Formulation and evaluation of controlled release matrix mucoadhesive tablets of domperidone using *Salvia plebeian* gum

**Abstract**

The aim of study was to prepare controlled release matrix mucoadhesive tablets of domperidone using *Salvia plebeian* gum as natural polymer. Tablets were formulated by direct compression technology employing the natural polymer in different concentrations (5, 10, 15 and 20% w/w). The prepared batches were evaluated for drug assay, diameter, thickness, hardness and tensile strength, swelling index, mucoadhesive strength (using texture analyzer) and subjected to *in vitro* drug release studies. Real-time stability studies were also conducted on prepared batches. *In vitro* drug release data were fitted in various release kinetic models for studying the mechanism of drug release. Tensile strength was found to increase from 0.808 ± 0.098 to 1.527 ± 0.10 mN/cm

2 and mucoadhesive strength increased from 13.673 ± 1.542 to 40.378 ± 2.345 N, with an increase in the polymer concentration from 5 to 20% (A1 to A4). Swelling index was reported to increase with both increase in the concentration of gum and the time duration. The *in vitro* drug release decreased from 97.76 to 83.4% (A1 to A4) with the increase in polymer concentration. The drug release from the matrix tablets was found to follow zero-order and Higuchi models, indicating the matrix-forming potential of natural polymer. The value of *n* was found to be between 0.5221 and 0.8992, indicating the involvement of more than one drug release mechanism from the formulation and possibly the combination of both diffusion and erosion. These research findings clearly indicate the potential of *S. plebeian* gum to be used as binder, release retardant and mucoadhesive natural material in tablet formulations.

**Key words:** Binder, drug release mechanism, mucoadhesion, release retardant, *Salvia plebeian* gum

**INTRODUCTION**

Oral route of drug administration is the ideal, convenient and preferred route.[1] Conventional oral drug administration does not generally offer target specificity or rate-controlled release. In controlled release drug delivery systems (CRDDSSs), an active therapeutic is incorporated in the network structure of the polymer in such a way that the drug is released in a predefined controlled manner.[2] Prolonging gastric residence time (GRT) is the most important objective of CRDDSSs as short GRT is the major hindrance in the development of CRDDSSs. The prolonged residence time of the drug in the body is believed to prolong its duration of action.[3,4] Mucoadhesive controlled drug delivery systems offer several advantages over other CR systems since they provide a controlled drug release over time, and target and localize the dosage form to a specific site.[5] Mucoadhesive drug delivery devices can be applied to any mucosal tissue in the body, including the gastrointestinal, ocular, respiratory, buccal, nasal, rectal, urethral and vaginal path.[6,7] Since the GI tract is covered by a mucus layer, localization of a mucoadhesive drug delivery system to a specific site is very beneficial. Depending upon the drug
delivery system, the drug release time may vary from a few hours to months or even several years. Gastroretentive drug delivery techniques (GRDDTs) are principally CRDDSs, which increase GRT, consequently serving in absorption of drug for the projected time duration. Diverse means for preparation of gastroretentive drug delivery formulations include mucoadhesive systems, floating systems, swellable and expandable systems, high density system, altered shape systems, gel forming solution or suspension system and sachet systems.[8-9] Mucoadhesion has been an extensively adapted approach of achieving site-specific drug delivery through the amalgamation of mucoadhesive polymers within pharmaceutical formulations along with the active pharmaceutical ingredient (API). Mucoadhesive materials are hydrophilic macromolecules containing numerous hydrogen bond forming groups. The mechanism by which mucoadhesion takes place has been said to have two stages, the contact (wetting) stage followed by the consolidation stage (the establishment of the adhesive interactions).[10]

Domperidone is an antidopaminergic drug widely used in the treatment of motion sickness. Domperidone is chemically known as 5-chloro-1-[1-[3-(2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1-yl)propyl]piperidin-4-yl]-1H-benzo[d]imidazol-2(3H)-one. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure. It is rapidly absorbed from the stomach and the upper part of the GIT by active transport, after oral administration, and few side effects have been reported. It is a weak base with good solubility in acidic pH, but in alkaline pH, the solubility is significantly reduced. Oral controlled release dosage forms containing drug, which is a weak base, are exposed to environments of increasing pH and poorly soluble freebase may get precipitated within the formulation in the intestinal fluid. Precipitated drug is no longer capable of being released from the formulation. The short biological half-life of the drug (7 hours) also favors development of a sustained release formulation.[11]

Salvia plebeian gum is obtained from Butea frondosa trees belonging to the family Papilionaceae. In India, this herb is known as kamarkas, which means fortification of back muscles; it acts as a tonic to pelvic and back muscles during menstruation, pregnancy and after delivery. The gum mainly contains tannins and gallic acid and for this reason is used as a mild astringent useful in phthisis and hemorrhage of the stomach and also as an anthelmintic. The plant is used as a refreshment and sterile for promoting urination and is useful in thread worm infections.[12] The pharmaceutical applications of S. plebeian gum as tablet binder, release retardant and as a mucoadhesive agent are unexplored.

The present study was aimed at the formulation and evaluation of controlled release matrix mucoadhesive tablets of domperidone using S. plebeian gum. The prepared batches were evaluated for tablet parametric test (drug assay, diameter, thickness, hardness and tensile strength), swelling index, mucoadhesive strength (using texture analyzer) and in vitro drug release studies. Real-time stability studies were also performed on all the formulated batches.

MATERIALS AND METHODS

Materials

Domperidone was received as a gift sample from Helios Pharmaceuticals, Baddi, India. Vivapur 102 was obtained as a gift sample from S. Zhaveri, Mumbai, India. S. plebian (powder) was procured from Yarrow Chem, Mumbai, India. Talc and magnesium stearate were purchased from S. D. Fine Chemicals Ltd., Mumbai, India. All other chemicals and reagents were of analytical grade and were used as such.

Methods

Preparation of S. plebeian gum tablet

S. plebeian gum based controlled release matrix mucoadhesive tablets containing domperidone were prepared using the direct compression technology. Vivapur 102 was used as filler for increasing the compressibility. Domperidone, S. plebeian gum and Vivapur 102 were passed through 60 mesh sieve and mixed thoroughly in varying concentrations according to formulae [Table 1]. Finally, talc and magnesium stearate were added and mixed thoroughly. The directly compressible mixture was compressed using single stroke multipunch tableting machine (AK Industries, Nakodar, Punjab, India) fitted with 8.40-mm, flat faced punch and die set possessing 50 ton compression force.

Evaluation of tablets

Friability

Twenty tablets of each batch were weighed and put into the friabilator drum (Digital friability test apparatus, Model 102 EL make). After 100 revolutions of friabilator, tablets were recovered. The tablets were then freed from dust and weighed. Friability was calculated from the following formula:

\[
\text{Percentage friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100
\]

\[\text{Table 1: Composition of the formulated batches of domperidone}\]

| Ingredients (mg) | A1 | A2 | A3 | A4 |
|------------------|----|----|----|----|
| Domperidone      | 30 | 30 | 30 | 30 |
| Salvia plebeian gum | 10 | 20 | 30 | 40 |
| Vivapur 102      | 156| 146| 136| 126|
| Talc             | 2  | 2  | 2  | 2  |
| Magnesium stearate | 2  | 2  | 2  | 2  |
**Tablet Crushing Strength**

A Monsanto tablet hardness tester was used to measure the force needed to fracture the tablets. The dimensions (the diameter and the thickness) were determined using calibrated vernier caliper. For measuring the hardness of the tablets, the plunger of the hardness tester was driven down at a speed of 20 mm/min. Tensile strength for crushing (T) was calculated using the equation:

\[ T = \frac{2F}{\pi dt} \]

where “F” is the crushing load and “d” and “t” denote the diameter and thickness of the tablet, respectively.

**Determination of Drug Content**

Twenty tablets from each batch were weighed and powdered. Powder equivalent of 30 mg of domperidone was accurately weighed and transferred into a 100 ml volumetric flask and dissolved in suitable quantity of 0.1 N HCl. The prepared solution was diluted up to 100 ml with 0.1 N HCl and sonicated for 60 min. Ten milliliters of the resulting solution was diluted to 100 ml with 0.1 N HCl to get a concentration in the range of 30 µg/ml. A portion of the sample was filtered through 0.45 µm membrane filter and analyzed at 284 nm by UV/Vis double-beam spectrophotometer (Systronics 2202, Ahmedabad, Gujarat, India).

**Swelling Index**

Swelling study of individual polymers and combinations was carried out using eight-stage USP type 1 (basket) Dissolution Test Apparatus (Lab India, DS 8000) at 50 rpm, and 0.1 N HCl was used as medium, and the temperature was maintained at 37 ± 0.5°C. Weight of individual tablet was taken prior to the swelling study (W₁). The tablet was kept in a basket. The weight of tablet was taken at time interval of 2, 4, 8, 12 hours (W₂). Percent hydration (swelling index) was calculated as shown in Table 2 using the following formula:

\[ \text{Swelling index} = \frac{(W₂ - W₁) \times 100}{W₂} \]

where W₁ is the initial weight of tablet and W₂ is the weight of hydrated tablet.

**In vitro Dissolution**

The release of domperidone from the mucoadhesive matrix tablet systems was measured by eight-stage dissolution apparatus II (paddles) USP (Lab India, DS 8000). The test was performed at 37 ± 0.5°C with a rotation speed of 50 rpm using 900 ml of 0.1 N HCl, pH 1.2, as a dissolution medium. According to the sampling plan, samples of 5 ml were withdrawn and immediately replaced with an equal volume of the respective dissolution medium maintained at 37 ± 0.5°C. Test samples were filtered through Whatman filter paper No. 41 (Whatman Paper Limited, Surrey, UK), and assayed for domperidone at 284 nm using a blank solution as reference with a UV-Vis double-beam spectrophotometer (Systronics 2202, India). The tests were performed in triplicate. The cumulative percentage of domperidone dissolved was calculated using a regression equation generated from the standard data.

**Kinetics and Mechanism of Release Analysis**

To study the release kinetics, the data obtained from *in vitro* drug release studies were plotted in various kinetic models.

Zero order, as cumulative amount of drug released versus time [Figure 1], describes concentration-independent drug release rate from the formulation (Equation 1):

\[ C = k₀t \]  \hspace{1cm} (1)

where \( k₀ \) is the zero-order rate constant expressed in units of concentration/time and \( t \) is the time in hours.

First order, as log cumulative percent drug remaining versus time [Figure 2], describes concentration-dependent drug release from the system (Equation 2):

\[ \log C = \log C₀ - \frac{kt}{2.303} \]  \hspace{1cm} (2)

where \( C₀ \) is the initial concentration of drug and \( k \) is the first-order constant.

Higuchi’s model,[13] as cumulative percentage of drug released versus square root of time [Figure 3], describes the release of drugs based on Fickian diffusion as a square root of time-dependent process from swellable insoluble matrix (Equation 3):

\[ Q = kt^{1/2} \]  \hspace{1cm} (3)

where \( k \) is the constant reflecting the design variables of the system.

Hixson-Crowell cube root law,[14] as the cube root of percentage drug remaining versus time [Figure 4],

![Figure 1: Zero-order release model of domperidone from *Salvia plebeian* tablets](image)
correlated the release from systems with polymer erosion/dissolution resulting in a change in surface area and diameter of particles or tablets (Equation 4):

\[ Q_0^{1/3} - Q_t^{1/3} = k_{HC}t \]  

(4)

where \( Q_t \) is the amount of drug released in time \( t \), \( Q_0 \) is the initial amount of the drug in the tablet, and \( k_{HC} \) is the rate constant for the Hixson-Crowell rate equation.

**Mechanism of drug release**

Korsmeyer et al.\[^{15,16}\] derived a simple relationship which described drug release from a polymeric system (Equation 5). To find out the mechanism of drug release, first 60% drug release data were fitted in Korsmeyer-Peppas model [Figure 5].

\[ M_t/M_\infty = k_{KP}t^n \]  

(5)

where \( M_t/M_\infty \) is fraction of drug released at time \( t \), \( k_{KP} \) is the rate constant and \( n \) is the release exponent. The \( n \) value is used to characterize different release mechanisms as given in table for cylindrical shaped matrices [Table 3].

**Ex vivo Bioadhesive Strength Determination**

Bioadhesion was evaluated using a texture analyzer (TAXT plus, Stable MicroSystems, Maidstone, UK) setup for adhesion experiments controlled by the Texture Exponent software with 50 N load cell equipped with mucoadhesive holder. Experimental conditions, such as the contact force, contact time and probe speed, were selected based on preliminary experiments. Porcine gastric mucosa was utilized as the model membrane for mucoadhesive strength determination of various formulations. Small portions (approximately 4 cm\(^2\)) were cut and each sample was placed on the sample holder. A tablet was carefully attached to a 10-mm cylindrical probe (TA probe) by a double-face tape. The upper platform was moved downward manually near to the mucosa surface and then the polymer sample was brought toward the mucosa at a constant speed of 0.5 mm/s until a predetermined compressive force of 1 N was applied for 60 s. The probe was then removed at 0.5 mm/s to a distance of 15 mm and maximum detachment force (N) was determined for each sample. For each new sample, a different mucosa sample was used.\[^{17}\]

**Real-time Stability Studies**

Real-time stability studies were carried out by keeping
the formulated tablets at room condition (at varying temperature and humidity of summer and winter of Punjab, India). One hundred tablets of each batch were securely packed in HDPE bottles (Riddhi Packages Private Limited, Baddi, HP, India) and kept in an isolated chamber in laboratory. Tablets were evaluated at 0 day and after 3 and 6 months for drug assay, tensile strength and mucoadhesive strength.

RESULTS AND DISCUSSION

Tablet Parametric Tests
The parametric tests were performed on formulated tablets [Table 4]. The assayed content of drug in various formulations varied between 98.52 ± 0.11 and 100.60 ± 0.34%. Thickness of tablets lied between 3.92 ± 0.01 and 3.96 ± 0.05 mm. Prepared tablets had hardness values ranging between 4.5 ± 0.50 and 8.5 ± 0.50 kg/cm², indicative of adequate strength to provide good tensile strength, matrix forming potential and dissolution profiles, and above all, to prevent friability losses. The formulation does not include binding agent. These values indicate the binding potential of S. plebeian gum. Tablets tested from each batch exhibited friability values ranging between 0.06 and 0.13% w/w (0.10 ± 0.01%), far less than the limit of 0.8% w/w, considered as acceptable by the official compendia. Tablet crushing strength increased from 0.808 ± 0.098 to 1.527 ± 0.10 (A1 to A4) on rising the polymer concentration from 5 to 20% (A1 to A4). This boost in crushing strength indicates extensive binding potential of S. plebeian gum in a concentration-dependent manner.

Swelling Index
The percentage water uptake of the formulations (A1-A4) was calculated [Table 2]. Results demonstrate enhancement in the swelling index with an increase in polymer concentration and also time duration. Increase in polymer concentration from 5 to 20% (A1-A4) increased the swelling after 12 hours from 57.44 ± 0.50 to 64.73 ± 0.78%. With increasing time from 2 to 12 hours in formulation A4, the swelling index increased from 33.33 ± 0.33 to 64.73 ± 0.78%. This may be due to the hydrophilic property of S. plebeian gum. The concentration-dependent increase in mucoadhesive strength may be due to the swelling of the gum aiding in the interpenetration of polymeric chains with the mucin present on the gastric mucosa. Moreover, swelling of the polymer also leads to the formation of matrix, thereby retarding the release of drug from the formulation.

Texture Profile
Textural analyses provide information on the mechanical properties of samples, namely, hardness, compressibility and adhesiveness. These properties can be directly correlated with sensory parameters in vivo and therefore are valuable in the development of a product with desirable attributes that contribute to patient acceptability and compliance. Increasing trends were seen in the mucoadhesive strength from 13.673 ± 1.542 to 40.378 ± 2.345 (A1 to A4) with increasing concentration of natural polymer from 5 to 20% (from A1 to A4) [Figure 6]. These trends indicate the extensive mucoadhesive potential of S. plebeian gum. This rise in mucoadhesive strength by increasing the polymer amount may provide more adhesive sites and polymer chains for interpenetration with mucin, resulting in augmentation of bioadhesive strength. Moreover, appropriate rise in tensile strength with the polymer concentration was sufficient to keep the formulation intact for exhibiting the phenomenon of mucoadhesion. This mucoadhesive strength is instrumental for the development of gastroretentive mucoadhesive controlled release formulations.

| Batch | Swelling index (%) |
|-------|--------------------|
|       | 2 hours | 4 hours | 8 hours | 12 hours |
| A1    | 24.53 ± 0.33 | 45.94 ± 0.87 | 54.54 ± 0.33 | 57.44 ± 0.50 |
| A2    | 25.92 ± 0.78 | 47.36 ± 0.65 | 52.60 ± 0.81 | 58.67 ± 0.65 |
| A3    | 28.57 ± 0.26 | 50 ± 0.89 | 58.33 ± 0.59 | 62.04 ± 0.45 |
| A4    | 33.33 ± 0.33 | 55.55 ± 1.09 | 60.25 ± 0.40 | 64.73 ± 0.78 |

**Table 2: Swelling index of various batches**

| Diffusion exponent (n) | Mechanism of drug release |
|------------------------|---------------------------|
| 0.45                   | Fickian diffusion         |
| 0.45 < n < 0.89        | Anomalous (non-Fickian) diffusion |
| 0.89                   | Case II transport         |

| n > 0.89              | Super case II transport   |

**Table 3: Diffusion exponent (n) and drug release mechanism for cylindrical shape**

| Parameters | A1 | A2 | A3 | A4 |
|------------|----|----|----|----|
| Diameter (mm) | 8.40 ± 0.06 | 8.42 ± 0.02 | 8.41 ± 0.03 | 8.42 ± 0.05 |
| Thickness (mm) | 3.94 ± 0.02 | 3.96 ± 0.05 | 3.92 ± 0.01 | 3.93 ± 0.04 |
| Hardness (kg/cm²) | 4.5 ± 0.50 | 5.5 ± 0.80 | 7.55 ± 0.60 | 8.5 ± 0.50 |
| Tensile strength (mN/m) | 0.808 ± 0.098 | 0.980 ± 0.15 | 1.362 ± 0.11 | 1.527 ± 0.10 |
| Friability (%) | 0.09 ± 0.01 | 0.06 ± 0.02 | 0.04 ± 0.02 | 0.03 ± 0.01 |
| Drug content (%) | 99.11 ± 0.23 | 98.52 ± 0.11 | 99.76 ± 0.67 | 100.60 ± 0.34 |

**Table 4: Physical evaluation of formulated batches of controlled release matrix mucoadhesive tablet**
**In vitro Drug Release**

In vitro drug release [Figure 1] shows release retardant and matrix development properties of *S. plebeian* gum. The in vitro drug release decreases from 97.76 to 83.4 (A1 to A4) with increasing polymer concentration from 5 to 20% (A1 to A4), demonstrating concentration-dependent matrix formation. Matrix formation ability and swell ability of the natural polymer may be retarding the drug release from the formulated tablets. Several kinetic models describe drug release from immediate and modified release dosage forms. The model that best fits the release data was evaluated by correlation coefficient (r) [Table 5]. The correlation coefficient (r) values were used as the criteria to choose the best model to describe drug release from the mucoadhesive controlled release tablets. The r-values ($r^2 = 0.9891$) obtained for fitting the drug release data to the Higuchi equation indicated that the drug release mechanism from these tablets was diffusion controlled. In most of the formulated tablets, the $r^2$ values (0.9805) were higher in zero-order models than in first-order (0.9401) model, indicating that the drug release from most of the tablets was according to zero-order kinetics and thus showing that the drug release rate was independent of the residual concentration of drug. The mechanism of drug release from polymer-based matrices is complex and not completely understood. Some systems may be classified as either purely diffusion or erosion controlled, while most systems exhibit a combination of these mechanisms. By using Korsmeyer-Peppas equation, the $n$ values obtained were between 0.5221 and 0.8992 [Table 5] for all formulations. These values are characteristic of anomalous kinetics (non-Fickian) and super case-II transport, suggesting that more than one mechanism may be involved in release kinetics, referring to combination of diffusion and erosion based drug release mechanism. This mechanism could result from an increased plasticization at the relaxing boundary.

**Real-time Stability Studies**

Effect of real-time storage conditions on the tensile strength, mucoadhesive strength and drug assay of various batches of domperidone tablets were studied [Table 6]. Results demonstrate there was no noteworthy alteration in the tensile strength, mucoadhesive strength and drug assay after 3 months, but a decrease in tensile and mucoadhesive strength was observed after 6 months, which may be due to absorption of water by the formulation, indicating more stringent packaging requirement of the formulation so as to protect the same from environmental conditions.

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**Table 5: Release kinetic data of the formulated tablet batches**

| Batch | Zero order | First order | Higuchi | Korsmeyer-Peppas | Hixson-Crowell |
|-------|------------|-------------|---------|------------------|---------------|
|       | $r^2$      | $K_0$ (h$^{-1}$) | $r^2$ | $K_1$ (h$^{-1}$) | $r^2$ | $K_H$ (h$^{-1/2}$) | $r^2$ | $n$ | $K_{kp}$ (h$^{-n}$) | $r^2$ | $K_{KP}$ (h$^{-n}$) |
| A1    | 0.937      | 0.1278      | 0.929   | -0.0026          | 0.9864  | 3.8259              | 0.9454  | 0.5221 | 0.46                | 0.9641  | -0.0055 |
| A2    | 0.9391     | 0.1266      | 0.9341  | -0.0025          | 0.987   | 3.7883              | 0.9402  | 0.6372 | 0.2137             | 0.9655  | -0.0053 |
| A3    | 0.9472     | 0.1149      | 0.9401  | -0.0024          | 0.9891  | 3.4261              | 0.9427  | 0.6968 | 0.0051             | 0.9544  | -0.0050 |
| A4    | 0.9805     | 0.1175      | 0.8632  | -0.0021          | 0.9853  | 3.4355              | 0.956   | 0.8992 | -0.5786            | 0.9048  | -0.0047 |

Mean ± SD, n = 3

**Table 6: Real-time stability studies**

| Batch | Tensile strength (mN/m$^2$) | Mucoadhesive strength (N) | Drug assay (%) |
|-------|----------------------------|---------------------------|---------------|
|       | 0          | 3            | 6          | 0       | 3           | 6       | 0        | 3      | 6      |
| A1    | 0.808 ±   | 0.800 ±     | 0.656 ±   | 13.673 ± | 12.543 ±   | 11.28 ± | 99.11 ±  | 98.90 ±| 99.7 ± |
| A2    | 0.980 ±   | 0.965 ±     | 0.873 ±   | 18.052 ± | 19.732 ±   | 15.402 ±| 98.52 ±  | 98.80 ±| 98.27 ±|
| A3    | 1.362 ±   | 1.323 ±     | 1.191 ±   | 23.287 ± | 22.400 ±   | 19.763 ±| 99.76 ±  | 99.7 ± | 99.57 ±|
| A4    | 1.527 ±   | 1.490 ±     | 1.320 ±   | 40.378 ± | 38.750 ±   | 35.264 ±| 100.60 ± | 99.97 ±| 99.5 ± |

Mean ± SD, n = 3
CONCLUSION

The evaluation studies on controlled release matrix mucoadhesive tablets using *S. plebeian* gum as natural material demonstrate the multifunctional application (binder, release retardant and mucoadhesive) of the gum in tablet formulation. The significant reduction in the release of drug and proportionate enhancement in mucoadhesive strength provided by *S. plebeian* gum could make it a favorable natural material for its applications in other pharmaceutical dosage forms.

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