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Research Article

PREPARATION AND EVALUATION OF GASTRORETENTIVE FLOATING TABLET CONTAINING ENALAPRIL MALEATE

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ABSTRACT

This study was aimed at developing an oral floating system of drug Enalapril Maleate. The objective of study was to increase Oral bioavailability& increase gastric residence time. There are 8 formulations were prepared using different ratios of natural polymers. Carrageenan is the rate controlling polymer& Carbopol934p having the adhesive property to bind the GIT wall. Also the xanthan gum for floating property, guar gum for binder and gelling property were used. F7 was the optimized formulation having floating time more than 15 hrs

Keywords: Gastro retentive floating tablet, Natural polymer, Enalapril maleate**.**

INTRODUCTION

Various oral dosage forms deliver the drug for longer period. & help in producing the therapeutic affect for 24hrs, For Drugs those which are having low plasma half life in GIT. Gastrointestinal tract have poor absorption for these drugs. To maintenance of constant therapeutic efficacy there are various approaches of Gastro retentive Floating Drug Delivery System-i.e. Floating System, Bioadesive System, Low Density System, High Density System, Expandable System. The drug Enalapril Maleate is ACE inhibitor class1 antihypertensive drug belonging criteria. The drug have an oral bioavailability 40-60% seems to be due to narrow absorption window in the Upper part of the Small intestine & drug get absorbed in the upper part of small intestine. In the present investigation, the gastro retentive tablet dosage form is prepared using Enalapril Maleate as drug candidate.[1,2,3,4,5,6]

MATERIALS AND METHODS

Materials

Enalapril Maleate was procured from the pharmaceutical company and all other ingredients were obtained procured from the college.

Methods

Preparation and formulation of floating tablet

The tablets were prepared by direct compression technique using 8 mm punch. The tablet of different concentration were prepared. The entire ingredient were mixed and punched in single punch machine (Cadmach). Each Tablet containing 20mg of Enalapril maleate, polymers and sodium bicarbonate and ingredients are listed in table of formulation (Table 1).

Evaluation of gatroretentive floating tablet

The General appearance of the tablet, its visual identification, overall elegance is essential for customer acceptance. It includes tablets size, shape, colour, presence or absence of an odor, taste, surface texture etc.

and diameter of tablets were important for uniformity of tablet size. Tablet hardness of three tablets was determined using Monsanto hardness tester. Weight variation, Friability, Drug content uniformity, swelling behavior, *In-Vitro* buoyancy study, *In-Vitro* dissolution study, was performed according to the official method in Indian Pharmacopoeia.[7,8,9,10].

Table 1: Formulation of gastro retentive floating tablet

S. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
1	Enalapril Maleate	20	20	20	20	20	20	20	20
2	Carrageenan	70	90	-	-	-	-	23	30
3	Carbopol934p	2	2	2	2	2	2	2	2
4	Xanthan gum	-	-	-	-	70	90	23	30
5	Guar gum	-	-	70	90	-	-	23	30
6	Sodium bicarbonate	4	4	4	4	4	4	4	4
7	Microcrystalline cellulose	98	78	98	78	98	78	99	98
8	Magnesium stearate	3	3	3	3	3	3	3	3
9	Talc	3	3	3	3	3	3	3	3
10	Total wt in mg	200	200	200	200	200	200	200	200

Table 2: Evaluation of enalapril maleate floating tablets

Batch	Tablet Size (mm)	Thickness±S.D (mm)	Hardness ±S.D	Weight variation ±S.D.	Friability (%)	Drug Content (%)
F1	8±0.2	3.25±0.045	4.03±1.05	196.6±8.16	1	91.73
F2	8±0.2	3.20±0.16	4.66±0.48	198.3±7.5	0.81	93.04
F3	8±0.2	4.16±0.28	4.76±0.58	200.0±8.9	0.82	96.87
F4	8±0.2	3.5 ±0.00	4.16±0.28	199.6±3.50	0.89	98.94
F5	8±0.2	3.25±0.045	4.00±0.5	203.3±5.16	0.47	90.62
F6	8±0.2	3.22±0.040	5.83±0.28	200.5±3.37	0.64	100.86
F7	8±0.2	3.12±0.05	5.5±0.5	199.5±3.35	0.71	100.55
F8	8±0.2	3.18±0.12	4.5±0.5	199.9±3.46	0.70	99.29

Table 3: Floating and buoyancy time of enalapril maleate tablets

Formulations	Floating Lag Time ±SD (sec)	Total floating time(hrs)
F1	50±10	>10
F2	40±8.6	>8
F3	22±7.5	>11
F4	42±1.52	>18
F5	61±1.15	>18
F6	59±10.06	>15
F7	69±2.88	>16
F8	63±4.04	>15

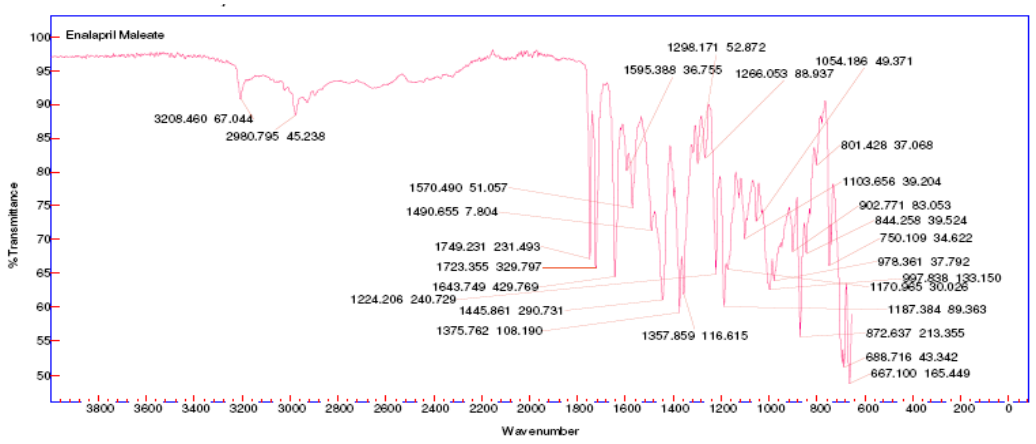

Fig. 1: Infrared spectrum of Enalapril maleate

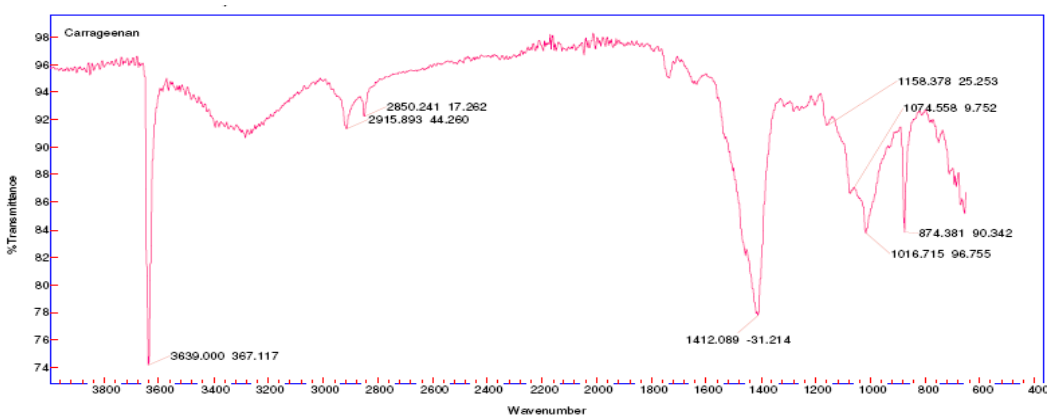

Fig. 2: Infrared spectrum of carrageenan

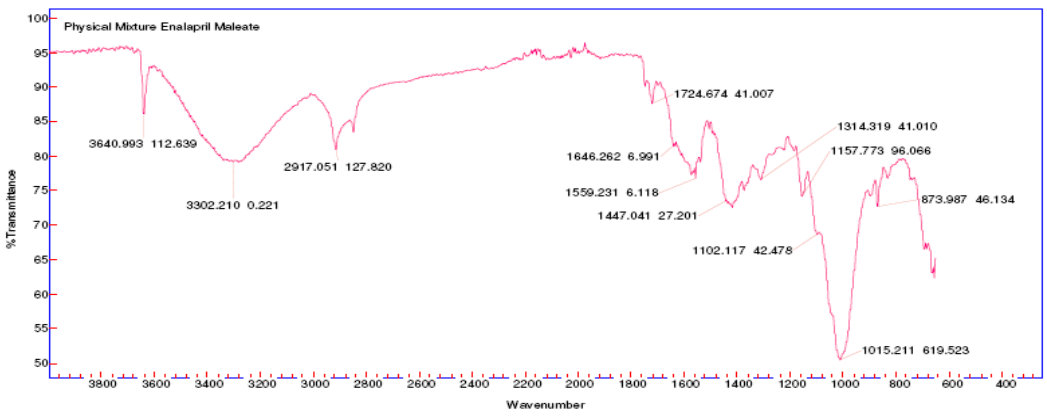

Fig. 3: Infrared spectrum of EM + Guar gum + Xanthan Gum+Carrageenan+Carbopol934P (F8)

At Initial Stage

after 15 Hours

Fig. 4: Floating tablet

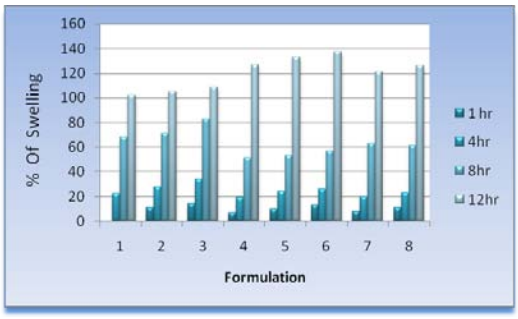

Fig. 5: Swelling time of formulation F1-F8

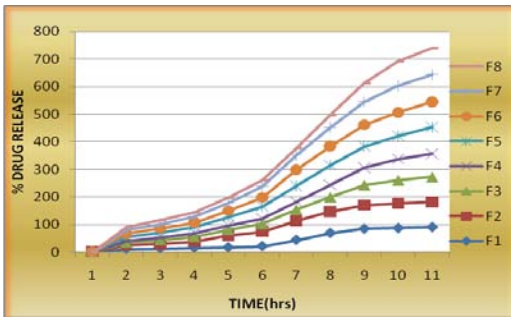

Fig. 6: Comparative % drug release of formulation f1-f8

RESULTS AND DISCUSSION

The sample of Enalapril Maleate procured as gift sample was found as a white, virtually odorless, crystalline powder. The average of three determination of melting point was carried out and the result is 136±2 ^{0}C.The melting point was found 145^0. Compatibility study of excipients and Enalapril Maleate alone and in combinations was completed with conclusion of no incompatibility between them (Fig.1, 2 and 3). Hardness of the tablet between the range 4-5.5., friability between the range 0.47-1%.& thickness was found to be 3.25-4.16(mm) (Table 2). F7 was the optimized formulation having floating time more than 15 hrs & floating lag time was found to be 69sec. (Table 3). The i*n vitro* dissolution studies were carried out by using USP apparatus type II at 50 rpm. The dissolution medium was 900ml 0.1N HCl maintained at 37± 0.5^{0}C. Aliquots of dissolution medium were withdrawn at predetermined intervals and content of EM was determined at 207 nm spectrophotometrically.% Drug release of optimized batch F7 was found to be 99.19%.

CONCLUSION

The aim of present study was to explore the feasibility of natural polymers in the acquiring the drug release profile, floating drug delivery system of Enalapril maleate for treatment of hypertension. It is concluded that, the natural polymers were used in floating tablet gave better application as they are easily available, biocompatible, nontoxic and float the tablet in GIT.

Hence, floating tablet is best way for retention of dosage form in gastrointestinal tract.

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