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3D-PRINTED PERSONALISED GASTRO-RETENTIVE MEDICINE: REVOLUTIONISING PEPTIC ULCER MANAGEMENT THROUGH ADVANCED MANUFACTURING AND CLINICAL INNOVATION

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Keywords:

3D printing, Gastro-retentive drug delivery systems, Fused deposition modelling, Personalised medicine, Peptic ulcer disease, Bioavailability

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ABSTRACT: Three-dimensional (3D) printing-based customised gastro-retentive drug delivery systems (GRDDS) present an innovative strategy for managing peptic ulcer disease by addressing the limitations of traditional dosage forms through precision manufacturing and patient-specific customisation. Conventional GRDDS exhibit significant variability in bioavailability due to differences in gastric physiology. This review highlights advanced 3D printing techniques, including fused deposition modelling (FDM), direct ink writing, inkjet printing, and binder jetting, which facilitate the development of floating systems with controlled lag times and extended floating durations. Systems produced using FDM significantly enhance relative bioavailability compared to immediate-release forms and notably reduce peak plasma concentration. Direct ink writing considerably reduces intersubject variability and allows for the incorporation of thermolabile active pharmaceutical ingredients (APIs). Furthermore, 3D printing enables the spatial separation of multiple APIs, dose individualisation based on factors such as body mass index and gastric motility, and cost-effective on-demand production with significantly lower manufacturing expenses. Pre-formulation studies employing thermogravimetric analysis, differential scanning calorimetry, Fourier-transform infrared spectroscopy, powder X-ray diffraction, and solubility profiling confirmed formulation stability and biocompatibility. Recent regulatory frameworks (UK MHRA, FDA/EMA draft guidelines) support point-of-care 3D printing in clinical settings. AI-driven quality control systems achieve high accuracy in defect detection. Despite challenges such as limited print resolution, thermal degradation risk, and shelf-life issues, interdisciplinary collaboration fosters the clinical translation of 3D printed GRDDS as personalised precision therapies to enhance treatment outcomes and patient quality of life.

INTRODUCTION: Peptic ulcer disease (PUD) is a widespread gastrointestinal condition characterised by damage to the stomach or duodenal lining caused by an imbalance between aggressive acid-peptic factors and protective mucosal mechanisms. It represents a significant global health problem and is associated with considerable clinical and economic burden worldwide. In the United States, PUD continues to contribute to substantial healthcare utilisation, including frequent clinical cases, hospitalisations, and treatment-related costs [1].

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The primary causes of PUD include *Helicobacter pylori* infection and prolonged use of nonsteroidal anti-inflammatory drugs (NSAIDs). *H. pylori* plays a dominant role in the pathogenesis of both gastric and duodenal ulcers, while NSAID-induced mucosal damage further contributes to disease

development [2]. Although the overall incidence and prevalence of PUD have declined in recent years due to improved sanitation, effective antimicrobial therapies, and more cautious NSAID use, the disease burden remains considerable, particularly among populations with lower socioeconomic status [3].

In response to the challenges associated with conventional therapy, pharmaceutical sciences have advanced the development of gastro-retentive drug delivery systems (GRDDS), which are designed to prolong drug retention in the stomach and enhance therapeutic outcomes [4]. These systems utilise various mechanisms, including floating systems, mucoadhesion, and high-density approaches, to ensure prolonged interaction with the gastric mucosa, thereby improving drug absorption and efficacy [5].

Furthermore, recent advancements in three-dimensional (3D) printing have revolutionised personalised medicine by enabling the fabrication of customised dosage forms tailored to individual patient needs [6]. This technology offers precise control over drug distribution, geometry, and release characteristics, allowing the on-demand production of complex gastro-retentive systems that are not achievable through conventional manufacturing techniques [7]. Additionally, 3D printing facilitates the separation of multiple active pharmaceutical ingredients, enables accurate dose individualisation based on patient-specific factors, and improves patient adherence through optimised design [8, 9].

The rationale for developing advanced gastro-retentive delivery systems for ulcer treatment is multifaceted. Prolonging gastric residence time ensures sustained drug availability at the target site, thereby supporting effective acid suppression and mucosal healing. These systems also help maintain more stable systemic drug levels, reducing dosing frequency and minimising peak-related adverse effects. They are particularly advantageous for drugs with narrow absorption windows or those affected by first-pass metabolism. Moreover, improved gastric retention enhances drug utilisation efficiency and may contribute to reduced treatment costs. The integration of 3D printing with gastro-retentive design as illustrated in **Fig. 1**, further enables personalised therapeutic approaches by accounting for individual variations in gastric physiology and patient-specific needs, ultimately improving clinical outcomes and quality of life [10, 11].

Literature Search and Selection Methodology: A comprehensive literature review as mentioned in **Table 1**, was conducted to identify relevant studies on gastro-retentive drug delivery systems (GRDDS) and the application of three-dimensional (3D) printing in the treatment of peptic ulcers. Systematic searches were performed in electronic databases, including PubMed, Scopus, Web of Science, and Google Scholar. The search strategy utilised combinations of keywords such as "gastro-retentive drug delivery systems," "GRDDS," "3D printing," "fused deposition modelling," "direct ink writing," "peptic ulcer disease," "Helicobacter pylori," and "personalised medicine," employing Boolean operators (AND, OR) to refine the search results. The literature search concentrated on articles published from 2010 to 2025 to encompass recent advancements in the field. Only publications in the English language were considered.

Inclusion and Exclusion Criteria:

Studies were included if they:

- Focused on GRDDS or 3D-printed drug delivery systems
- Reported formulation strategies, evaluation, or clinical relevance
- Were original research articles, review articles, or systematic studies

Studies were excluded if they:

- Were not related to gastro-retentive systems
- Lacked sufficient methodological detail
- Were conference abstracts, editorials, or non-peer-reviewed sources

Screening and Data Extraction: Initially, titles and abstracts were reviewed to identify pertinent articles. Subsequently, full-text screening was conducted for selected studies to verify eligibility. Relevant data were extracted and categorised

according to formulation strategies, technologies, and therapeutic outcomes.

Data Synthesis: The collected studies were analysed and synthesised qualitatively to summarise key advancements, challenges, and future perspectives in 3D-printed gastro-retentive drug delivery systems (GRDDS) for the management of peptic ulcer disease.

TABLE 1: SUMMARY OF KEY STUDIES ON 3D-PRINTED GRDDS

Author (year)	3D printing platform	Drug	Polymer used	Design type	Key performance metrics	Evidence level
Chai *et al.* (2017)	FDM	Domperidone	PLA	Hollow floating system	>24h floating, controlled release	*In-vitro*
Qian *et al.* (2022)	FDM	Verapamil HCL	PLA	Cylinder /hemisphere shapes	Shape- dependent release	*In-vitro*
Alqahtani *et al.* (2023)	FDM	Propranolol HCL	PVA	Gastro-retentive tablet	Improved gastric retention	*In-vitro*
Wang *et al.* (2024)	Binder jetting	Multiple APIs	Powder-based matrix	Multi-compartment tablet	High precision, multi-drug delivery	Review

Rationale for Drug Selection: The drug candidates discussed in this review can be broadly categorised based on their therapeutic application and relevance to gastro-retentive drug delivery systems (GRDDS).

Drugs such as famotidine and antibiotics, including amoxicillin and clarithromycin, represent primary anti-ulcer agents used in the management of peptic ulcer disease and *Helicobacter pylori* infection. These serve as the principal focus for the application of GRDDS in this review. In contrast, other drugs such as metformin, propranolol, domperidone, verapamil, and sildenafil are included as representative model drugs frequently reported in the literature to demonstrate the feasibility and versatility of GRDDS and 3D printing technologies.

These examples highlight formulation strategies and design principles rather than specific anti-ulcer applications.

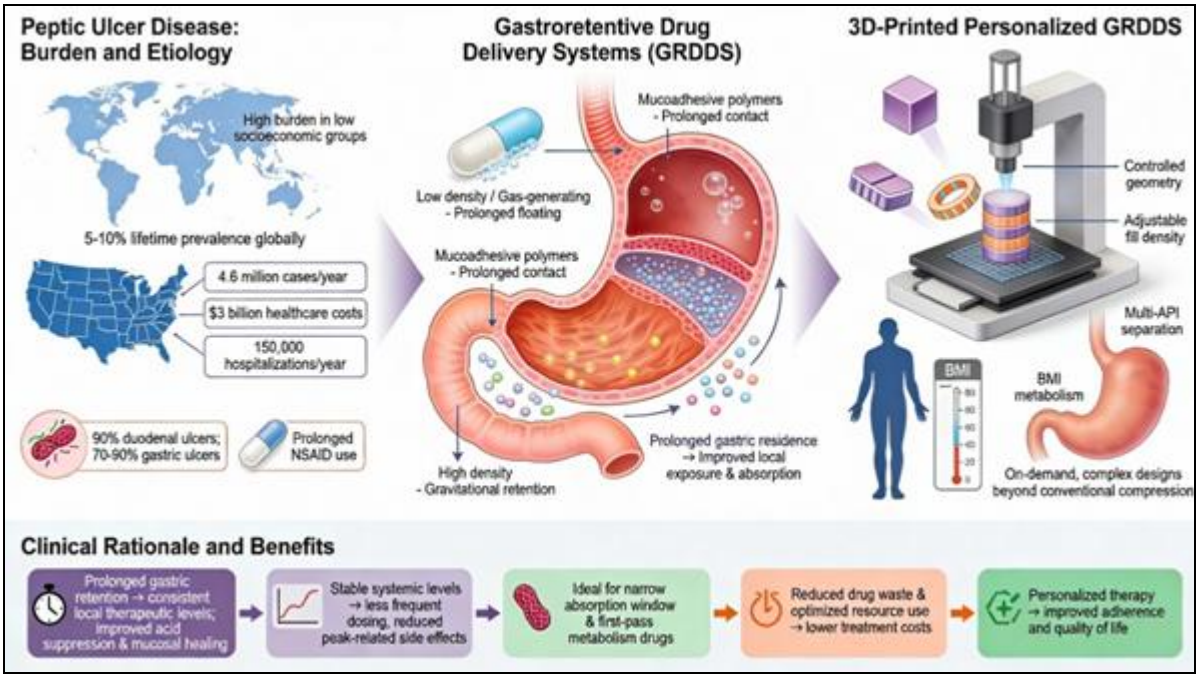

FIG. 1: RATIONALE AND EVOLUTION OF 3D-PRINTED GASTRO-RETENTIVE DRUG DELIVERY SYSTEMS IN PEPTIC ULCER MANAGEMENT

Fundamental Principles of Gastro-retentive Drug Delivery Systems (GRDDS) Table 2 [12-14]:

TABLE 2: FUNDAMENTAL PRINCIPLES AND MATERIAL SELECTION FOR VARIOUS GASTRO-RETENTIVE TECHNOLOGIES

Gastro-retentive drug delivery system category	Mechanism of action	Materials	Retention time
Floating/Low-Density Systems (Buoyancy and hydrodynamic equilibrium)	Formulation maintains density < 1 g/cm³ by incorporating gas-generating agents or hydrophilic polymers; the system floats on gastric contents, preventing gastric emptying	Sodium bicarbonate, calcium carbonate, Hydroxypropyl methylcellulose (HPMC), polyethylene oxide, ethyl cellulose, sodium alginate	Exhibits short floating lag time (FLT) and prolonged total floating time (TFT)
Mucoadhesive/Bio-adhesive Systems (Adhesion via polymer-mucus interactions)	Mucoadhesive polymers containing hydrogen bond donors/acceptors form reversible bonds with the mucus layer, creating prolonged intimate contact with the gastric epithelium	Chitosan, polyacrylic acid (Carbopol), sodium hyaluronate, cellulose derivatives, polycarbophil, lectins	Retention is dependent on mucoadhesive strength and mucus interaction
High-Density/Sinking Systems (Density-based gravitational retention)	Formulation density increased to > 1.5 g/cm³ (heavier than gastric content); system sinks to fundus and remains there due to gravity	Barium sulfate, zinc oxide, iron oxide, titanium dioxide, bismuth subcarbonate	Retention depends on density and gastric motility conditions
Swelling/Expanding Systems (Size expansion to prevent pyloric passage)	Hydrophilic polymers absorb gastric fluid and swell to several times original size (reaching 15-25 mm diameter); enlarged formulation cannot pass through pyloric sphincter (7-9 mm diameter)	Super porous hydrogels, cross-linked polyacrylate, chitosan, Polyvinyl alcohol (PVA), Hydroxypropyl methylcellulose (HPMC), calcium alginate	Retention based on swelling behaviour and structural integrity
Raft-Forming Systems (Foam/raft formation with gastric contents)	Polymers (alginates, xanthan gum) form viscous gel layer that traps gas and floats on gastric contents, creating protective barrier (raft) between drug and gastric acid	Sodium alginate, calcium carbonate, xanthan gum, gelatin	Retention based on gel formation and gastric content interaction

Critical Challenges of Traditional GRDDS: Rationale for Technological Advancement:

Core Challenges: Conventional gastro-retentive drug delivery systems (GRDDS) rely on standardised methodologies that inadequately address substantial physiological variability among individuals and the inherent limitations of traditional manufacturing processes. This fundamental misalignment between formulation design and biological realities results in a range of clinical and production challenges, underscoring the urgent need for technological advancement.

Gastric Emptying Variability and Bioavailability Disparities: The process of gastric emptying is characterised by considerable variability, influenced by factors such as gastric motility, metabolic status, and pathological conditions. This variability has a substantial impact on gastric residence time and drug absorption, resulting in inconsistent bioavailability and therapeutic outcomes. Conventional gastro-retentive drug delivery systems (GRDDS), typically designed based on average physiological conditions, fail to account for such interindividual differences. Consequently, these systems may demonstrate unpredictable performance due to premature clearance or extended retention, ultimately affecting drug release and absorption[15].

Manufacturing Complexity and Batch Inconsistency: Traditional methods for producing gastro-retentive drug delivery systems (GRDDS) often face obstacles such as complex formulations, limited scalability, and inconsistent product performance. The use of natural polymers can result in variability in essential quality attributes like swelling behaviour, mechanical strength, and drug release. On the other hand, synthetic polymers, though more consistent, may present difficulties in terms of processability and regulatory approval. Additionally, conventional techniques for integrating gas-generating agents require precise optimisation to achieve dependable buoyancy and controlled drug release, with even slight changes in formulation or processing potentially affecting system performance significantly. These challenges highlight the need for more flexible and precise manufacturing strategies [16].

Physiological State Dependency and Dietary Requirements: Conventional gastro-retentive drug delivery systems (GRDDS), especially those using flotation mechanisms, rely heavily on fed-state conditions. High-calorie, fat-rich meals can extend gastric retention by 4-10 h compared to fasting, turning the stomach from a rapid-transit organ, with "migrating motor complex" (MMC)-driven emptying every 90-120 min, into one with prolonged retention. This creates a practical issue: patients must follow specific diets for effective drug delivery, requiring high-protein and high-fat meals with medications. This dependency challenges compliance, especially for those with dietary restrictions, like the elderly or those with gastric disorders. It also introduces variables that affect therapeutic consistency. Traditional GRDDS face challenges during fasting. In the inter-digestive phase, the "pyloric sphincter" expands to about 19 mm, and the "housekeeper wave" (Phase III of the MMC) causes strong gastric contractions every 90-120 minutes, expelling dosage forms regardless of design. Thus, conventional GRDDS offer limited benefits to patients who can't eat large meals, such as post-surgery patients or those with reduced appetite, limiting clinical applications [17].

Gastric pH Variability and Unpredictable Dissolution Profiles: The gastric environment is marked by fluctuating pH levels that can greatly affect drug dissolution and the behaviour of polymers. These variations may impact drug solubility, polymer expansion, and the integrity of the matrix, resulting in inconsistencies in drug release and the overall performance of the formulation. Traditional gastro-retentive drug delivery systems (GRDDS), which are generally tailored for a specific pH range, often show erratic behaviour under these changing physiological conditions.

This can lead to unpredictable drug release patterns and a weakened *in-vitro in-vivo* correlation. Moreover, pH-dependent shifts in drug solubility might encourage occurrences like supersaturation and precipitation, further adding to the variability in bioavailability. As a result, forecasting *in-vivo* performance based on standard *in-vitro* testing conditions becomes difficult, creating uncertainty in formulation development and therapeutic effectiveness [18].

Severe Limitations in Combination Therapy Formulations: The management of peptic ulcer disease frequently necessitates the use of a combination of pharmacological agents that operate through distinct mechanisms. The effective treatment of Helicobacter pylori infections depends on the coordinated administration of acid-reducing medications and antibiotics, each of which requires specific release conditions to optimize therapeutic outcomes [19]. Traditional gastro-retentive drug delivery systems (GRDDS) face considerable challenges in accommodating such complex multi-drug regimens. These systems lack the flexibility to incorporate multiple active pharmaceutical ingredients (APIs) with diverse physicochemical properties and tailored release profiles within a single dosage form, thereby complicating synchronized and controlled drug delivery [20]. Moreover, fixed-dose combination formulations offer limited adaptability, as modifying one component often necessitates the reformulation of the entire system. Issues related to drug–drug and drug–excipient compatibility can further affect formulation stability, dissolution behavior, and overall bioavailability, resulting in inconsistencies in therapeutic efficacy. Additionally, ensuring effective drug exposure at both local and systemic levels introduces another layer of complexity to formulation design, which conventional GRDDS often struggle to address efficiently. These limitations highlight the challenges in developing reliable gastro-retentive systems for combination therapy [21].

3D printing offers a practical solution to these challenges by enabling the fabrication of multi-compartmental dosage forms with precise spatial separation of active pharmaceutical ingredients. This approach minimises drug–drug and drug–excipient interactions, thereby improving formulation stability and compatibility. In addition, 3D printing technologies such as fused deposition modelling and inkjet printing allow the design of layered or compartmentalised systems that can deliver multiple drugs with distinct and controlled release profiles. For example, polypill-based 3D-printed systems have demonstrated the ability to incorporate multiple drugs within a single dosage form while maintaining independent release characteristics. Such design flexibility enhances the

effectiveness of combination therapy and supports improved therapeutic outcomes [22].

Rationale for Technological Advancement: Primary constraints, including physiological unpredictability, limited manufacturing adaptability, food dependence, geometric limitations, and regulatory inadequacies, underscore the urgent need for personalised 3D-printed GRDDS. 3D printing technology enables patient-specific dosages tailored to an individual's BMI, metabolism, and gastric physiology; refines complex geometries to enhance muco-adhesion and peristalsis resistance; spatially separates multiple APIs for concurrent delivery of complementary agents; and allows rapid, on-demand production at reduced costs. By addressing individual variability through customised designs, enabling complex formulation structures unattainable by traditional methods, and supporting swift prototyping and manufacturing, 3D-printed personalised GRDDS represent a significant advancement in precision medicine. This innovation ensures predictable therapeutic outcomes, improves patient adherence through optimised design, enhances clinical effectiveness with customised formulations, and accelerates regulatory approval using a data-driven quality-by-design approach. Ultimately, it transforms the management of peptic ulcer disease and broader gastrointestinal treatments into evidence-based, individualised therapies that maximise therapeutic benefits while minimising side effects and drug wastage [23].

3D Printing Technologies for GRDDS Fabrication:

Fused Deposition Modelling (FDM): Fused deposition modelling (FDM) is an advanced additive manufacturing technique that facilitates the creation of customised gastro-retentive drug delivery systems (GRDDS) with remarkable precision, surpassing traditional tablet compression methods. This process entails the thermal extrusion of polymer filaments, which are deposited sequentially in layers and cooled to form intricate three-dimensional structures as shown in **Fig. 2**, left panel [24]. The best method combines hot-melt extrusion (HME) with FDM. In this process, drug-filled filaments are made by mixing active pharmaceutical ingredients (API) with safe plastic materials like polylactic acid (PLA), polyvinyl alcohol (PVA), and hydroxypropyl cellulose (HPC). This is done at temperatures higher than the polymer's softening point but lower than the point where it breaks down [25]. These filaments were subsequently introduced into an FDM printer, heated to a temperature range of 180–240 °C, and extruded layer-by-layer onto a heated build platform, adhering to computer-aided design (CAD) instructions. As each layer is deposited and cooled, it solidifies through hydrogen bonding and progressively forms a final three-dimensional structure. Critical process parameters, including nozzle temperature, infill density (0-100%, typically 0-50% for floating systems), layer height (0.1-0.4 mm), and print speed (30-80 mm/min), directly influence the characteristics of the resulting GRDDS [26].

Operational Behaviour of FDM-Based GRDDS in GIT: FDM-printed GRDDS with an infill density ranging from 0% to 25% achieved densities between 1.004 and 1.010 g/mL, corresponding to the density of gastric fluid, thereby facilitating flotation in the stomach through hydrodynamic equilibrium. The internal chambers, filled with air, trap gases that counterbalance the gravitational and peristaltic forces that would otherwise propel the gastric contents into the duodenum [26]. Notably, FDM-printed formulations demonstrated a floating lag time (FLT) of 0.5-2 h, significantly shorter than the 4–6 h observed in conventional floating systems, thus preventing premature gastric clearance before flotation. The total floating time (TFT) for PLA-based systems exceeded 24 h, whereas PVA-based formulations floated for 3-10 h, both surpassing the typical gastric residence time of 3-6 h [27].

Drug release is facilitated through strategically positioned release windows that are openings measuring 2-4 mm. These windows regulate the ingress of gastric fluids into the drug's internal compartment, thereby modulating the release kinetics *via* Fickian diffusion driven by concentration gradients and erosion-mediated release, which involves gradual degradation of the polymer matrix [28]. The geometric flexibility of FDM allows for the creation of unconventional shapes, such as ellipsoids, stars, and custom designs, exceeding 7-9 mm in size, which are intended to prevent passage through the pyloric

sphincter. Additionally, complex surface textures enhance frictional resistance against peristaltic movements [29].

Direct Ink Writing (DIW): Direct Ink Writing (DIW) is a three-dimensional printing technique that uses extrusion to achieve remarkable precision and material versatility, making it particularly suitable for fabricating customised gastro-retentive drug delivery systems (GRDDS) [30]. This method surpasses both traditional manufacturing processes and other three-dimensional (3D) printing technologies. DIW operates by employing controlled pneumatic or piston-driven extrusion to propel highly viscous inks, such as hydrogels, polymer solutions, or suspensions, through precision nozzles onto a moving XY stage, thereby depositing the layers along the Z-axis. Unlike fused deposition modelling (FDM), which employs thermal extrusion and limits drug compatibility to heat-resistant substances, DIW functions at ambient temperature, thus facilitating the incorporation of thermolabile active pharmaceutical ingredients (APIs), such as antibiotics for *Helicobacter pylori* eradication and heat-sensitive vitamins, without degradation. This process requires precise pressure control and careful selection of the nozzle diameter to achieve feature sizes ranging from 100 nm to 1000μm, enabling the creation of complex geometries with controlled porosity, internal channels, and release windows [31]. Critical parameters, including viscosity, nozzle diameter, deposition rate, and stage speed, directly influence the structural integrity, resolution, and drug release kinetics. Following the deposition of each layer, the Z-stage was elevated by one slice thickness, and new ink was applied, progressively constructing the final three-dimensional structure. For GRDDS applications, DIW facilitates the production of hollow multi-compartment structures with precisely positioned release windows that regulate gastric fluid penetration, as shown in **Fig. 2**, middle panel [32].

Operational Behaviour of DIW-Based GRDDS in GIT: Direct ink writing (DIW) of gastro-retentive drug delivery systems (GRDDS) with infill densities ranging from 0 to 30% achieves rapid floating lag times of 0.5–1.5 h, facilitating immediate buoyancy before gastric clearance. The internal voids and strategically designed channels support hydrogel-based sustained release, wherein water absorption initiates gradual polymer swelling and drug diffusion over 4–8 h. For the treatment of peptic ulcer disease, DIW forms bilayer structures with outer hydrogel layers that provide buoyancy and rapid initial acid suppression, while the inner compartments ensure the sustained release of famotidine, thereby maintaining therapeutic levels during gastric residence. The room-temperature fabrication process preserves the thermolabile properties of amoxicillin and clarithromycin for Helicobacter pylori combination therapy, resulting in a 1.8–2.5 fold increase in relative bioavailability compared with immediate-release tablets [33].

The precision of DIW allows for the creation of mucoadhesive texture patterns that enhance interactions with the gastric mucosa, reducing inter-subject variability from 20–40% (in conventional GRDDS) to less than 10% (in DIW-personalised systems). The room-temperature advantage of fused deposition modelling (FDM) enables the simultaneous multi-material printing of incompatible components (acid-sensitive and acid-stable active pharmaceutical ingredients) in spatially separated compartments, thereby transforming the delivery of combination therapy for peptic ulcer disease [34].

Inkjet and Binder Jetting: Inkjet and binder jetting are precise 3D printing methodologies that facilitate the creation of customised gastro-retentive drug delivery systems (GRDDS) with high accuracy, minimal waste, and pharmaceutical-grade adaptability. Inkjet printing functions by selectively depositing liquid droplets (ranging from 10 to 1000 picolitres per drop) containing dissolved drug-polymer solutions onto a substrate, where they solidify through solvent evaporation or photopolymerization under standard conditions[35]. In contrast, binder jetting uses a powder-based technique, wherein an atomised binder liquid is selectively applied to a powder bed containing pre-mixed drug particles and excipients, with each layer being sequentially constructed and solidified through controlled binder penetration and evaporation. Both techniques present significant advantages: operation at room temperature (preventing thermal degradation of APIs), layer-by-layer precision for the fabrication of complex internal structures, high spatial resolution, and the

ability to incorporate multiple active pharmaceutical ingredients with independently controlled release profiles within a single dosage form, as shown in **Fig. 2**, right panel [36]. Process parameters, such as droplet velocity, jetting frequency, binder concentration, and powder particle size, are critical in determining the structural properties, porosity, and drug release kinetics of the resulting GRDDS [37].

Operational Behaviour of IJB -Based GRDDS in GIT: Both inkjet and binder-jetting gastro-retentive drug delivery systems (GRDDS) exhibited rapid floating lag times of 0.5–1.5h by optimising porosity levels, facilitating immediate flotation in gastric fluid. The high porosity of these methods, in contrast to traditional compressed tablets, enhances rapid water absorption and gradual polymer hydration, resulting in sustained drug release over 4–10h *via* Fickian diffusion and matrix erosion [38]. In the treatment of peptic ulcer disease, inkjet printing produces multi-zone tablets, with outer zones delivering fast-release famotidine for immediate acid reduction, while core zones release long-acting components to ensure ongoing therapeutic effects [39]. The powder-based binder jetting technique uniquely permits the simultaneous inclusion of acid-sensitive antibiotics (amoxicillin and clarithromycin) and acid-stable H_2-antagonists in separate chambers without thermal damage, resulting in relative bioavailability enhancements of 1.5–2.8 times compared to that of immediate-release tablets. Both technologies support personalised dosing with patient-specific shapes and infill densities, reducing intersubject bioavailability variability from 20–40% (traditional GRDDS) to less than 12% (inkjet/binder-jetted personalised formulations) [40]. The high precision and reduced waste (compared to conventional tablet compression) lower manufacturing costs by 30–50%, rendering personalised GRDDS production economically viable to meet individual patient requirements [41].

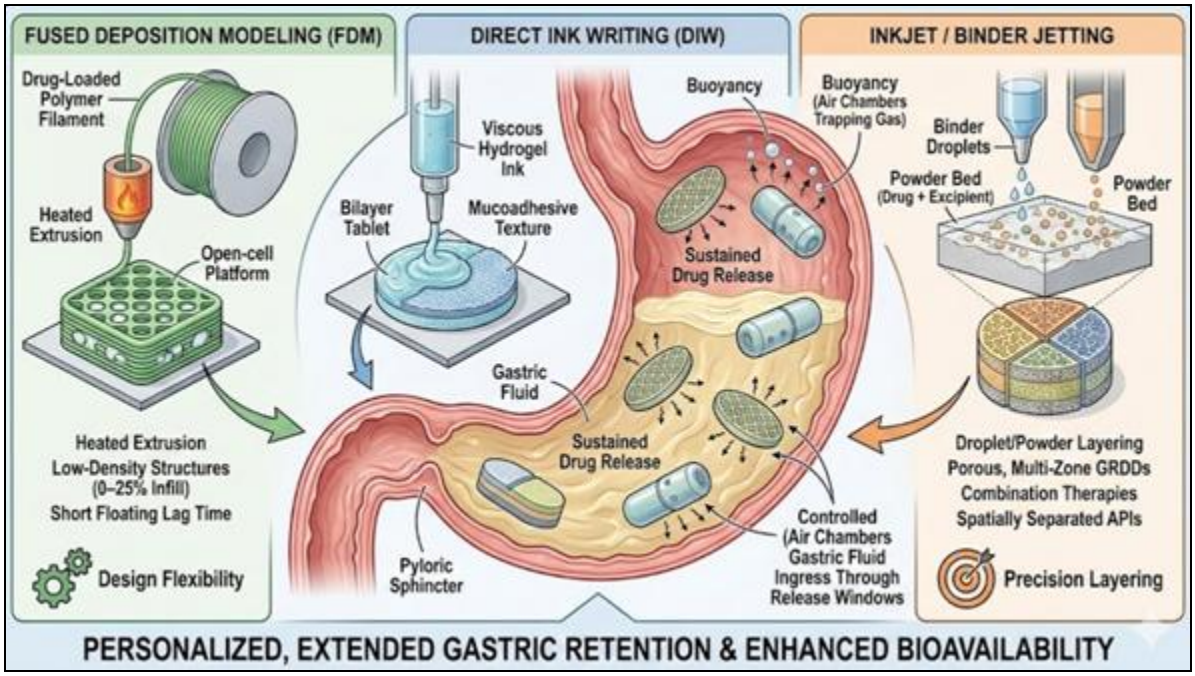

FIG. 2: 3D PRINTING TECHNOLOGIES (FDM, DIW, AND INKJET/BINDER JETTING) FOR THE FABRICATION OF PERSONALISED GASTRO-RETENTIVE DRUG DELIVERY SYSTEMS

A Comparative Overview of Different 3D Printing Technologies used in Gastro-Retentive Drug Delivery Systems is Presented in Table 3 [42]:

TABLE 3: COMPARATIVE ANALYSIS OF 3D PRINTING TECHNOLOGIES IN GRDDS

Technology	Advantages	Limitations	Suitable polymers	Temperature conditions	Drug suitability	GRDDS outcomes
FDM (fused deposition modelling)	Simple, cost-effective, good mechanical	High temperature may degrade	Polyvinyl Alcohol, Polylactic Acid,	High temperature required	Thermostable	Good floating, sustains release

	strength, controlled release	drugs	Hydroxypropyl Methylcellulose			
DIW (direct ink writing)	Suitable for thermolabile drugs, flexible formulations	Requires viscosity optimisation	Hydrogels, alginate, gelatin	Room/low temperature	Thermosensitive	Controlled release, good gel strength
Inject printing	High precision, accurate dosing	Limited viscosity range, low drug loading	Polymer solutions	Low temperature	Potent	Fast disintegration, rapid release
Binder jetting	No heat required, suitable for multiple drugs	Poor mechanical strength	Powder-based polymers	Ambient conditions	Heat-sensitive	Porous structure, fast release

Formulation Strategies and Materials Selection for 3D-Printed Gastro-Retentive Drug Delivery Systems: Foundational design principles are employed in the development of three-dimensional printed gastro-retentive drug delivery systems (GRDDS) to harness the distinct advantages of additive manufacturing. The predominant strategy involves the creation of hollow or dual-compartment structures [43]. An external chamber, typically filled with air and possessing a density ranging from 0.2 to 0.6g/cm³, imparts buoyancy. Concurrently, the internal compartment containing the drug facilitates the independent modulation of the release kinetics. Adjusting the infill density, which ranges from 0 to 100%, is pivotal for controlling porosity, the time required to achieve flotation, and the duration of drug release. Internal mesh configurations, such as linear, hexagonal, and diamond patterns, are used to optimise water penetration pathways without altering the polymer composition [44]. Bilayer or multilayer designs establish distinct zones for immediate and cores intended for sustained release. The strategic placement of release windows and sealing techniques ensures immediate flotation and controlled ingress of gastric fluid as mentioned in **Table 4** [45]**.**

TABLE 4: DESIGN STRATEGIES AND PERFORMANCE CHARACTERISTICS OF 3D-PRINTED GRDDS

Design Strategy	Structural Configuration	Infill Density Range	Buoyancy behaviour	Drug Release Profile	Clinical advantage
Single-Compartment Floating	Hollow cylinder with sealed perimeter	Low infill to reduce density	Rapid onset of buoyancy	Sustained drug release	Simple design, easy manufacturing, cost-effective
Dual-Compartment Structure	Outer buoyant chamber with internal drug-loaded core	Differential infill between compartments	Immediate and stable floating	Independent and controlled release from compartments	Improved control over floating and release behaviour
Bilayer Design	Immediate-release outer layer with sustained-release inner core	High infill outer layer with lower infill core	Quick floating initiation	Biphasic release (initial burst followed by sustained release)	Suitable for combination therapy and improved therapeutic response

Material Requirements: The successful development of three-dimensional (3D) printed pharmaceutical dosage forms necessitates the selection of materials with specific physicochemical and biological properties to ensure the efficient production, stability, biocompatibility, and therapeutic efficacy of the dosage forms [46]. The polymers employed in these formulations must exhibit sufficient thermal stability to withstand the processing temperatures characteristic of 3D printing methods, such as fused deposition modelling (FDM), which typically ranges from 160–220 °C, without compromising the active pharmaceutical ingredients [47]. Commonly utilised polymers include polyvinyl alcohol (PVA), polylactic acid (PLA), polyethylene glycol (PEG), and hydroxypropyl methyl cellulose (HPMC), which are selected for their capacity to maintain structural integrity during hot-melt extrusion and dissolve appropriately under physiological conditions [48]. These materials must be biocompatible and safe for oral consumption,

adhering to regulatory standards or recognised as nontoxic and nonimmunogenic within the gastrointestinal tract [49]. Drug compatibility is crucial to prevent degradation during printing, avoid adverse drug-polymer interactions that could diminish efficacy, and facilitate a controlled drug release tailored to the delivery system. Processability factors, such as viscosity, melt flow, and printability, must support the formation of filaments or inks that are compatible with the printing technology [50].

The mechanical properties of printed dosage forms should provide sufficient hardness, flexibility, and durability to withstand manufacturing, handling, and storage, maintaining their integrity throughout their shelf life and their use [51]. Additionally, pharmaceutically acceptable excipients such as plasticisers, surfactants, and colourants are incorporated to enhance processing and functional performance without compromising safety or effectiveness [52].

Pre-formulation and Characterisation Studies: Pre-formulation studies are integral to the initial phases of developing three-dimensional (3D)-printed gastro-retentive drug delivery systems (GRDDS). These investigations evaluate the physicochemical compatibility, thermal stability, and production feasibility of all formulation components before the commencement of intricate 3D printing processes. Through these comprehensive assessments, it is ensured that active pharmaceutical ingredients (APIs), polymeric carriers, plasticisers, and other excipients maintain their chemical and physical stability during hot-melt extrusion and fused deposition modelling (FDM) manufacturing processes at elevated temperatures (150–210°C). Furthermore, these studies confirmed the absence of deleterious interactions among the components that could potentially undermine drug efficacy, formulation integrity, or *in-vivo* performance.

Thermal Stability: Thermal analysis is widely used to evaluate the stability and compatibility of drug–polymer systems. Techniques such as differential scanning calorimetry and thermogravimetric analysis help identify changes in thermal behaviour, including melting transitions and degradation patterns. The absence of significant shifts or additional peaks is generally considered indicative of compatibility and thermal stability of the formulation components [53].

Differential Scanning Calorimetry (DSC): Differential scanning calorimetry (DSC) is extensively utilised to assess the thermal behaviour and compatibility of drug–polymer systems in formulation development. It offers insights into critical thermal transitions, such as the melting behaviour of the drug and the glass transition characteristics of polymers, which are essential for understanding formulation stability. In the literature, DSC is predominantly employed to identify potential interactions between the drug and excipients by comparing the thermal profiles of individual components with those of their mixtures. The retention of characteristic thermal peaks without significant shifts or the absence of unexpected transitions is generally considered indicative of compatibility. Furthermore, changes in peak intensity or the disappearance of crystalline melting peaks may suggest alterations in the physical state of the drug, such as partial amorphisation or dispersion within the polymer matrix. Overall, stable and reproducible thermal behaviour without evidence of degradation or undesirable transitions is regarded as a key acceptance criterion in formulation design.

Fourier-Transform Infrared Spectroscopy (FTIR): Fourier-transform infrared spectroscopy (FTIR) is extensively employed to assess the chemical compatibility between active pharmaceutical ingredients (APIs) and polymer excipients during formulation development. This technique offers insights into potential molecular interactions by identifying characteristic functional group vibrations and monitoring alterations in the infrared spectra. In the literature, compatible drug–polymer combinations are typically indicated by the preservation of characteristic API peaks without significant shifts, broadening, or disappearance. Conversely, notable spectral changes may suggest interactions such as hydrogen bonding or complex formation, which could impact stability, solubility, or drug release. Overall, the maintenance of spectral integrity in drug–polymer mixtures and final dosage forms is considered a critical

acceptance criterion for ensuring chemical compatibility and formulation stability [54].

Solubility Profile: Evaluating drug solubility across physiological pH conditions is a crucial pre-formulation parameter in the development of gastro-retentive drug delivery systems (GRDDS). Solubility behaviour directly affects drug dissolution, absorption, and overall formulation performance during gastric retention and subsequent intestinal transit. Solubility assessment aids in determining the suitability of a drug candidate for GRDDS design and guides the selection of appropriate polymer matrices and release mechanisms.

Drugs exhibiting higher solubility in acidic gastric conditions and comparatively lower solubility at intestinal pH are considered more suitable for gastro-retentive approaches, as prolonged gastric residence enhances drug dissolution and absorption. Consistent solubility behaviour across relevant pH conditions, along with the absence of precipitation or instability, is regarded as an essential acceptance criterion. These attributes contribute to predictable drug release and improved bioavailability in GRDDS.

Powder X-Ray Diffraction (PXRD): Powder X-ray diffraction (PXRD) is an essential analytical technique employed to assess the solid-state properties of drug substances and formulations. It yields vital information regarding the crystalline or amorphous nature of the active pharmaceutical ingredient (API), which directly affects solubility, dissolution behaviour, and overall formulation performance. PXRD analysis is predominantly utilised to identify changes in crystallinity following formulation processing. The presence of distinct diffraction peaks signifies a crystalline structure, whereas their reduction or absence indicates partial or complete amorphization of the drug within the polymer matrix. Such transformations are often linked to enhanced dissolution behaviour but may also influence physical and chemical stability. A balanced solid-state profile, wherein sufficient amorphization improves dissolution without compromising stability, is considered a critical acceptance criterion. Consequently, PXRD plays a pivotal role in optimising formulation design by ensuring appropriate solid-state characteristics for reliable drug performance.

Filament Characterization and Mechanical Evaluation: Filament characterisation is a pivotal process in the development of 3D-printed gastro-retentive drug delivery systems (GRDDS), as it assesses the material's suitability for effective printing and subsequent performance. Mechanical properties, including flexibility, strength, and structural integrity, are crucial for ensuring smooth extrusion and consistent fabrication of dosage forms. The evaluation of filament properties emphasises maintaining uniformity in physical dimensions and ensuring sufficient mechanical robustness to withstand processing without breakage or deformation. Furthermore, resistance to the gastric environment is a significant consideration, as filament-derived dosage forms must maintain structural integrity under acidic conditions to achieve effective gastric retention and controlled drug release. Filaments exhibiting appropriate mechanical strength, flexibility, and environmental stability are deemed suitable for further optimisation and formulation development. These attributes are essential acceptance criteria for ensuring reproducible printing performance and reliable therapeutic outcomes in GRDDS [55].

Preclinical Studies: Preclinical research serves as a crucial link between initial formulation characterisation and the start of human clinical trials. It thoroughly assesses the safety, biological compatibility, pharmacokinetics, and therapeutic effectiveness of advanced 3D-printed gastro-retentive drug delivery systems (GRDDS) in controlled laboratory and animal-model settings [56]. These detailed studies provide proof-of-concept that the extended gastric retention enabled by 3D printing leads to significant enhancements in drug bioavailability, therapeutic effectiveness, and safety profiles compared to traditional immediate-release formulations. Preclinical evaluation involves four interconnected investigative methods: in vitro biocompatibility tests to ensure cellular safety, pharmacokinetic studies in animal models to track changes in drug absorption and plasma levels, advanced imaging techniques to observe actual gastric retention and tablet positioning, and histopathological analysis to verify gastrointestinal

safety and the absence of harmful tissue reactions [57].

***In-vitro* Biocompatibility Assessment:** *In-vitro* assessment of biocompatibility is crucial to ensure that the constituents of a formulation, including polymers, excipients, and active pharmaceutical ingredients, do not elicit cytotoxic or inflammatory responses in gastrointestinal tissues. This evaluation constitutes a fundamental preliminary step prior to advancing to *in-vivo* experiments. Typically, biocompatibility is evaluated using cell culture models that replicate the integrity of intestinal epithelial cells and immune responses. Key considerations include cell viability, membrane integrity, and the potential for inflammatory activation following exposure to formulation extracts. A formulation is deemed biocompatible if it sustains acceptable cell viability relative to untreated controls and does not induce significant cellular damage or adverse reactions. Conversely, reduced viability or indications of cytotoxicity imply that the formulation components are incompatible and necessitate further refinement [58].

Pharmacokinetic Evaluation: Pharmacokinetic evaluation is crucial for assessing the in vivo performance of gastro-retentive drug delivery systems (GRDDS) and their capacity to enhance drug absorption and bioavailability. Parameters such as maximum plasma concentration (Cmax), time to reach maximum concentration (Tmax), and area under the plasma concentration–time curve (Area Under Curve) are commonly employed to characterise the rate and extent of drug absorption. The AUC represents the total systemic exposure to the drug, while Cmax and Tmax provide insights into the absorption profile. Additional parameters, including elimination half-life ($t_{1/2}$), elimination rate constant (Kel), volume of distribution (Vd), and clearance (CL), are utilised to further describe drug disposition and elimination behaviour. Relative bioavailability serves as an important comparative measure to evaluate the performance of GRDDS in relation to conventional formulations.

It is expressed as:

$$\text{Relative Bioavailability (RBA, \%)} = (\text{AUC\_test} / \text{AUC\_reference}) \times (\text{Dose\_reference} / \text{Dose\_test}) \times 100$$

Where, AUC_test and AUC_reference represent the area under the concentration–time curve of the test (GRDDS) and reference formulations, respectively, and Dose test and Dose reference correspond to the administered doses of each formulation.

Enhanced area under the curve (AUC), reduced peak fluctuations, and prolonged time to maximum concentration (Tmax) typically signify improved gastric retention and sustained drug release behaviour. These pharmacokinetic characteristics contribute to enhanced therapeutic efficacy and decreased dosing frequency. Consistent and reproducible pharmacokinetic profiles are regarded as essential criteria for assessing the effectiveness and reliability of gastro-retentive drug delivery systems (GRDDS) [59].

Plasma Drug Quantification: Plasma drug quantification employs validated methodologies, such as high-performance liquid chromatography (HPLC) or liquid chromatography-tandem mass spectrometry (LC-MS/MS). These techniques offer sensitivity levels, specifically the lower limit of quantification (LLOQ) and lower limit of detection (LLOD), that are at least 5–10 times lower than the anticipated minimum plasma concentrations. This ensured precise measurements across the entire concentration-time curve. The validation of these methods confirmed analytical accuracy, with a recovery rate of 80–120% for spiked samples, precision characterised by an intra-assay relative standard deviation of ≤15% and inter-assay variation of ≤15%, and the absence of matrix effects or analyte instability during storage [60].

Gamma Scintigraphy: Gamma scintigraphy is a prevalent non-invasive imaging modality employed to evaluate the *in-vivo* behaviour of gastro-retentive drug delivery systems (GRDDS). This technique facilitates real-time visualisation of dosage form positioning, buoyancy, and gastric residence, thereby elucidating the correlation between *in-vitro* floating behaviour and *in-vivo* gastric retention. It is primarily utilised to monitor the movement and localisation of dosage forms within the gastrointestinal tract and to assess the duration of gastric retention. The imaging data yield valuable insights into the site-specific behaviour of GRDDS, including their capacity to remain in the stomach

and resist premature transit. Prolonged and consistent gastric retention, as observed through imaging, is regarded as a critical indicator of successful gastro-retentive performance. However, retention behaviour may vary based on formulation design, physiological conditions, and study models, necessitating cautious interpretation [61].

Magnetic Resonance Imaging (MRI): Magnetic resonance imaging (MRI) is a non-invasive technique that offers detailed visualisation of dosage form structure and behaviour within the gastrointestinal environment without employing ionising radiation. It is particularly advantageous for assessing morphological changes such as swelling, hydration, and structural integrity of gastro-retentive drug delivery systems (GRDDS) during gastric residence. MRI facilitates the evaluation of dynamic changes in dosage form size, shape, and positioning within various regions of the stomach. These observations aid in elucidating the relationship between formulation design and *in-vivo* performance. Consistency between *in-vitro* and *in-vivo* swelling behaviour is generally regarded as a crucial indicator of formulation reliability. MRI findings contribute to the validation of GRDDS design by confirming predictable structural and functional behaviour under physiological conditions [62].

Histopathological Analysis: Histopathological analysis is conducted to assess the safety and biocompatibility of gastro-retentive drug delivery systems (GRDDS) following extended gastric residence. This evaluation aims to identify any potential tissue alterations or adverse effects associated with the formulation. Microscopic examination of gastrointestinal tissues is employed to detect signs of inflammation, epithelial damage, oedema, haemorrhage, or foreign body reactions. The absence of significant pathological changes compared to control tissues is considered indicative of good biocompatibility. Overall, minimal or no tissue irritation and the preservation of normal histological architecture are regarded as key acceptance criteria, supporting the safe application of GRDDS for prolonged gastric retention [63].

Proposed Clinical Evaluation Framework: The clinical evaluation of three-dimensional (3D) printed gastro-retentive drug delivery systems (GRDDS) is expected to follow established regulatory protocols, including phased clinical trials. The initial phases typically focus on assessing pharmacokinetics, examining parameters such as maximum plasma concentration (Cmax), time to reach peak concentration (Tmax), and the area under the concentration–time curve (AUC) to evaluate bioavailability and drug release characteristics. Subsequent clinical phases aim to evaluate therapeutic efficacy, optimise dosage, and ensure safety within the target patient populations. These trials assess clinical outcomes relevant to the specific disease while continuing to monitor pharmacokinetic behaviour and tolerability. Regulatory guidelines for 3D-printed dosage forms emphasise the importance of consistent manufacturing, reproducibility, and the establishment of *in-vitro in-vivo* correlation to ensure reliable clinical performance [64].

Clinical Translation and Prospects of 3D-Printed Gastro-Retentive Drug Delivery Systems:

Early Clinical Investigations: Initial clinical trials of 3D-printed gastro-retentive drug delivery systems (GRDDS) have shown proof-of-concept in humans, transitioning from animal studies to human pharmacokinetic and safety evaluations. These studies, with healthy participants, used randomised crossover designs to compare single doses of 3D-printed GRDDS with reference tablets containing the same API dose [65].

Conducted under fasting conditions, they followed scheduled blood sampling. Pharmacokinetic assessments aimed to see if extended *in-vitro* floating and sustained dissolution affected plasma concentrations, like reduced peak plasma concentrations (Cmax), prolonged time-to-peak (Tmax), and potentially enhanced bioavailability (AUC), compared to immediate-release formulations. These trials are crucial for testing formulations meeting preclinical safety and efficacy standards in humans, requiring comprehensive safety monitoring, including vital signs, electrocardiography, lab parameters, and adverse event documentation [66].

Subsequent studies in patient cohorts with targeted diseases (e.g., peptic ulcer for famotidine GRDDS or migraine for antimigraine formulations) focus on

clinical endpoints, such as symptom severity reduction, relief duration, endoscopic healing rates, and biomarker changes (e.g., serum gastrin or H. pylori serology). These studies demonstrate that extended gastric residence via 3D printing enhances therapeutic outcomes over traditional formulations, moving from theoretical benefits to tangible clinical advantages, warranting regulatory investment and patient exposure [67].

Patient-Centric Benefits: The incorporation of three-dimensional (3D) printing technology within the pharmaceutical industry is revolutionising patient care by facilitating personalised medicine. A notable benefit is the enhancement of medication adherence, as 3D-printed gastro-retentive drug delivery systems (GRDDS) can be tailored to individual preferences concerning dosage form size, shape, colour, texture, and taste [68]. These attributes are crucial for ensuring treatment completion, particularly among pediatric and geriatric populations, where taste, pill size, or swallowing difficulties impede compliance. Research indicates that approximately 50% of patients fail to adhere to prescribed medication regimens, often due to unpalatable formulations, inconvenient dosing schedules, or the inability to utilize standard dosage forms [69]. 3D printing technology enables individualized dosing regimens, allowing precise medication dosage adjustments based on patient characteristics, such as body weight, age, renal or hepatic function, and concurrent medications. This approach facilitates dose optimization, which is unattainable with conventional fixed-dose formulations, and is especially advantageous in pediatric care, where dosing is weight-based. Available tablet strengths frequently do not align with the precise doses required for children, resulting in manual tablet splitting and potential dosing inaccuracies. Clinical research demonstrates that first-in-human trials with 3D-printed chewable tablets for maple syrup urine disease (MSUD) and levothyroxine sodium tablets for transient hypothyroxinemia in infants are highly acceptable and effective, with uniform drug distribution ensuring consistent bioavailability. Optimised pharmacokinetic profiles, achieved through prolonged gastric retention, reduce side effects by enabling sustained drug absorption over extended periods [70]. This strategy mitigates peak plasma concentrations, which are responsible for dose-dependent adverse effects such as nausea, dizziness, and tachycardia for propranolol, hepatotoxicity for metformin, and gastrointestinal irritation for NSAIDs. The implementation of 3D-printed GRDDS decreases Cmax by 20–40% compared to immediate-release formulations. This reduction is clinically significant for minimising dose-related adverse effects while maintaining therapeutic efficacy through controlled, sustained drug delivery [71]. Furthermore, pill burden is alleviated by integrating multiple therapeutic agents into a single 3D-printed dosage form or extended-release designs, thereby reducing the frequency of daily medication intake and enhancing patient quality of life and treatment satisfaction [72].

Regulatory and Manufacturing Considerations: Regulatory and manufacturing considerations are pivotal in the transition of three-dimensional (3D)-printed gastro-retentive drug delivery systems (GRDDS) from research to clinical practice. The incorporation of 3D printing into pharmaceutical manufacturing has led regulatory bodies to develop frameworks that address the distinctive characteristics of this technology, such as personalised dosing, decentralised production, and intricate dosage form design. Regulatory agencies, including the U.S. Food and Drug Administration and the European Medicines Agency, have recognised the potential of 3D printing in pharmaceuticals and have issued general guidance for its integration within existing quality systems. These frameworks underscore the significance of quality-by-design (QbD) principles, which involve the identification and control of critical material attributes (CMAs), critical process parameters (CPPs), and critical quality attributes (CQAs) to ensure consistent product performance and safety [73]. Furthermore, regulatory discussions are increasingly considering the feasibility of decentralised or point-of-care manufacturing models, particularly in hospital or clinical environments. While these approaches offer benefits in terms of personalised medicine and on-demand production, they also present challenges related to quality assurance, standardisation, and regulatory oversight. From a manufacturing standpoint, the reproducibility of printed dosage forms, process validation, and batch-to-batch consistency remain essential considerations. Advanced monitoring techniques, including

automated and digital quality control systems, are being investigated to enhance manufacturing reliability; however, their routine regulatory acceptance necessitates further validation. In summary, the regulatory landscape for 3D-printed pharmaceuticals is evolving, and ongoing efforts are necessary to establish clear guidelines that ensure product quality, safety, and efficacy while fostering innovation in GRDDS development [74].

Challenges and Future Directions in 3D-Printed Gastro-Retentive Drug Delivery Systems: Three-dimensional printing technology faces technical challenges, including limitations in resolution and material compatibility, as well as obstacles related to regulatory approvals and clinical validation. However, recent advancements, such as stimuli-responsive polymers, AI-driven formulation design, and on-site manufacturing, have the potential to revolutionise personalised drug delivery systems [75].

Technical Hurdles and Material Limitations: Despite notable advancements at the laboratory level, three-dimensional printing technology faces significant technical challenges that currently impede its application in the pharmaceutical sector. A primary limitation is the print resolution: contemporary fused deposition modelling (FDM) machines can only achieve a layer resolution of approximately 200µm, which is considerably coarser than the micro meter-scale precision required for consistent drug release from thin polymer barriers or ensuring uniform drug distribution in dosage forms. This resolution limitation directly impacts the capacity to make precise dose adjustments within individual tablets or to fabricate micro-scale structures essential for certain advanced delivery systems, such as microparticulate suspensions and nanoscale polymer composites [76].

Material Compatibility: Material compatibility challenges limit the selection of polymers suitable for pharmaceutical three-dimensional (3D) printing. The elevated processing temperatures required for hot-melt extrusion and fused deposition modelling (FDM), typically ranging from 150–210°C, can induce thermal degradation, polymorphic transformations, or chemical modifications in numerous polymers and active pharmaceutical ingredients (APIs) pertinent to the pharmaceutical sector. Thermosensitive APIs and excipients, including certain peptides, proteins, and heat-sensitive small molecules, cannot withstand these high temperatures, thereby excluding entire classes of drugs from 3D printing applications unless substantial reformulation is undertaken. Furthermore, moisture-sensitive ingredients necessitate specialised handling and controlled environments during the printing process, complicating manufacturing and increasing operational costs [77].

Long-term Stability: Concerns regarding the long-term stability of 3D-printed formulations introduce considerable uncertainties regarding their shelf life. Extended processing at elevated temperatures and mechanical stress during extrusion may induce subtle physicochemical alterations, such as partial polymer crystallisation, hydrolysis, or drug amorphization, potentially impacting the formulation's stability during the storage periods required for regulatory approval and commercial distribution. Currently, regulatory agencies have not established specific guidelines for acceptable stability parameters for 3D-printed pharmaceuticals, resulting in uncertainty regarding the expectations for generating long-term stability data [78].

Clinical and Regulatory Barriers: Validation challenges present substantial obstacles to the clinical implementation of 3D-printed formulations, as regulatory authorities require comprehensive evidence demonstrating that these formulations consistently yield superior clinical outcomes compared to traditional dosage forms, thereby justifying their significantly higher production costs and complexities. Existing regulatory frameworks lack specific guidelines for the approval of 3D-printed pharmaceuticals, resulting in uncertainty regarding requisite documentation, acceptable manufacturing validation methods, and quality control measures. Clinical acceptance issues stem from the hesitancy of patients and healthcare providers to adopt new manufacturing techniques, which are perceived as experimental despite their established safety. Concerns regarding traceability, batch-to-batch consistency, and reproducibility of manufacturing across various 3D printers and locations impede their adoption in conservative clinical settings.

Economic feasibility is perhaps the most significant barrier. Extensive interviews with stakeholders indicate that the current costs associated with acquiring 3D printers, ongoing expenses for filament materials, facility requirements, and staff training necessitate substantial capital investments that are only viable in high-volume environments, such as large university hospital pharmacies with a sufficient patient base requiring personalised medicines. Smaller community pharmacies and mid-sized healthcare facilities find it economically unfeasible to invest in 3D printing infrastructure [79].

Emerging Innovations and Future Prospects: The advancement of stimuli-responsive materials represents a significant area of innovation, focusing on polymers engineered to respond to specific gastrointestinal stimuli, such as pH variations, enzymatic degradation, and bacterial fermentation byproducts in the colon. These materials enable sophisticated drug release mechanisms activated by environmental changes, surpassing existing methods that rely on passive dissolution control. This technology facilitates precise delivery to the targeted intestinal regions or colon, providing localised therapeutic effects or treatments that modulate the microbiota [80]. The application of artificial intelligence and machine learning markedly accelerated the optimisation of formulations by analysing extensive datasets from the literature (968 formulations from 114 published articles). Machine learning algorithms can predict key printing parameters, printability features, and in vitro dissolution profiles with an accuracy exceeding 90–93%, thereby reducing the trial-and-error optimisation process from months to weeks in duration. Neural network models predicted drug release times with an average error of ±24.29min, aiding rational formulation design prior to experimental validation. AI algorithms identify the most critical formulation variables, guiding prioritised experimental studies and significantly expediting the development timelines. The implementation of point-of-care 3D printing in hospital pharmacies and specialised compounding facilities has emerged as the most feasible short-term solution. In these settings, personalised formulations are produced on demand within pharmacy environments close to patient care areas, eliminating the need for pharmaceutical scale-up and centralised manufacturing. Regulatory bodies, such as the FDA and UK MHRA, have begun to establish frameworks to support point-of-care manufacturing, with the MHRA regulations scheduled to take effect in July 2025, creating regulatory pathways for decentralised pharmaceutical production. This approach circumvents scalability challenges while enabling true personalisation by customising individual doses and dosage form characteristics to meet specific patient needs rather than mass-producing standardised formulations [81].

CONCLUSION: Three-dimensional (3D) printing has become a promising approach for creating gastro-retentive drug delivery systems (GRDDS), offering greater flexibility in designing dosage forms, controlled drug release, and the potential for personalized treatment. The ability to adjust structural parameters like geometry, density, and internal architecture allows for enhanced gastric retention and customized drug release profiles, which are particularly relevant for treating peptic ulcer disease. Current evidence from preclinical studies and early-stage research supports the feasibility of 3D-printed GRDDS in achieving extended gastric residence and controlled drug delivery. These findings highlight the potential of advanced manufacturing technologies to overcome the limitations of traditional gastro-retentive systems. However, there are significant gaps in the clinical translation of these systems. Well-designed clinical studies specifically assessing 3D-printed GRDDS for peptic ulcer disease are scarce, and further research is needed to establish their therapeutic efficacy, safety, and long-term performance. Additionally, challenges related to large-scale manufacturing, regulatory standardisation, and cost-effectiveness must be addressed before these systems can be widely adopted in clinical settings. Future research should focus on developing robust and reproducible formulations, optimising multi-drug delivery strategies, and generating high-quality clinical evidence. Greater emphasis on in vitro–in vivo correlation, patient-specific design approaches, and regulatory alignment will be crucial to support the successful integration of 3D-printed GRDDS into clinical practice. Overall, while 3D printing offers a valuable platform for advancing gastro-retentive drug delivery, its transition from experimental research to routine clinical application will depend

on continued interdisciplinary efforts and evidence-based validation.

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