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Formulation and Evaluation of Sustained Release Floating Matrix Tablet of Domperidone Maleate

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ABSTRACT: The present study was undertaken to develop and evaluate a gastro-retentive sustained-release floating matrix tablet of Domperidone Maleate. Domperidone Maleate is an antiemetic drug with a short duration of action and limited aqueous solubility, particularly at alkaline pH. These characteristics may necessitate repeated administration and make it suitable for investigation through a gastro-retentive drug delivery approach. The objective of the study was to develop a floating matrix tablet capable of maintaining the dosage form in the stomach and providing controlled drug release for an extended period.

Floating matrix tablets were prepared by the direct compression method using **Polyox WSR 1105 and xanthan gum** as release-retarding polymers. Sodium bicarbonate and citric acid were incorporated to generate carbon dioxide and provide buoyancy. PVP K30 was used as a binder, while microcrystalline cellulose served as a diluent. Magnesium stearate and talc were used as lubricating agents. Preliminary formulations were evaluated for physical characteristics, floating behaviour and drug release.

A **3² factorial design** was subsequently employed to investigate the influence of polymer concentration and sodium bicarbonate concentration on floating lag time and drug release. The selected polymer system consisted of Polyox WSR 1105 and xanthan gum, while sodium bicarbonate concentration was varied as the gas-generating component.

The optimized formulation demonstrated a floating lag time of approximately **39 seconds** and provided **96.88% drug release after 10 hours**. The study indicated that the combination of Polyox WSR 1105 and xanthan gum was capable of extending Domperidone Maleate release for approximately 10 hours while maintaining satisfactory floating behaviour.

Thus, the developed gastro-retentive floating matrix tablet provided sustained delivery of Domperidone Maleate and may help reduce dosing frequency and maintain drug release over an extended period. The thesis concludes that the formulation was successfully developed using a **3² factorial design**, with further in-vivo investigation suggested for future development.

KEYWORDS: Domperidone Maleate, Gastro-retentive drug delivery system, Floating matrix tablet, Sustained release, Polyox WSR 1105, Xanthan gum, Sodium bicarbonate, Factorial design.

I. INTRODUCTION

Oral administration is one of the most convenient routes for drug delivery; however, the therapeutic performance of an oral dosage form can be influenced by gastric residence time and gastrointestinal transit. Gastro-retentive drug delivery systems (GRDDS) are designed to remain in the upper gastrointestinal tract for an extended period and thereby provide prolonged and controlled drug release.

1.1 Gastro-retentive Drug Delivery System

Gastro-retentive systems are particularly useful for drugs that require prolonged residence in the stomach, have a narrow absorption window, or require controlled drug release to maintain therapeutic concentrations. Gastric retention can increase the duration of drug contact with the upper gastrointestinal tract, potentially reducing dosing frequency and improving patient compliance.

The stomach consists principally of the **fundus, body and antrum**. Gastric motility occurs through the migrating motor complex, which consists of four phases with different patterns of gastric activity. These physiological movements influence the residence and eventual emptying of orally administered dosage forms.

1.2 Floating Drug Delivery System

Among the different gastro-retentive approaches, floating drug delivery systems are designed with a density lower than gastric contents so that the dosage form remains buoyant in the stomach. Floating systems can provide prolonged gastric residence while allowing controlled drug release. Other approaches include high-density systems, expandable systems, super-porous hydrogels, mucoadhesive systems, magnetic systems and raft-forming systems.

Floating systems offer potential advantages such as prolonged drug delivery, reduced dosing frequency, reduced fluctuations in drug concentration and improved patient compliance. However, their performance may be influenced by gastric contents, gastric motility and drug suitability for the gastric environment.

1.3 Domperidone Maleate

Domperidone Maleate is a benzimidazole derivative used as an antiemetic and gastrointestinal prokinetic agent. The thesis describes it as a weakly basic, BCS Class II drug with very low aqueous solubility. Its reported aqueous solubility is **0.986 mg/L**, while oral bioavailability is approximately **13.17%**. The drug has an elimination half-life in the range of approximately **5–7 hours** in the study rationale.

Domperidone acts primarily through peripheral dopamine receptor blockade. Its gastroprokinetic activity is associated with increased gastric and oesophageal peristalsis and improved gastric emptying, while its antiemetic effect is related to dopamine receptor blockade at the chemoreceptor trigger zone.

The thesis reports rapid oral absorption but relatively low bioavailability, attributed to extensive first-pass metabolism. These characteristics provided the basis for investigating a gastro-retentive sustained-release formulation of Domperidone Maleate.

1.4 Rationale of the Study

The study was undertaken to develop a floating matrix tablet capable of providing prolonged drug release and reducing the frequency of administration. **Polyox WSR 1105 and xanthan gum** were selected as release-retarding polymers, while sodium bicarbonate was incorporated as a gas-generating component to provide buoyancy.

A **3² factorial design** was used to investigate the effects of polymer concentration and sodium bicarbonate concentration on the two principal responses: **floating lag time and percentage drug release**.

1.5 Aim and Objectives

Aim:

To formulate and evaluate a sustained-release floating matrix tablet of Domperidone Maleate.

Objectives:

1. To develop a gastro-retentive drug delivery system of Domperidone Maleate.
2. To obtain controlled drug release for approximately **10 hours**.
3. To investigate the influence of polymer concentration and sodium bicarbonate concentration on floating behaviour and drug release.
4. To optimize the formulation using a **3² factorial design**.
5. To evaluate the optimized floating matrix tablet for its physical characteristics, buoyancy and in-vitro drug release.

II. MATERIALS AND METHODS

2.1 Materials

Domperidone Maleate was obtained from **Wockhardt Ltd., Aurangabad**. Polyox WSR 1105 was also obtained from Wockhardt Ltd. The remaining excipients—xanthan gum, sodium bicarbonate, citric acid, magnesium stearate, PVP K30, talc and microcrystalline cellulose—were procured from the local market, Pune.

2.2 Preformulation Studies

Preformulation evaluation included examination of the drug's organoleptic properties, melting point, solubility, FT-IR characteristics and UV spectroscopic behaviour. Flow properties of the drug and excipients were also investigated before formulation development.

2.3 Selection of Manufacturing Method

The **direct compression method** was selected for preparation of the floating matrix tablets based on the flow characteristics of the drug and excipients.

For preliminary formulations, Polyox WSR 1105 and xanthan gum were used as release-retarding polymers, microcrystalline cellulose as diluent and magnesium stearate as lubricant. The ingredients were sieved and blended to obtain a uniform powder mixture. The blend was compressed using a **10-mm flat punch**, with each tablet containing **30 mg Domperidone Maleate**. Sodium bicarbonate was investigated at different concentrations.

2.4 Preliminary Formulation and Optimization

Preliminary batches were prepared using different concentrations of Polyox WSR 1105, xanthan gum and sodium bicarbonate. The trial formulations were evaluated for floating lag time, floating duration, hardness, thickness and drug-release behaviour.

Among the preliminary batches, **B9** showed a floating lag time of **38 seconds**, floating duration of approximately **11 hours**, hardness of **4.6 kg/cm²**, thickness of **4.46 mm** and **95.28% drug release in 10 hours**. Based on its overall performance, B9 was selected for further optimization.

2.5 Experimental Design

A **3² factorial design** was employed to optimize the floating matrix tablet. The two independent variables were:

X₁: concentration of polymer mixture (Polyox WSR 1105 and xanthan gum)

X₂: concentration of sodium bicarbonate

The polymer ratio of **Polyox WSR 1105:xanthan gum = 2:1** was selected. Polymer concentration was investigated at **110, 120 and 130 mg**, while sodium bicarbonate was studied at **15, 25 and 35 mg**. The dependent responses were **floating lag time (Y₁)** and **percentage drug release (Y₂)**

Table.1. Factorial Design Variables

Variable	Low	Medium	High
Polymer concentration (X ₁)	110 mg	120 mg	130 mg
Sodium bicarbonate (X ₂)	15 mg	25 mg	35 mg

2.6 Preparation of Factorial Batches

The required quantities of Domperidone Maleate, Polyox WSR 1105, xanthan gum and sodium bicarbonate were accurately weighed and mixed. PVP K30, talc and magnesium stearate were subsequently incorporated into the powder blend. The final mixture was compressed by direct compression to obtain the floating matrix tablets.

All factorial batches contained **30 mg Domperidone Maleate**. The concentrations of Polyox WSR 1105, xanthan gum and sodium bicarbonate were varied according to the factorial design, while the remaining formulation components were incorporated as described in the thesis.

2.7 Evaluation of Floating Matrix Tablets

The prepared tablets were evaluated for:

- Appearance
- Thickness
- Hardness
- Weight variation
- Friability
- Tablet density
- Drug content
- In-vitro buoyancy

- Swelling behaviour
- In-vitro drug release

For weight variation, **20 tablets** were individually weighed and compared with their average weight. Friability was determined using a Roche friabilator at **25 rpm for 4 minutes**.

2.8 Drug Content

Twenty tablets were randomly selected, weighed and powdered. A quantity equivalent to **0.1 g Domperidone Maleate** was transferred to a 200-mL volumetric flask, extracted using **0.1 N HCl** and shaken for 10 minutes. After filtration and dilution, absorbance was measured at **284 nm**.

2.9 In-vitro Buoyancy Study

Buoyancy testing was performed using a **USP Type II apparatus** with **0.1 N HCl** as the medium. The apparatus was operated at **50 rpm** using **900 mL** dissolution medium at the temperature reported in the thesis. Floating lag time and total floating duration were observed.

2.10 In-vitro Dissolution Study

Drug release was studied using a **USP Type II paddle apparatus** containing **900 mL of 0.1 N HCl** at **50 rpm**. The study was continued for **10 hours**. Samples of **5 mL** were withdrawn at 1-hour intervals from 1 to 10 hours and replaced with fresh dissolution medium. The samples were filtered and analysed spectrophotometrically at **284 nm**

III. RESULTS AND DISCUSSION

3.1 Preformulation and Powder Flow Properties

The preformulation study included evaluation of the drug for organoleptic characteristics, melting point, solubility, FT-IR and UV spectroscopic behaviour. Flow properties were also investigated before tablet formulation.

The powder-flow results for the formulation batches showed acceptable flow characteristics, with Carr's index, angle of repose and Hausner's ratio evaluated for the different batches. For example, B9 showed a bulk density of **0.65 ± 0.046 g/cm³**, tapped density of **0.75 ± 0.22 g/cm³**, Carr's index of **17.89 ± 0.96** , angle of repose of **$27.35 \pm 0.21^\circ$** and Hausner's ratio of **1.11 ± 0.01** .

3.2 Preliminary Formulation Study

Initial formulations were prepared using either Polyox WSR 1105 or xanthan gum, with different concentrations of sodium bicarbonate. The preliminary batches showed drug release up to approximately 7–8 hours, indicating that a combination of the two polymers was required to obtain the desired 10-hour sustained-release profile.

The subsequent trial batches used Polyox WSR 1105 and xanthan gum at ratios of **1:1**, **1:1.5** and **1:2**, with different concentrations of sodium bicarbonate. The results showed that the **1:2 polymer combination** provided better sustained-release behaviour.

3.3 Evaluation of Trial Batches

The trial formulations demonstrated floating lag times between **38 and 52 seconds** and floating durations ranging from **8 to more than 11 hours**. Drug release varied according to polymer composition and formulation variables.

Batch	Floating Lag Time	Floating Time	Hardness	Drug Release
B1	52 sec	8 h	4.5 kg/cm ²	93.83%
B2	45 sec	8 h	5.0 kg/cm ²	92.71%
B3	40 sec	8 h	4.7 kg/cm ²	92.73%
B4	50 sec	10 h	4.8 kg/cm ²	85.00%
B5	47 sec	>11 h	5.5 kg/cm ²	82.00%
B6	42 sec	>11 h	5.8 kg/cm ²	86.00%
B7	51 sec	>11 h	5.0 kg/cm ²	90.38%
B8	44 sec	>11 h	4.5 kg/cm ²	94.07%
B9	38 sec	11 h	4.6 kg/cm ²	95.28%

Among these batches, **B9** showed the shortest floating lag time and a high drug-release value and was selected for further factorial optimization.

3.4 Effect of Sodium Bicarbonate on Buoyancy

The buoyancy study demonstrated that sodium bicarbonate concentration influenced floating behaviour. The thesis reports that a **10% sodium bicarbonate concentration** produced approximately **10 hours of floating duration** with a low floating lag time. Increasing sodium bicarbonate altered the carbon-dioxide generation and consequently affected the floating lag time.

The results also indicated that a single polymer was insufficient for the desired release behaviour. The combination of **xanthan gum and Polyox WSR 1105 at 1:2 ratio** provided better sustained drug release.

3.5 Evaluation of Optimized Matrix Tablets

The prepared matrix tablets were white with smooth surfaces. Tablet thickness was reported within **3.96–4.33 mm**, while hardness ranged from approximately **4.4–5.23 kg/cm²**, indicating satisfactory mechanical strength.

The evaluation data for the selected batches showed acceptable weight variation, friability and drug content. For example, B5 showed a drug content of **97%**, friability of **0.33%**, floating lag time of **39 seconds**, floating duration of **10 hours** and drug release of **96.88% at 10 hours**.

3.6 Factorial Design Optimization

A **3² factorial design** was applied to investigate the influence of polymer concentration and sodium bicarbonate concentration on the two response variables: floating lag time and percentage drug release. The polymer concentration was studied at **110, 120 and 130 mg**, while sodium bicarbonate was varied between **15, 25 and 35 mg**.

The formulation composition for the factorial batches incorporated **30 mg Domperidone Maleate**, Polyox WSR 1105, xanthan gum and varying amounts of sodium bicarbonate.

3.7 In-vitro Buoyancy and Drug Release

The factorial formulations were evaluated using 0.1 N HCl in a USP Type II apparatus. The study showed that the polymer ratio and sodium bicarbonate level affected both floating behaviour and drug release.

The thesis reports that the selected formulation containing the **1:2 xanthan gum:Polyox WSR 1105 ratio and 10% sodium bicarbonate** showed a floating lag time of approximately **39 seconds** and **96.88% drug release after 10 hours**.

This formulation therefore provided the desired combination of rapid buoyancy and prolonged drug release.

3.8 Statistical Analysis

The factorial data were analysed using **Design-Expert software** to determine the effects of the independent formulation variables. For percentage drug release, the overall model was reported as significant with a **p-value of 0.0344**. The quadratic effect of polymer concentration was also significant (**p = 0.0206**), whereas the individual linear effects of polymer ratio and sodium bicarbonate concentration were not statistically significant at the reported level. These findings indicate that the formulation variables, particularly the polymer-related quadratic effect, contributed to the observed drug-release behaviour.

3.9 Overall Discussion

The study demonstrated that combining **Polyox WSR 1105 with xanthan gum** was more effective for obtaining prolonged drug release than using a single polymer system. Sodium bicarbonate provided the gas-generating mechanism required for tablet buoyancy, while the hydrophilic polymers formed the matrix responsible for controlling drug diffusion and release.

The optimized formulation maintained buoyancy for approximately **10 hours** and released **96.88% of Domperidone Maleate within 10 hours**, meeting the principal objective of developing a sustained-release gastro-retentive formulation.

IV. CONCLUSION

The present study successfully developed a **gastro-retentive sustained-release floating matrix tablet of Domperidone Maleate** using Polyox WSR 1105 and xanthan gum as release-retarding polymers. The formulation was prepared by direct compression and evaluated for physical properties, buoyancy and in-vitro drug release.

The combination of **Polyox WSR 1105 and xanthan gum** provided prolonged drug release, while sodium bicarbonate generated the gas required for tablet buoyancy. The optimized formulation demonstrated a floating lag time of approximately **39 seconds** and **96.88% drug release after 10 hours**.

The application of a **3² factorial design** allowed investigation of the effects of polymer concentration and sodium bicarbonate concentration on floating behaviour and drug release. Overall, the study demonstrated that a floating matrix system can provide prolonged release of Domperidone Maleate for approximately **10 hours**.

Further **in-vivo studies and in-vitro-in-vivo correlation** were suggested in the thesis to establish the performance and potential for further development of the formulation.

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