until failure, allowing determination of the maximum supported force. The tests were performed on filaments stored at ambient temperature and at 4 °C in order to investigate the influence of storage conditions on mechanical properties.

2.5. Drug Release Study

In vitro drug release studies were carried out in simulated gastrointestinal media, namely simulated gastric fluid (pH 1.2), an intermediate medium (pH 4.8), and simulated intestinal fluid (pH 6.8). Each filament was individually immersed in 500 mL of medium maintained under constant agitation (200 rpm) at controlled temperature. Aliquots of 5 mL were withdrawn at regular time intervals and analyzed by UV-visible spectrophotometry at the specific wavelengths of methylene blue (665 nm) and ibuprofen (265 nm). Drug concentrations were determined using previously established calibration curves. Release profiles were

expressed as a function of time in order to compare the behavior of the different formulations.

In vitro drug release studies were conducted in simulated gastrointestinal media in order to evaluate the pH-dependent behavior of Eudragit®-based systems, following experimental approaches widely reported for enteric polymers and delayed-release dosage forms^{12,17}.

3 RESULTS

3.1. Development and Selection of Filament Formulations

The development of the filaments required approximately forty formulation trials involving various polymers and excipients commonly used in pharmaceutical technology. The polymers evaluated included Kollidon® 30, hydroxypropyl methylcellulose (HPMC), crospovidone, croscarmellose sodium, gum arabic, Sepifilm® 752, and Eudragit® L100. Several plasticizers and solvents (glycerin, butyl phthalate, propylene glycol, ethanol, and distilled water) were tested in order to adjust the mechanical properties of the filaments. The raw materials used are presented in the table below.

Table I: Excipients Used for Filament Fabrication

Product	Role	Main technological function
Kollidon® 30 (PVP K30)	Binder	Improves matrix cohesion and mechanical integrity
PEG 4000	Plasticizer	Reduces brittleness; enhances flexibility
Crospovidone	Superdisintegrant	Accelerates disintegration
Croscarmellose sodium	Superdisintegrant	Enhances water uptake and matrix breakup
Avicel® PH 102	Filler / binder	Improves compressibility and strength
Sepifilm™ 752	Film former	Provides protective polymer coating
Eudragit® L100	Enteric polymer	Enables pH-dependent (intestinal) drug release
Gum arabic	Natural binder	Acts as stabilizer/reducing agent
Wax	Lipophilic excipient	Modulates drug release
Suppocire® C	Lipophilic base	Controls melting and release behavior
HPMC	Matrix-forming polymer	Controls drug release and shape fidelity
Butyl phthalate	Plasticizer	Increases rigidity and mechanical stability
Propylene glycol	Plasticizer	Improves flexibility and miscibility
Glycerin	Plasticizer	Enhances ductility and extrudability
Ethanol	Solvent	Polymer dissolution and extraction
Purified water	Solvent	Dispersion and formulation medium

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3.2. Visual Appearance and Homogeneity of the Filaments

Eudragit® L100-based filaments exhibited a macroscopically homogeneous appearance, a relatively smooth surface, and an overall regular diameter. Drug-free filaments were whitish, opaque, and displayed a matte finish. Incorporation of methylene blue or ibuprofen imparted a uniform coloration to the filaments, indicating good dispersion of the active pharmaceutical ingredient within the polymeric matrix. Figures 1 and 2 below illustrate the appearance of the filaments after extrusion.



Figure 1: Ibuprofen-loaded filament after extrusion.



Figure 2: Methylene blue-loaded filament after extrusion.

No visible segregation, cracking, or surface defects were observed after drying, indicating satisfactory physical stability of the selected formulations.

3.3. Hardness and Time-Dependent Evolution of Mechanical Properties

Filament hardness was measured over several days in order to assess the evolution of their mechanical properties after fabrication. The results showed a progressive increase in rigidity for all the filaments studied.

The values obtained from filament hardness measurements are summarized in Table II. The recorded values represent the applied load required to induce deformation of the filament.

Filament A, plasticized with butyl phthalate, exhibited the highest hardness values from the first days, reflecting a rigid mechanical behavior. In contrast, Filaments B and C, plasticized with glycerin, initially showed lower

hardness values, consistent with enhanced flexibility. However, a gradual increase in hardness over time was observed, likely associated with partial moisture loss.

Comparison between Filaments B and C highlights an influence of the nature of the incorporated active pharmaceutical ingredient on mechanical properties, with the methylene blue-loaded filament exhibiting slightly higher rigidity than the ibuprofen-loaded filament.

Table II: Load required to deform the filament as a function of time (days).

Day	Filament A	Filament B	Filament C
Day 1	8,5 kg	6,5 kg	6,9 kg
Day 2	11,0 kg	9,0 kg	7,0 kg
Day 3	12,5 kg	11,0 kg	9,0 kg
Day 4	14,0 kg	14,5 kg	9,0 kg
Day 5	15,0 kg	16,0 kg	11,0 kg
Day 6	>16,5 kg	16,5 kg	13,0 kg

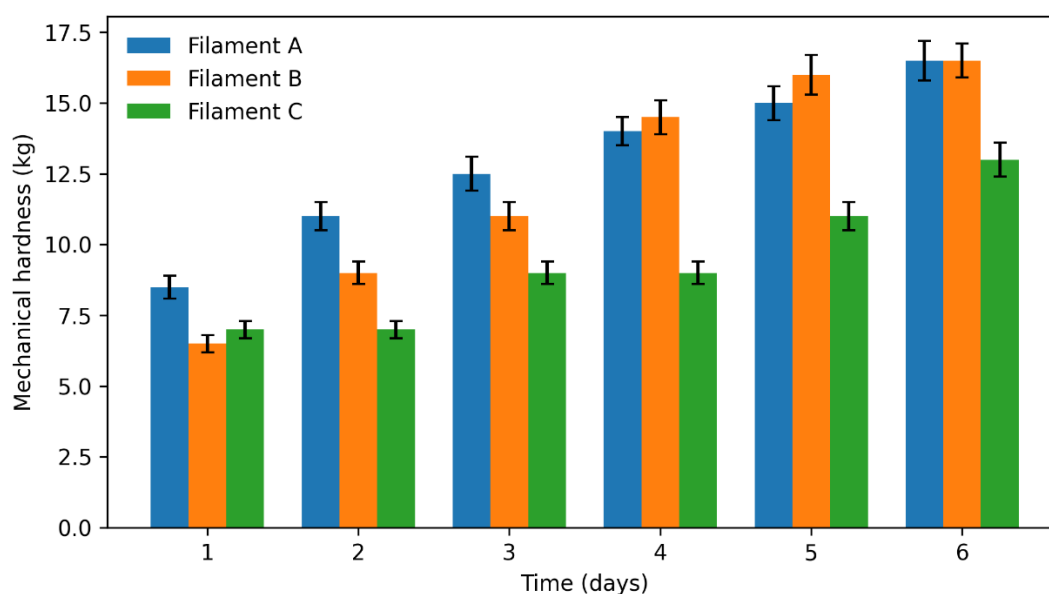


Figure 3: Evolution of Mechanical Resistance over Time

3.4. Mechanical Resistance to Breakage

Mechanical resistance to breakage was evaluated by tensile testing of the filaments. Filament C, which exhibited the best compromise between rigidity and flexibility, was selected as the model formulation for this study.

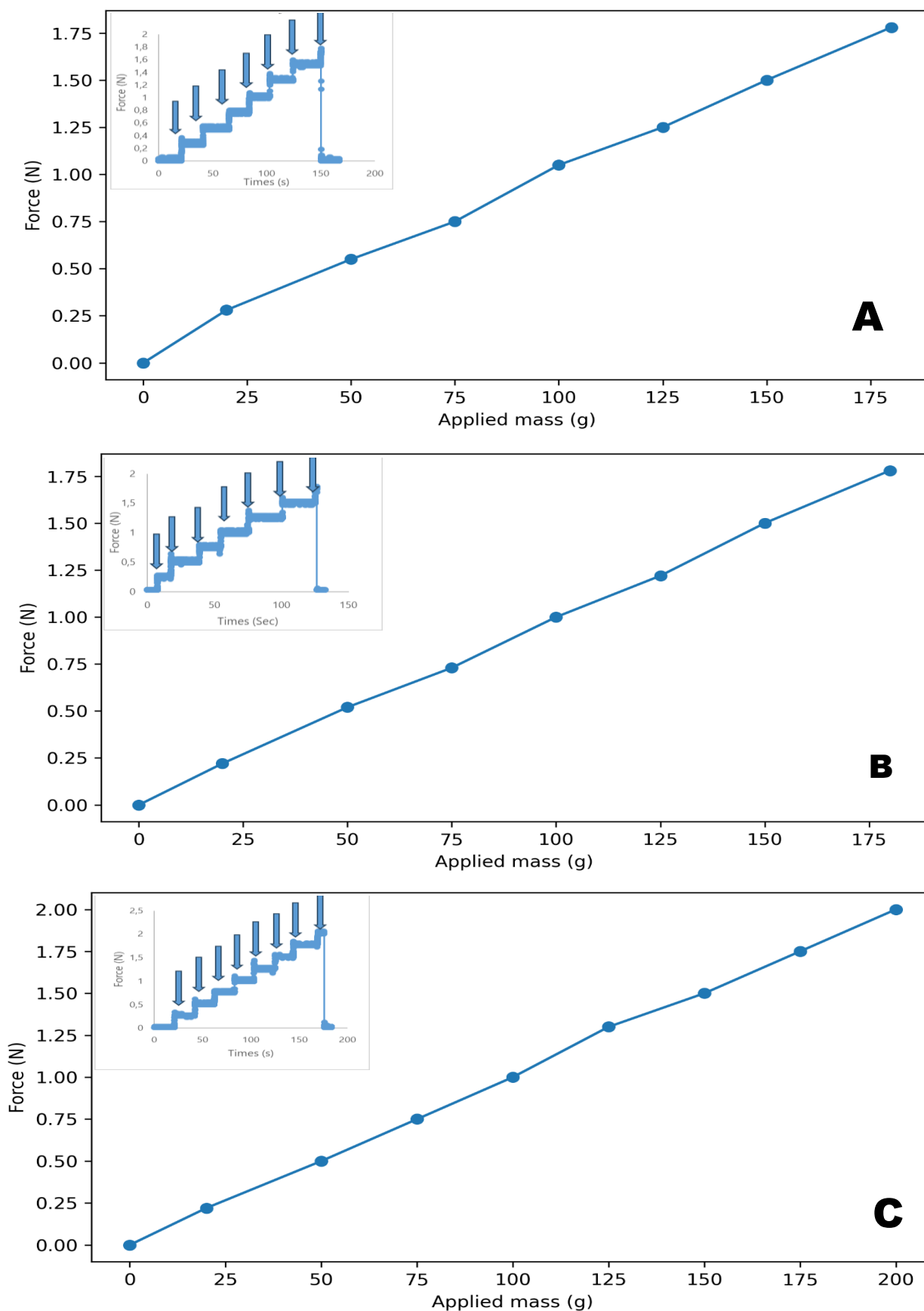


Figure 4: Mechanical resistance to breakage of the filaments determined by tensile testing.

The results show that the force required to break the filament stored at ambient temperature remains overall comparable between the first and the fifth day after fabrication, although the filament tends to become more brittle over time. In contrast, the filament stored at 4 °C retained higher elasticity and flexibility, requiring the application of a higher breaking force than that measured at the initial state.

3.5. Drug Release Profiles

The in vitro release profiles of Filaments A, B, and C were evaluated in simulated gastrointestinal media. A very limited release of both methylene blue and ibuprofen

was observed in simulated gastric medium (pH 1.2) as well as in the intermediate medium (pH 4.8).

In contrast, a marked increase in the amount of active pharmaceutical ingredient released was observed in simulated intestinal medium (pH 6.8). Eudragit® L100-based filaments gradually dissolved in this medium, leading to near-complete release of the active ingredient. For ibuprofen-loaded Filament C, complete dissolution of the filament was observed after approximately 1 h 40 min. Figures 5, 6, and 7 illustrate the amount of active ingredient released over time.

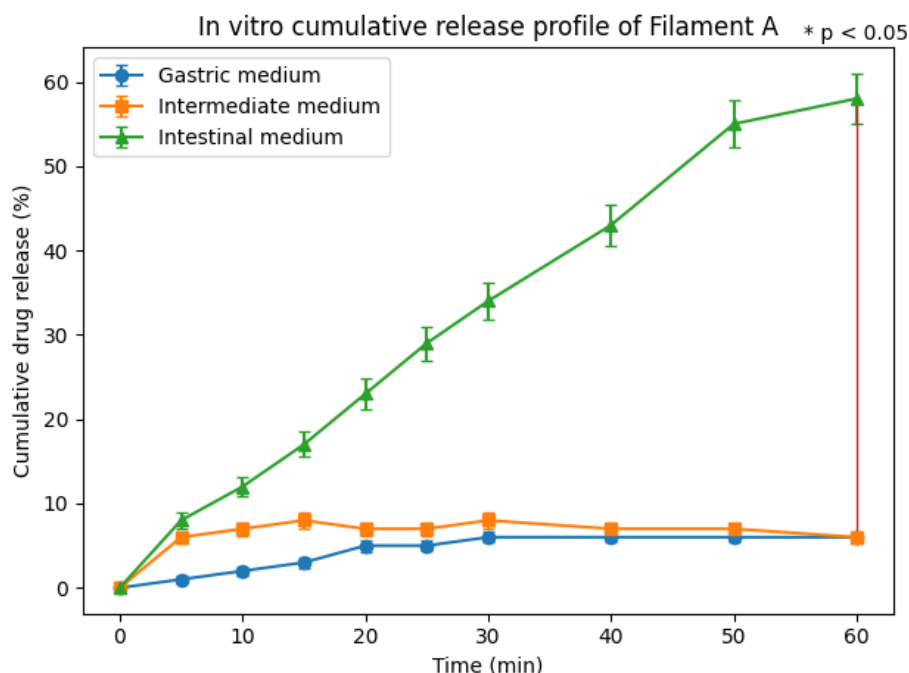


Figure 5: Drug release profile of Filament A in simulated gastric, intermediate, and intestinal media.

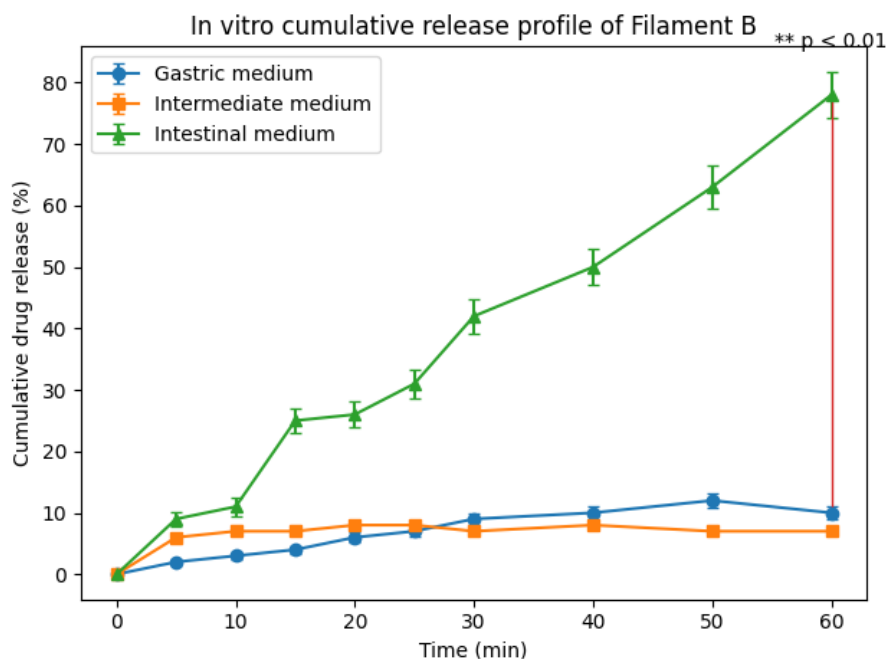


Figure 6: Drug release profile of Filament B in simulated gastric, intermediate, and intestinal media.

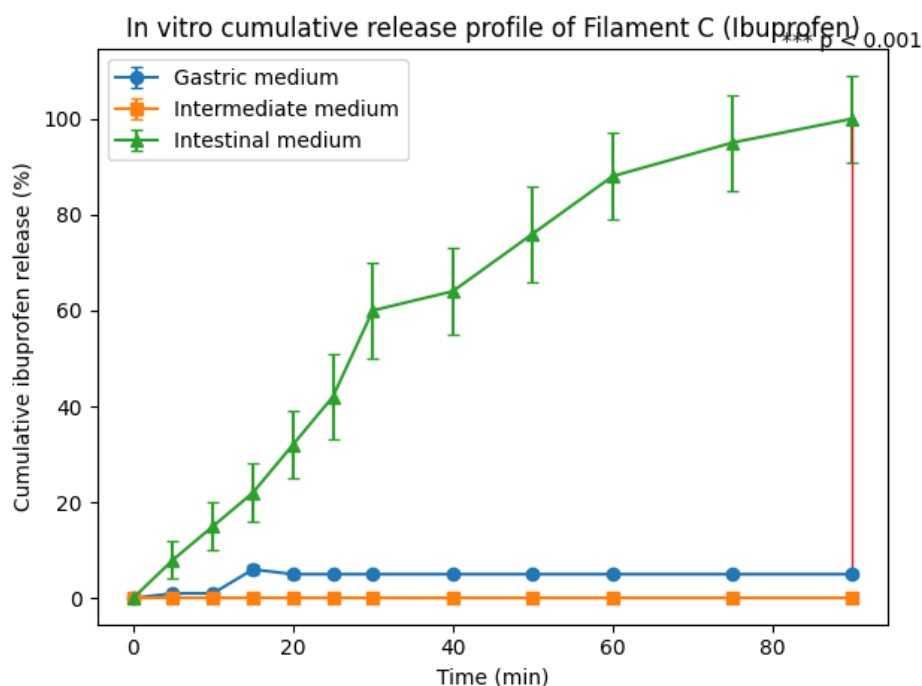


Figure 7: Drug release profile of Filament C in simulated gastric, intermediate, and intestinal media.

DISCUSSION

Fused deposition modeling (FDM) 3D printing represents a major technological advancement in pharmaceutical formulation, particularly in the context of personalized medicine and on-demand manufacturing of solid oral dosage forms^{24,28}. However, the implementation of this technology in pharmaceutical practice remains largely dependent on the availability of filaments specifically designed from pharmaceutical-grade excipients, capable of meeting both the mechanical requirements of the printing process and the biopharmaceutical performance criteria of medicinal products^{13,17}.

In the present study, an extensive exploratory phase comprising approximately forty formulation trials enabled the evaluation of various polymers commonly used in pharmaceutical technology. The results indicate that the majority of hydrophilic or highly swelling polymers, such as Kollidon® 30, hydroxypropyl methylcellulose (HPMC), croscopovidone, and croscarmellose sodium, did not allow the production of mechanically stable filaments compatible with 3D printing, as previously reported in the literature²⁵. Filaments derived from these polymers were found to be either too fragile, excessively adhesive, or insufficiently rigid, thereby limiting their applicability. These findings confirm that polymer selection is a critical factor in the development of pharmaceutical filaments intended for 3D printing (Prasad and Smyth, 2016).

In contrast, Eudragit® L100 distinguished itself by its ability to form continuous, homogeneous, and easily handleable filaments. This anionic acrylic polymer is already widely used in delayed-release solid oral dosage forms, which further reinforces its relevance for pharmaceutical 3D printing applications. The obtained

results confirm that Eudragit® L100 provides a favorable compromise between structural rigidity and processability, a prerequisite for filament extrusion, in agreement with previous studies on pH-dependent polymers^{21,27}.

The role of plasticizers proved to be central in tuning the mechanical properties of the filaments. Butyl phthalate imparted high rigidity to the filaments, as reflected by the elevated hardness values observed for Filament A. While this increased rigidity may represent an advantage for mechanical feeding in a 3D printer, it limits filament flexibility and may promote brittle behavior.

In contrast, the use of glycerin as a plasticizer resulted in more flexible filaments (Filaments B and C), which were better suited for continuous extrusion. The humectant properties of glycerin promote water retention within the polymeric matrix, thereby delaying filament hardening—an effect that has also been described in the context of pharmaceutical hot-melt extrusion^{12,18}.

The temporal evolution of hardness revealed a progressive increase in rigidity for all formulations, suggesting partial moisture loss during storage. This phenomenon was particularly pronounced for glycerin-plasticized filaments, highlighting the critical importance of storage conditions.

Tensile breakage tests further confirmed this observation: filaments stored at ambient temperature tended to become more brittle over time, whereas storage at 4 °C preserved filament elasticity and flexibility. Similar observations have been reported for other thermoplastic polymer systems used in 3D printing^{6,17}.

Incorporation of the active pharmaceutical ingredients also influenced the mechanical properties of the

filaments. Comparison between Filaments B and C suggests that the nature of the incorporated API can modulate filament rigidity, likely due to physicochemical interactions between the drug and the polymeric matrix. Such interactions have previously been described in polymer–drug systems produced by hot-melt extrusion and additive manufacturing ^{6,20,25}.

In vitro release studies represent a central component of this work. The obtained profiles show very limited release of the active pharmaceutical ingredients in simulated gastric and intermediate media, followed by a pronounced release in simulated intestinal medium. This behavior is directly related to the pH-dependent properties of Eudragit® L100, which is insoluble under acidic conditions and soluble at pH values above 6, a feature widely exploited for intestinal targeting ^{22,27}. The progressive dissolution of the filaments in the intestinal medium results in targeted drug release, confirming their suitability for delayed-release or site-specific delivery applications.

The complete dissolution of ibuprofen-loaded Filament C after approximately 1 h 40 min in simulated intestinal medium highlights the ability of this system to deliver poorly soluble active pharmaceutical ingredients under physiologically relevant conditions. These findings are consistent with literature data regarding the use of Eudragit® L100 and the optimization of drug release profiles through pharmaceutical 3D printing ^{9,10}.

Despite these encouraging results, several limitations should be acknowledged. The present study did not investigate parameters such as softening temperature, melt viscosity, biodegradability, or process scalability to an industrial level. Furthermore, the use of a semi-artisanal extrusion approach represents a preliminary step that will need to be replaced by controlled extrusion processes for industrial application, as recommended within emerging regulatory frameworks for pharmaceutical additive manufacturing ^{20,28,30}.

Overall, this work highlights the potential of 3D printing for the development of personalized solid oral dosage forms and emphasizes the relevance of Eudragit® L100 as a polymer of choice for the fabrication of functional pharmaceutical filaments. The results obtained provide a solid foundation for future investigations aimed at optimizing formulations, assessing long-term stability, and evaluating compatibility with industrial-scale 3D printing systems.

CONCLUSION

This study demonstrates the feasibility of developing pharmaceutical-grade filaments based on Eudragit® L100 suitable for fused deposition modeling (FDM) 3D printing. The results highlight the critical influence of plasticizer selection on filament mechanical performance, with glycerin providing optimal extrusion behavior and butyl phthalate increasing rigidity. The pH-dependent drug release profile of the printed matrices confirms their potential for delayed or targeted oral delivery. Overall, Eudragit® L100-based filaments represent a promising platform for the development of personalized solid dosage forms, while further

optimization and scale-up studies are required to support industrial and regulatory implementation.

Conflicts of Interest: The authors declare that they have no conflicts of interest.

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Data Availability: The data generated during this study are available from the corresponding author upon reasonable request

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