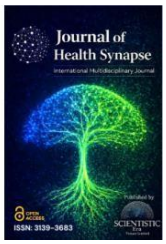
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# Development of a Gastro-Retentive Floating Drug Delivery System for Sustained Oral Delivery of Quercetin as a Natural Antidiabetic Bioactive

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**A B S T R A C T**

Quercetin (3,3′,4′,5,7-pentahydroxyflavone) is a naturally occurring dietary flavonol abundant in onions, apples, berries, and medicinal plants, recognized for its antioxidant, anti-inflammatory, and preclinical antidiabetic properties. Experimental evidence indicates that quercetin modulates glucose homeostasis by scavenging hyperglycemia-induced reactive oxygen species (ROS), protecting pancreatic β-cells, sensitizing insulin signaling pathways, and inhibiting carbohydrate-hydrolyzing enzymes. Nevertheless, its pharmaceutical translation as an oral therapeutic candidate is severely restricted by poor aqueous solubility, slow gastrointestinal dissolution, chemical degradation at alkaline intestinal pH, and extensive intestinal and hepatic phase-II conjugation, leading to low and variable systemic bioavailability. Gastro-retentive floating drug delivery systems (GRFDDS) are engineered to remain buoyant in gastric fluid for prolonged durations, releasing incorporated bioactives in a sustained manner into the upper small intestine. Integrating a solubility-enhancing quercetin solid dispersion (using polyvinylpyrrolidone, PVP K30) within an effervescent hydroxypropyl methylcellulose (HPMC K100M) matrix containing sodium bicarbonate and citric acid provides a rational formulation platform for sustained oral delivery. This review examines quercetin's antidiabetic mechanisms, biopharmaceutical barriers, effervescent and non-effervescent floating principles, solid-dispersion formulation design, pre- and post-compression characterization, in vitro dissolution kinetics, Box–Behnken Quality by Design (QbD) optimization, ICH Q1A(R2) stability requirements, and the necessity for comparative pharmacokinetic and in vivo antidiabetic confirmation.

## 1. Introduction

Diabetes mellitus is a chronic, multifactorial metabolic disorder characterized by persistent hyperglycemia resulting from impaired pancreatic insulin secretion, peripheral insulin resistance, or a combination of both [3,9]. Its rapidly rising global prevalence has intensified scientific efforts toward sustainable, long-term glycemic management strategies [3]. Although conventional oral hypoglycemic drugs and exogenous insulin regimens remain clinical mainstays, chronic pharmacotherapy frequently entails gastrointestinal side effects, hypoglycemic episodes, secondary drug failure, and pill-burden adherence challenges [9]. Consequently, plant-derived polyphenolic bioactives are actively investigated as complementary therapeutic candidates [3,10].

Quercetin, a widely distributed dietary flavonol, exhibits well-

documented antioxidant, anti-inflammatory, and preclinical glucose-lowering properties [9–14]. However, translating quercetin into a reliable oral pharmaceutical dosage form is impeded by poor aqueous solubility, slow dissolution in gastrointestinal fluids, chemical instability at neutral-to-alkaline intestinal pH, and rapid phase-II metabolism [15–18]. Gastro-retentive floating drug delivery systems (GRFDDS) offer a promising oral platform to prolong gastric residence time and meter solubilized drug steadily to the upper small intestine [4,5,21–23]. Combining a solubility-enhancing quercetin solid dispersion with an effervescent hydrophilic matrix provides a rational formulation strategy, provided that enhanced gastric retention is rigorously verified to improve intestinal absorption and systemic pharmacokinetics [1–3].

## 2. Quercetin as a Natural Antidiabetic Bioactive

### 2.1. Chemical and Physicochemical Properties

Chemically designated as 3,3′,4′,5,7-pentahydroxyflavone (molecular formula C15H10O7; molecular weight 302.24 g/mol), quercetin belongs to the flavonol subclass of polyphenolic compounds [15,18]. It occurs as a yellow crystalline powder abundant in onions (Allium cepa), apples (Malus domestica), berries, tea (Camellia sinensis), and numerous medicinal herbs, exhibiting extremely low water solubility (<10 µg/mL) and high lipophilicity [16,18,34].

### 2.2. Preclinical Antidiabetic Mechanisms

Experimental in vitro and animal investigations indicate that quercetin modulates glycemic control through multiple complementary molecular pathways [3,9–14]:

- **Antioxidant Defense:** Quercetin scavenges hyperglycemia-induced reactive oxygen species (ROS) and suppresses lipid peroxidation, mitigating systemic oxidative stress [10,12].
- **Pancreatic β-Cell Protection:** Radical-scavenging and anti-apoptotic actions protect pancreatic islet β-cells from streptozotocin- and cytokine-induced oxidative injury while potentiating glucose-stimulated insulin secretion [12,13].
- **Insulin Signaling Sensitization:** Preclinical studies demonstrate activation of AMP-activated protein kinase (AMPK) and phosphoinositide 3-kinase (PI3K)/Akt cascades, promoting GLUT4 translocation and peripheral skeletal muscle glucose uptake [9,11].
- **Carbohydrate Enzyme Inhibition:** Quercetin competitively inhibits intestinal α-amylase and α-glucosidase, delaying starch hydrolysis and blunting postprandial blood glucose excursions [14].
- **Anti-Inflammatory Modulation:** Downregulation of NF-κB, TNF-α, and interleukin-6 (IL-6) alleviates low-grade adipose and hepatic inflammation linked to insulin resistance [9,11].

Crucially, these preclinical findings justify pharmaceutical formulation research but do not constitute proof of clinical antidiabetic efficacy; quercetin must not be used as a substitute for prescribed antidiabetic medications [2,3].

## 3. Biopharmaceutical Challenges and Gastro-Retentive Rationale

Oral delivery of conventional quercetin powders or tablets yields low and highly variable systemic bioavailability (<2–17% in humans) due to three major barriers [2,15,16]: (1) poor aqueous solubility and crystalline lattice energy, which restrict gastrointestinal dissolution; (2) extensive intestinal and hepatic phase-II conjugation—via UDP-glucuronosyltransferases (UGTs), sulfotransferases (SULTs), and catechol-O-methyltransferase (COMT)—converting quercetin primarily into glucuronide, sulfate, and methyl metabolites [15,16]; and (3) susceptibility to oxidative and alkaline degradation upon exposure to light, elevated temperature, oxygen, and intestinal pH >7 [18,34].

Gastro-retentive drug delivery systems (GRDDS)—classified into floating, raft-forming, mucoadhesive, expandable, and high-density systems—prolong dosage-form residence in the stomach [4,5,21–24]. While floating systems offer sustained release and potential dosing-frequency reduction, their in vivo performance can be influenced by fed/fasted state, posture, gastric motility, and gastric fluid volume [21,25]. Because quercetin is predominantly absorbed and conjugated in the small intestine, prolonged gastric retention must be experimentally proven to enhance duodenal availability and plasma exposure [2,3].

## 4. Floating Mechanism and Formulation Design of Quercetin Tablets

### 4.1. Effervescent vs. Non-Effervescent Floating Mechanisms

Floating drug delivery systems maintain a bulk apparent density lower than that of gastric fluid (~1.004 g/cm³), enabling buoyancy without impairing normal gastric emptying [5,25,26]. Non-effervescent systems rely on high-viscosity swellable hydrocolloids or low-density porous matrices that entrap air upon hydration [5,21]. In contrast, effervescent floating systems incorporate a gas-generating couple—typically sodium bicarbonate and anhydrous citric acid—within a hydrophilic polymer network [27,30].

As illustrated in Figure 1, contact with acidic gastric fluid triggers rapid hydrocolloid hydration alongside an acid–base reaction generating carbon dioxide (CO2) microbubbles. Entrapment of CO2 within the swollen gel matrix lowers tablet density, causing upward flotation while quercetin diffuses gradually through the hydrated polymer barrier [27,29,30].

Figure 1. Effervescent Buoyancy and Controlled Release Mechanism of Quercetin Solid-Dispersion Floating Tablets

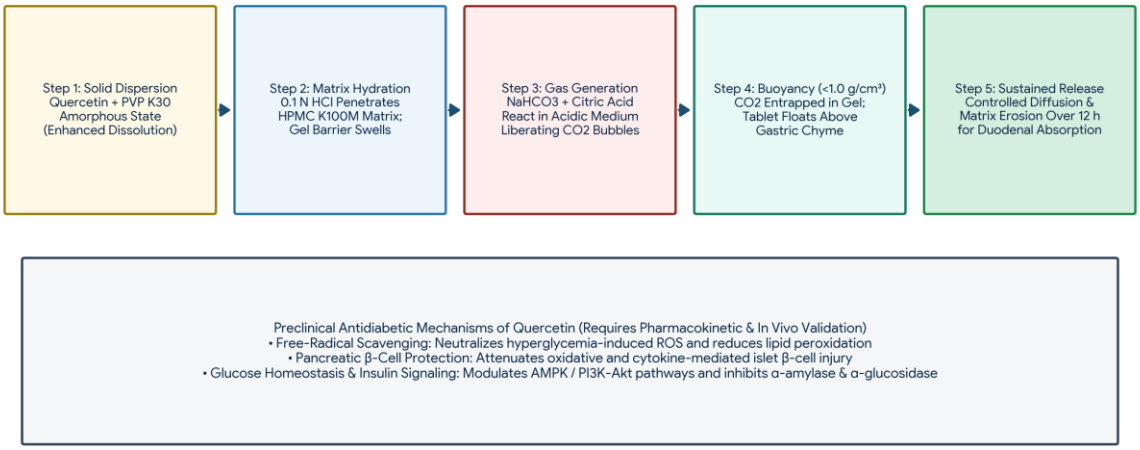



**Figure 1.** *Effervescent buoyancy and controlled-release mechanism of quercetin solid-dispersion floating tablets in acidic gastric fluid, alongside preclinical antidiabetic pathways.*

**4.2. Solid-Dispersion Strategy and Excipient Selection**

To overcome quercetin's dissolution bottleneck prior to matrix compression, a binary solid dispersion is prepared with polyvinylpyrrolidone (PVP K30) via solvent evaporation or fusion, converting crystalline quercetin into an amorphous, rapidly dissolving state [1,31–33,54]. As detailed in Table 1, the dried quercetin–PVP K30 solid dispersion is blended with high-viscosity HPMC K100M (or sodium alginate for raft-forming variants), gas-generating agents, microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate [1,27,30,42].

**Table 1. Proposed Formulation Components and Functional Roles in Quercetin Solid-Dispersion Floating Tablets**

| Ingredient Category | Selected Material | Pharmaceutical Function in Dosage Form |
|---|---|---|
| **Natural Antidiabetic Bioactive** | Quercetin (3,3′,4′,5,7-pentahydroxyflavone) | Flavonol bioactive modulating oxidative stress, insulin signaling, and carbohydrate enzymes |
| **Solubility-Enhancing Carrier** | Polyvinylpyrrolidone (PVP K30) | Amorphous hydrophilic carrier in solid dispersion to accelerate apparent dissolution |
| **Floating & Matrix Polymer** | HPMC K100M (or Sodium Alginate) | High-viscosity swellable hydrocolloid forming a cohesive gel barrier for CO2 entrapment and sustained release |
| **Gas-Generating Agent** | Sodium Bicarbonate (NaHCO3) | Reacts with acidic medium/acidifier to liberate carbon dioxide microbubbles |
| **Acidifying Agent** | Citric Acid (anhydrous) | Ensures reproducible effervescence independent of inter-individual gastric pH variability |
| **Directly Compressible Diluent** | Microcrystalline Cellulose (MCC PH102) | Provides tablet bulk, compactibility, and mechanical crushing strength |
| **Lubricant & Glidant** | Magnesium Stearate & Colloidal Silicon Dioxide | Reduces die-wall friction and improves hopper powder flow during compression |

## 5. Proposed Manufacturing Outline and Quality Control Evaluation

A systematic five-stage laboratory development workflow is recommended [1,26,27]: (Step 1) Preformulation authentication of quercetin, equilibrium solubility determination across pH 1.2–6.8 media, validated HPLC assay development, and FTIR/DSC excipient compatibility screening [34]; (Step 2) Preparation of quercetin–PVP K30 solid dispersions across screened weight ratios (e.g., 1:1 to 1:5), drying, pulverization, sieving, and comparative dissolution testing; (Step 3) Geometric blending of the dried solid dispersion with HPMC K100M, microcrystalline cellulose, sodium bicarbonate, and citric acid, followed by terminal lubrication; (Step 4) Compression on a rotary or single-punch tablet press under controlled force; and (Step 5) Screening batches for buoyancy, swelling, and 12-hour release.

Comprehensive pre-compression micromeritic tests, post-compression physical/buoyancy evaluations, and mathematical drug-release kinetic models are summarized in Table 2 [29,35–38]. Swelling index is calculated gravimetrically using standardized blotting intervals [27]:

$$\text{Swelling Index (\%)} = [(Wt - W0) / W0] \times 100$$

where Wt is the swollen tablet weight at time t and W0 is the initial dry weight. Preliminary in vitro dissolution is performed in USP Apparatus II (paddle) using 900 mL of 0.1 N HCl (pH 1.2) at 37 ± 0.5°C and 50 rpm over 12 hours with sink-condition medium replacement, quantifying quercetin via stability-indicating HPLC to prevent excipient UV interference [1,38, 76-79].

**Table 2. Pre-Compression, Post-Compression, and Drug Release Kinetic Evaluation Parameters for Floating Tablets**

| Evaluation Stage | Parameter / Kinetic Model | Analytical Purpose & Formulation Interpretation |
|---|---|---|
| **Pre-Compression Flow** | Angle of Repose (tan θ = h/r), Bulk & Tapped Density | Evaluates inter-particulate friction and powder packing behavior |
| **Compressibility Indices** | Carr's Index [(ρt − ρb)/ρt × 100] & Hausner Ratio (ρt/ρb) | Predicts powder flowability and uniform die filling during compression |
| **Physical & Mechanical QC** | Weight Variation, Thickness, Hardness, Friability (<1%) | Confirms dose uniformity and mechanical resistance to handling/packaging |
| **Buoyancy & Hydration** | Floating Lag Time (FLT), Total Floating Time (TFT), Swelling Index | Verifies rapid flotation onset and sustained gastric buoyancy (>12 h) |
| **In Vitro Dissolution** | USP Apparatus II (0.1 N HCl, 37 ± 0.5°C, 50 rpm) + HPLC | Quantifies sustained quercetin release profile under simulated gastric conditions |
| **Zero-Order & First-Order** | $Qt = Q0 + k0t$ \| $\log Qt = \log Q0 - k1t/2.303$ | Distinguishes constant-rate release from concentration-dependent release |
| **Higuchi & Korsmeyer–Peppas** | $Qt = kH \cdot t^{1/2}$ \| $Mt/M\infty = k \cdot tn$ | Characterizes Fickian diffusion, anomalous transport, or matrix erosion mechanisms |

## 6. Biological Evaluation, Box–Behnken QbD Optimization, and Stability

In vitro antioxidant potency is evaluated using the DPPH radical-scavenging assay (% Inhibition = [(Ac − As)/Ac] × 100) alongside polymer blanks [43, 66-70], complemented by α-amylase inhibition, α-glucosidase inhibition, and cellular glucose uptake assays [11,14]. Following Institutional Animal Ethics Committee (IAEC) approval, in vivo antidiabetic and pharmacokinetic evaluation in validated diabetic rodent models compares vehicle control, disease control, pure quercetin suspension, optimized floating tablet, and a standard oral hypoglycemic agent across fasting blood glucose, oral glucose tolerance test (OGTT), serum insulin, glycated hemoglobin (HbA1c), lipid profile, oxidative stress markers, pancreatic histopathology, and plasma AUC/Cmax of unchanged and conjugated quercetin [3,12,44, 61-65].

As illustrated in Figure 2, Quality by Design (QbD) optimization under ICH Q8(R2) utilizes a three-factor Box–Behnken Design of Experiments (DoE) evaluating independent variables—X1 (HPMC K100M level), X2 (sodium bicarbonate level), and X3 (citric acid level)—against Critical Quality Attributes Y1 (FLT), Y2 (TFT), Y3 (cumulative release), Y4 (swelling index), and Y5 (tablet hardness) [7,39–41]. Stability protocols aligned with ICH

Q1A(R2) (detailed in Table 3) prioritize moisture-impermeable packaging to prevent premature acid–base effervescence during storage [6, 71-75].

Figure 2. Systematic Formulation Development, Box–Behnken QbD Optimization, and Preclinical Evaluation Workflow

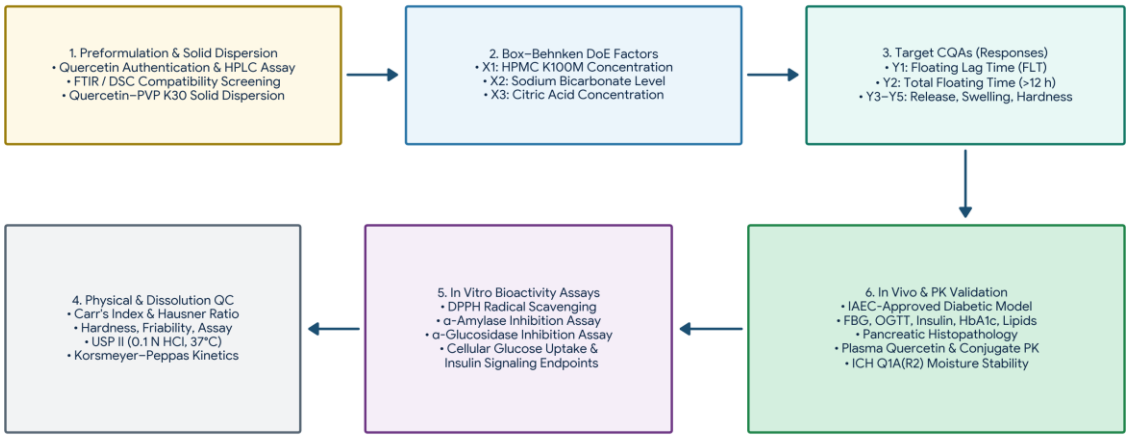



**Figure 2.** *Systematic formulation development, Box–Behnken Design of Experiments (DoE) optimization, and preclinical evaluation workflow for quercetin floating tablets.*

**Table 3. ICH Q1A(R2) Stability Testing Protocol and Critical Quality Monitoring for Effervescent Floating Tablets**

| Stability Study Type | Storage Condition (Climatic Zone II / IVb) | Critical Parameters Monitored |
|---|---|---|
| **Long-Term Stability** | 25 ± 2°C / 60 ± 5% RH (or 30 ± 2°C / 65–75% RH) | Appearance, moisture uptake, HPLC quercetin assay, FLT, TFT, and dissolution profile |
| **Accelerated Stability** | 40 ± 2°C / 75 ± 5% RH (6 months) | Premature effervescence, discoloration, degradation products, hardness, and buoyancy |
| **Packaging Protection** | Moisture-barrier Alu-Alu blister or desiccant-lined HDPE | Prevents atmospheric moisture ingress triggering premature NaHCO3–citric acid reaction |

## 7. Literature Precedent, Research Gap, and Future Perspectives

Precedent research by Bunlung et al. established the feasibility of incorporating quercetin–PVP K30 solid dispersions into sodium alginate raft-forming liquid and chewable tablet formulations for gastric ulcer therapy [1]. However, a clear translational gap remains in demonstrating whether a specifically engineered quercetin effervescent floating matrix tablet provides reproducible 12-hour sustained release while maintaining duodenal availability and improving systemic pharmacokinetic exposure and glycemic endpoints in diabetes [2–4]. Future research should explore hybrid nanocrystal-floating matrices, gastro-retentive lipid-polymeric systems, and randomized human pharmacokinetic trials to confirm clinical translation [17,51–53-60].

## 8. Conclusion

Quercetin possesses compelling antioxidant, anti-inflammatory, and preclinical antidiabetic mechanisms, yet its oral utility is constrained by poor aqueous solubility, chemical instability, and extensive phase-II metabolism. Combining a solubility-enhancing quercetin–PVP K30 solid dispersion with an HPMC K100M-based effervescent floating matrix represents a rational formulation strategy to achieve sustained gastric release. Through Box–Behnken QbD optimization, validated USP II dissolution testing, moisture-barrier ICH Q1A(R2) stability studies, and paired pharmacokinetic-pharmacodynamic evaluation, researchers can rigorously determine whether prolonged gastric buoyancy translates into enhanced intestinal absorption and reproducible antidiabetic efficacy.

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