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Preparation and *In-Vitro* Evaluation of Sodium Alginate Based Gastroretentive Floating Tablet of Domperidone

Tushar Saha[1], Zia Uddin Masum[1] and Sania Ashrafi[2]

[1]Department of Pharmaceutical Technology, [2]Department of Pharmacy,
Faculty of Pharmacy, University of Dhaka, Dhaka-1000, Bangladesh

Corresponding Author: Tushar Saha

ABSTRACT

The current study demonstrates the preparation and *in vitro* evaluation of gastroretentive floating tablet of Domperidone where sodium alginate was used as release controlling polymer. For gas generating agent, sodium bicarbonate was used. Tablet was prepared by direct compression technique. Physical parameters, *in vitro* buoyancy study, total floating time and zero order drug release study were performed. 0.1N HCl (pH 1.2) was used as dissolution medium which was used in USP II apparatus for 12 hours in order to find out the drug release pattern. Evaluated physical parameters were within acceptable range. Compatibility between drug and polymer was found in Fourier Transform Infrared Spectroscopy (FTIR) study.

Key words: Gastro retentive floating tablets, sodium alginate, compatibilty

INTRODUCTION

Oral sustained release dosage forms have been increased as they have considerable advantages. [1] Again, many drugs are not suitable to administer in oral sustained form because of the narrow absorption window in the upper part of GIT because of the short transit time in this regions. Therefore, after a short time later (<6hr), this dosage forms lefts the upper part of GIT and it is released in the non-absorbing distal part of the GIT. This reduces the bioavailability of the drug because of short absorption phase. It is often suggested to formulate this narrow absorption window drug in gastro retentive dosage form so as to extend the absorption phase. This dosage form helps to release drug in a sustained manner in the upper part of stomach after the oral administration of the drug. This way of administration would achieve the pharmacokinetic and pharmacodynamics advantages of sustained release dosage form for these types of drugs. [2,3] This is why gastro retentive dosage form has become popular and industry as well as academia is formulating this dosage form. [4] The approaches may be a) low density dosage form [5] b) high density dosage form c) mucoadhesive dosage form [6] d) lowered motility of GIT by administration of drugs and/or excipients [7] e) self-unfolding dosage form. Among those, low density dosage form which is floating drug delivery is getting preference day by day.

Domperidone is a benzimidazole derivative and is structurally related to butyrophenone neuroleptics like haloperidol. It is an antiemetic drug. It has wide range of use in the treatment of nausea, vomiting, gastroparesis, Parkinson's disease, lactation as well as upper gastrointestinal motility disorders. [8,9] There have been several reports concerning the degradation of Domperidone in intestinal fluid and its influence on bioavailability. [10]

Based on this, this experiment is design to formulate the gastro retentive floating tablet of Domperidone using sodium alginate as sustained release polymers and gas forming agent ($NaHCO_3$). After the preparation, physical characterization, floating property, drug release, drug polymer compatibility study was evaluated.

MATERIALS AND METHODS

Domperidone was obtained from ACI Pharmaceuticals Ltd. Bangladesh and Sodium Alginate was obtained from Loba Chemie, India. Other chemicals used in this experiment were of analytical grade.

Preparation of gastroretentive floating Domperidone tablet. Direct compression technique was applied to prepare gastroretentive floating tablet of Domperidone. Drug and polymer and other excipients were weighed according to the proposed formulations shown in table 1. Drug (Domperidone) and other excipients were blended and mixed. After mixing, direct compression was applied in tablet machine to prepare the tablets. [11]

Table.1: The composition of different gastroretentive floating Domperidone (DOM) formulations.

Formulation	DOM (mg)	Sodium Alginate (mg)	Microcrystalline cellulose (mg)	Sodium Bi-carbonate (mg)	Magnesium Stearate (mg)	Talc (mg)	Total weight (mg)
X-1	30	15	110	20	2	3	180
X-2	30	30	95	20	2	3	180
X-3	30	45	80	20	2	3	180
X-4	30	60	65	20	2	3	180
X-5	30	75	50	20	2	3	180

Physical properties characterization of prepared gastroretentive floating tablets. Tablet average weight, diameter, thickness, hardness, friability were measured according to the official USP pharmacopeia method.

***In vitro* buoyancy study.** Prepared floating tablet was placed in a 100ml beaker containing 0.1N HCl. Floating lag time and floating duration time was measured from there to study the *in vitro* buoyancy study.

***In vitro* dissolution study.**USP dissolution testing apparatus II (paddle type) was used to determine the release rate of Domperidone from tablets. 900 ml of simulated gastric fluid containing phosphate buffer of pH 1.2 at 37 ± 0.5 ºC and 50 rpm was maintained to perform the dissolution test. Definite volume was withdrawn from the dissolution apparatus hourly for 12h and the samples were replaced with fresh dissolution medium. The amount of drug release was determined from the standard calibration curve of pure drug after completing the filtration. Drug release was studied by different kinetics and models to get the release pattern. Zero order kinetics was applied to find out the release pattern of the floating tablets.

Drug- polymers compatibility study. Fourier Transform Infrared Spectroscopy (FTIR) was used and scanned (4000 cm^{-1} to 500 cm^{-1}) for checking any interaction between drug and polymer. For this purpose Fourier Transform Infrared Spectroscopic (FTIR) study was conducted for pure drug (Domperidone), sodium alginate and physical mixture of drug and polymer.

RESULTS AND DISCUSSION

Physical properties of prepared gastroretentive floating tablets of Domperidone. Physical properties of tablets which are diameter, thickness, hardness, weight variation, friability were measured by according to the official USP pharmacopeia method and all the data were within the range of official value. All the data are tabulated in table 2

Table.2: Physical properties of gastroretentive floating tablets of Domperidone.

Formulation Code	Average Weight (mg)	Diameter(mm)	Thickness(mm)	Hardness(kg/cm^2)	Friability(%)
X-1	178±2.21			5.45±0.27	0.27
X-2	178±3.65			5.58±0.13	0.16
X-3	179±4.43	7.04±0.03	4.04±0.02	5.43±0.41	0.44
X-4	180±3.24			5.51±0.18	0.32
X-5	178±3.12			5.63±0.29	0.56

***In vitro* buoyancy study of prepared gastroretentive floating tablets of Domperidone.** *In vitro* buoyancy study which was floating lag time and total floating time were performed for all the formulations. Maximum lag time was observed for formulation X-5 and minimum lag time was observed for formulation X-1. (Table 3) Total floating time for all formulations is tabulated in table 3.

***In vitro* drug release study.** Drug release patterns are demonstrated in figure 1. From figure, it is clear that, the higher the amount of polymers used the release pattern became more sustained. This is why X-1 showed better release than X-5. X-5 showed the best sustaining properties.

Table.3: *In vitro* buoyancy characterization of gastroretentive floating tablets of Domperidone.

Formulation Code	Floating lag time (sec)	Total floating time (hour)
X-1	12	>12
X-2	19	>12
X-3	23	>12
X-4	29	>12
X-5	31	>12

Drug-polymers compatibility study. FTIR spectrum of Domperidone, Sodium alginate and the physical mixture of Domperidone and polymer are shown in figure 2. From figure 2 it is clear that, no absence of identical peaks are observed in case of pure drug (Domperidone) and the physical mixture of drug and polymer which indicated that, no polymorphic changes are occurred and good compatibility of drug with polymers.

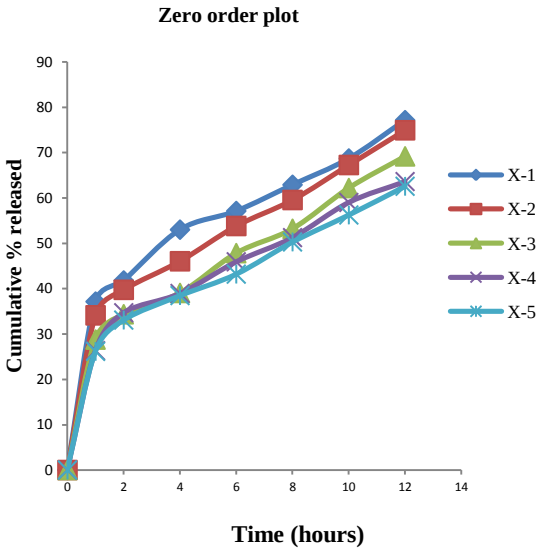
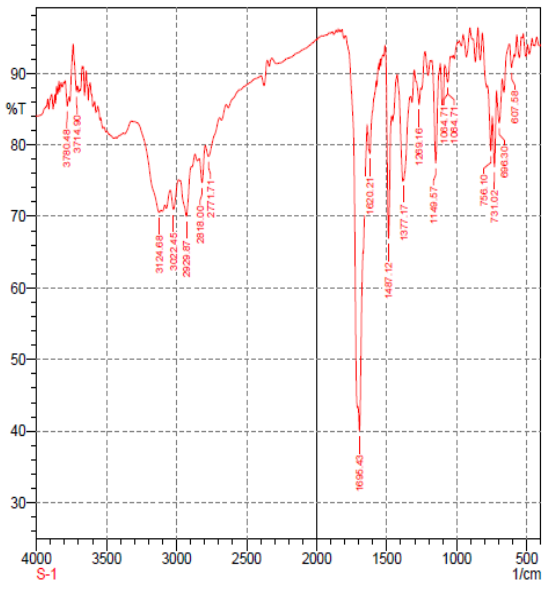
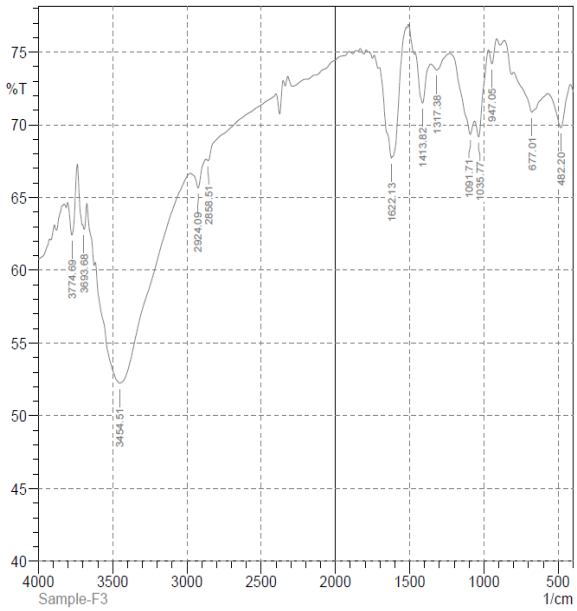


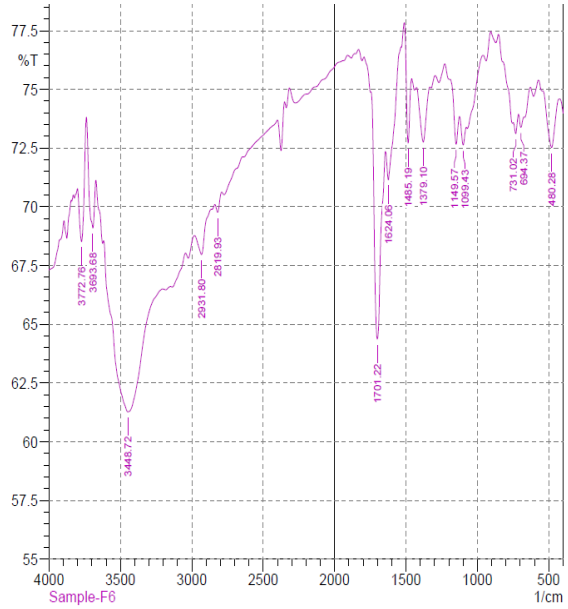
Figure 1. Different release patterns of formulations (X1-X5)



(A)



(B)



(C)

Figure 2.FTIR spectrum of (A) Domperidone (B) Sodium alginate (C) Domperidone and Sodium alginate mixture.

CONCLUSIONS

Gastroretentive floating tablets of Domperidone was successfully formulated and prepared. Drug release enhanced and sustained release property was achieved which was reflected from the obtained result.

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