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Formulation, Development and Evaluation of Floating Tablets of Antibiotics Used in The Treatment of Peptic Ulcer

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ABSTRACT:
The treatment of peptic ulcer disease involves multi drug regimen which causes patient discomfort. Roxithromycin and Omeprazole are successful agents used in the treatment of peptic ulcer disease, but are available as separate unit dosages. Roxithromycin has broad spectrum of antibacterial activity and previous literature shows it inhibits *H. Pylori*. Omeprazole is unstable in acidic pH but a valued proton pump inhibitor. Therefore, a humble effort was made in this investigation, to formulate a tablet dosage form containing both these drugs. Core tablets containing Omeprazole and a floating type coat formulation containing Roxithromycin, compressed into a single unit were developed and prepared. A buoyant tablet where made to float over the surface of the gastric fluids and thereby increasing the gastric retention time (GRT) of the drugs like Roxithromycin, thereby increased bioavailability and hence therapeutic efficacy is might improve. Also, it was planned to evaluate such tablets for their various pre-compression and compression characteristics, *in vitro* drug release kinetics and stability of the dosage forms. The present study outlines a systematic approach for designing and development of Omeprazole and Roxithromycin floating tablets to enhance the bioavailability and therapeutic efficacy of the drug in the peptic ulcer disease.

INTRODUCTION:
Floating drug delivery system (FDDS)[1, 2]
Floating drug delivery system (FDDS) are the solid oral dosage regimens, which have a bulk density less than gastric fluids and because of this, system remains buoyant (3-4 h) for a prolonged period of time in the stomach without affecting the gastric emptying rate. FDDS helps in the local drug delivery to the stomach and proximal small intestines. FDDS helps to provide better availability of new products with new therapeutic possibilities and substantial benefits for patients. In the development of oral controlled drug delivery system, one of the main challenges is to modify the GI transit time. Gastric emptying of pharmaceuticals is highly variable and is

dependent on the dosage form and the fed/fasted state of the stomach. Normal gastric residence times usually range between 5 minutes and 2 hours. In the fasted state the electrical activity in the stomach – inter digestive myoelectric cycle or migrating myoelectric complex (MMC) governs the activity and, hence, the transit of dosage forms. It is characterized by four phases: Phase I–Period of no contraction (40-60 minutes), phase II –Period of intermittent contractions (20-40 minutes),phase III–Period of regular contractions at the maximal frequency that travel distally also known as house keeper wave. (10-20 minutes) and phase IV–Period of transition between phase III and phase I (0-5 minutes).Gastric emptying is unpredictable if there are physiological problems and other factors like the presence of food. Drugs having a short half-life are eliminated quickly from the blood circulation. Various oral controlled delivery systems have been designed which can overcome these problems and release the drug to maintain its plasma concentration for a longer period of time. This has led to the development of oral gastro retentive dosage forms. Gastro retention is essential for drugs that are absorbed from the stomach, drugs that are poorly soluble or degraded by the higher pH of intestine, and drugs with an absorption which can be modified by changes in gastric emptying time. Gastro retentive dosage forms are also useful for local as well as sustained drug delivery for certain conditions, like *H. pylori* infection which is the cause of peptic ulcers. This dosage form improves bioavailability, therapeutic efficacy and may even also allow a possible reduction in the dose because of steady therapeutic levels of drug.

Mechanism of floating systems [3,4]

Floating drug delivery systems (FDDS) have a bulk density less than gastric fluids and so remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period of time. While the system is floating on the gastric contents, the drug is released slowly at the desired rate from the system. After release of drug, the residual system is emptied from the stomach. This results in an increased GRT and a better control of the fluctuations in plasma drug concentration. However, besides a minimal gastric content needed to allow the proper achievement of the buoyancy retention principle, a minimal level of floating force (F) is also required to keep the dosage form reliably buoyant on the surface of the meal. To measure the floating force kinetics, a novel apparatus for determination of resultant weight has been reported in the literature.[5] The apparatus operates by measuring continuously the force equivalent to F (as a function of time) that is required to maintain the submerged object. The object floats better if F is on the higher positive side. This apparatus helps in optimizing FDDS with respect to stability and durability of floating forces produced in order to prevent the drawbacks of unforeseeable intra gastric buoyancy capability variations.

$$F = F_{buoyancy} - F_{gravity}$$
$$= (Df - Ds)\, gv$$

Where, F= total vertical force,
Df = fluid density,
Ds = object density,
v = volume and
g = acceleration due to gravity.

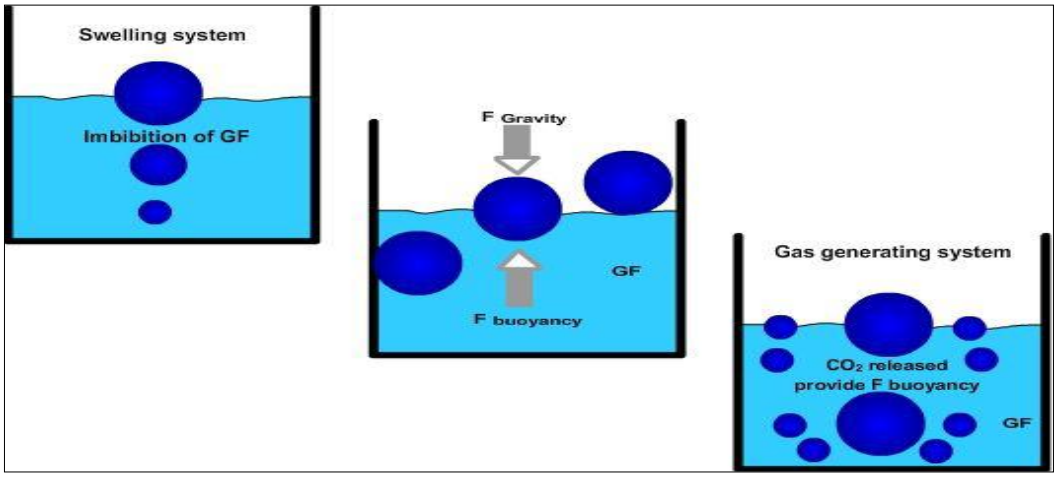

Fig.1 Mechanism of floating systems, GF= Gastric fluid

Classification of FDDS

A. Single Unit Floating Dosage Systems

a) Effervescent Systems (Gas-generating Systems)
b) Non-effervescent Systems

B. Multiple Unit Floating Dosage Systems

a) Non-effervescent Systems
b) Effervescent Systems (Gas-generating Systems)
c) Hollow Microspheres

C. Raft Forming Systems

An overview of peptic ulcer[5,6, 7]

Peptic ulcer is an open sore in the lining of the stomach or intestine, much like mouth or skin ulcers. Peptic ulcers are usually caused by acid and pepsin, a digestive stomach enzyme. The ulcers in stomach are called as gastric ulcers and the ulcers in the first portion of the intestine are called duodenal ulcers. "Peptic ulcer" is the term used to describe either or both of these two types of ulcers. One cause of peptic ulcer is bacterial infection, but some ulcers are caused by long term use of non-steroidal anti-inflammatory agents (NSAID's) like aspirin, and ibuprofen. In a few cases cancerous tumors in the stomach or pancreas can cause ulcers. Peptic ulcers are not caused by spicy food or stress. The term "peptic ulcer" refers to an ulcer in the lower part of esophagus or stomach or duodenum or in the jejunum after surgical anastomosis to the stomach or rarely in the ileum adjacent to a meckel's diverticulum. Ulcers in the stomach or duodenum may be acute or chronic; both penetrate the muscular is mucosae but the acute ulcer shows no evidence of fibrosis. *Helicobacter pylori* (*H. pylori*) is a type of bacteria, researchers believe that it is responsible for the majority of peptic ulcers. *H. pylori* infection is common in the United States about 20% of people under 40 years old and half of these over 60 suffer from *H. pylori* infection. In India about 45% of people under 45 years suffer from peptic ulcer.

Treatment [8, 9]

Two types of acid suppressing drugs are available to the treatment of gastric ulcers, like H_2receptor blockers and proton pump inhibitors. H_2 receptor blockers work by blocking histamine, which stimulates acid secretion, they help reduce ulcer pain after a few weeks. Proton pump inhibitors suppress acid production by halting the mechanism that pumps the acid in to the stomach. H_2 receptor blockers and proton pump inhibitors have been prescribed alone.

Drugs used to treat *Helicobacter pylori* peptic ulcer:

Many drugs are available for the treatment of peptic ulcer symptoms and other dyspeptic disorders.

Antacids:

These are widely available for self-medication and are used for relief of minor dyspeptic symptoms. The majority are based on combinations of calcium, aluminum and magnesium salts.Proton pump inhibitorsare substituted Benz imidazole compounds that specifically and irreversibly inhibit the proton pump hydrogen [potassium ATPase] in the parietal cell membrane. They are most powerful inhibitors of gastric secretion yet discovered, with maximal inhibition occurring 3-6 hours after oral dose.

Formulation development of FDDS[10]

Comprehensive knowledge about GI dynamics such as gastric emptying, small intestine transit, colonic transit, etc. is key for the optimum design of a oral controlled release dosage forms. The rate and extent of drug absorption from different sites of GI tract and factors that govern the absorption further assist the design of dosage form.Three major requirements for FDDS formulations are: (1) It must form an adhesive gel barrier. (2) It must maintain specific gravity lower than gastric contents (1.004-1.01 gm./ml). (3)It should release contents slowly to serve as a reservoir.

Evaluation of FDDS [11, 12]

Any drug product must be evaluated to ensure its performance characteristics and to control batch-to-batch quality. In addition to routine tests for general appearance, hardness, friability, drug content, weight variation, uniformity of content, disintegration time, and drug release, the gastro retentive performance of GRDDS must be evaluated.

Floating/buoyancy time [13, 14, 15]
The test for buoyancy is usually determined in 900 mL of simulated gastric maintained at 37ºC using the USP dissolution apparatus. These fluids simulate the surface tension of human gastric juice (35–50 mN/m^2). The period of time the dosage form floats is termed the floating time.

MATERIALS AND METHODS:

Omeprazole and Roxithromycin was purchased from A.G. Traders, Panvel. HPMC K4M, PVP K30 and Xanthan Gum were purchased from YashChemiclal, Pune. All other reagents used were of analytical reagent grade.

Analytical method development for the estimation of Omeprazole and Roxithromycin pure drugs either in bulk or in tablets:

1. Calibration curve of Omeprazole:
Stock solution of Omeprazole was prepared by dissolving 100 mg of accurately weighed amount of Omeprazole in 10 mL of distilled water and then the volume was adjusted to 100 mL (100 µg /mL) with the dist. water. The stock solution withdrawn 1 mL solution than the adjusted volume was distilled waters this solution called as resulting solution (10 µg /mL). The above resulting solution of drug was subsequently diluted with distilled water to get 2 µg, 4 µg, 6 µg, 8 µg and 10 µg, of drug per mL.

2. Calibration curve of Roxithromycin:
Stock solution of Omeprazole was prepared by dissolving 100 mg of accurately weighed amount of Omeprazole in 10 mL of distilled water and then the volume was adjusted to 100 mL (100 µg /mL) with the dist. water. The stock solution Withdrawn 1 mL solution then the adjusted volume was distilled waters this solution called as resulting solution (10 µg /mL). The above resulting solution of drug was subsequently diluted with distilled water to get 2 µg, 4 µg, 6 µg, 8 µg and 10 µg, of drug per mL.

Drug-excipients compatibility study by FTIR Spectroscopy: [16]
IR spectral studies lies more in the qualitative identification of substances either in pure form or in combination with polymers and excipients and acts as a tool in establishment of chemical interaction. Since IR is related to covalent bonds, the spectra can provide detailed information about the structure of molecular compounds. For FTIR study potassium bromide (KBr) pellet technique was employed and scanned between 400 to 4000 cm^{-1}(Varian Carry FTIR 630instrument).

Formulation Design to prepare Core in Coat Floating Tablets containing Omeprazole and Roxithromycin

Table No. 1 Formulation of Core

Sr. No.	Ingredients	Cr1 (mg)
1	Omeprazole magnesium	20
2	PVP K-30	1.4
3	Xanthan Gum	47.55
4	Magnesium Stearate	0.35
5	Talc	0.7
	Total core tab weight	**70**

*****All values are in mg

Table No. 2 Formulation of Coat

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6
1	Roxithromycin	200	200	200	200	200	200
2	Sodium bicarbonate (%w/w)	13.20(4%)	19.80 (6%)	26.40(8%)	13.20(4%)	19.80(6%)	26.40(8%)
3	Citric acid (%w/w)	6.6 (2%)	6.6(2%)	6.6(2%)	-	-	-
4	Tartaric acid (%w/w)	-	-	-	6.6(2%)	6.6(2%)	6.6(2%)
5	Aerosil ®	3.3(1%)	3.3(1%)	3.3(1%)	3.3(1%)	3.3(1%)	3.3(1%)
6	HPMC K4M	106.9	100.3	93.7	106.9	100.3	93.7
	Total tablet weight (mg)	**330**	**330**	**330**	**330**	**330**	**330**

*****All values are in mg

Compression of Tablets:

a. Core tablet (Direct compression):
The Omeprazole formulations constituted core of the tablets, and were prepared by direct compression technology. All the ingredients of core tablets were weighed accurately to produce a batch of minimum 100 tablets. Later, the

powder bed was milled further to pass through sieve # 160 and then thoroughly blended in a double cone. The powder blended was later, studied for rheological characteristics.

The uniformly blend of powder containing Omeprazole was then compressed in a 10 station tablet punching machine (Cemach, Ahmedabad) using 6 mm flat punches at a pressure of 3 kg/cm^2. The tablets obtained were stored in a clean and dry container until further studies.

b. Compression of Coat over the Core tablets:
The Roxithromycin formulations constituting coat of the tablets were prepared by direct compression technology. The ingredients as mentioned in the formulae above (table no. 2) of different coat formulations were accurately weighed, milled and passed through sieve # 160 and then thoroughly blended in a double cone blender. The powder blended was studied for rheological characteristics.

A weight constituting nearly 66.66 % w/w of coat containing Roxithromycin was first placed into the die cavity (10 mm) and then core tablets of Omeprazole (6 mm) was placed into the same die cavity and manipulated it to the center of the powder bed inside the die cavity and upon this core and another 33.33% w/w of remaining coat powder was placed over the core. The core is completely and uniformly surrounded by the coat powder and was then punched in a 10 station tablet press Machine at a pressure of 4 kg/cm^2. These tablets were studied for compression characteristics and later, *in vitro* dissolution studies were carried out.

Evaluation parameters of tablets [17, 18]
Thickness and Diameter test:
The tablets were evaluated for their thickness and diameter using a micrometer (Mitutoyo, Japan). Average of three readings were taken and the results were tabulated (n = 3).

Hardness test:
The tablets were evaluated for their hardness using Pfizer hardness tester. Average of three reading were taken and tabulated (n = 3).

Density measurement [19]
The apparent density of the tablets was calculated from their volumes and masses. The volumes V of the tablets were calculated from their height h and radius r using micrometer. Volume of the tablets was calculated by using the following equation:
$V = \prod x\ r^2 x\ h$

Disintegration test[20]
The disintegration time of tablet was determined by placing one tablet in each of the six tubes of the basket and operated the apparatus, using 0.1 N HCL Ph buffers solution maintained at 37 ± 5° C. At the end basket was lifted from the fluid, and tablets were observed. All the tablets disintegrated completely (n = 3).

Uniformity of weight
Uniformity of weight and Friability: Both parameters are carried out as per Pharmacopeia[20]
Determination of drug content
Ten tablets from each formulation were powdered. The powder equivalent to 200mg Roxithromycin of was weighed and dissolved in water in 100 mL standard flasks and equivalent 20 mg Omeprazole of was weighed and dissolved in water in 100 ml standard flask. From this, an aliquot was pipetted out and suitable dilution was prepared and the solution was analyzed at 370.4(Omeprazole)and 300.4 nm (Roxithromycin) using UV double beam spectrophotometer using water as blank.[9]

Buoyancy time: [21]
The buoyancy of tablets was studied at 37 ± 0.5 °C, in 100 mL of 0.1N HCl. A glass beaker containing 100 mL of 0.1N HCl was taken, in which a tablet was placed for observation. The duration taken by the tablet to float or rise was noted with the help of a digital clock. Average of three readings were taken and tabulated.

Duration of floating time: [22]
A glass beaker containing 100 mL of 0.1N HCl was taken, in which a tablet was placed for observation. The total

duration for which a tablet remains floating (Buoyant) was recorded with the help of a digital clock, as duration of floatation. Average of three readings were taken and tabulated (n = 3).

***In-vitro* drug release profile of Roxithromycin and Omeprazole**

The release from tablets of core in coat tablets containing Roxithromycin and Omeprazole was studied in a USP dissolution testing apparatus method 1, using a basket. The actions mimicked the gastro intestinal transit time. The dissolution media consisted of 900 ml of either 0.1 N hydrochloric acid (first 2 h) or phosphate buffer of pH 6.8 (next 3 h) or phosphate buffer of pH 7.4 (for remaining 3h) at a temperature of 37±0.5ºC and the media were stirred at 50 rpm. Samples of 1 mL were withdrawn periodically and the same volume of respective buffer was replaced into the dissolution jar.The sample was suitably diluted and analyzed in a UV spectrophotometer. Absorbances of these solutions were measured separately, Omeprazole at 370.4 nm and roxithromycin at 300.4 nm using a UV Visible double beam spectrophotometer (Jasco v-630).

The release profiles of the drugs were plotted separately and the release rate was computed for each drug from the slopes of the curve obtained.

Stability Studies:

Stability of a formulation can be defined as the time from date on manufacture of the formulation until its chemical or biological activity is not less than a predetermined level of labeled potency and its physical characteristics have not changed appreciably or deleteriously.

ICH/ WHO protocol was followed to study the shelf life of dosage forms. The tablets were randomly selected, and stored at 40 ± 1º C/ 75 ± 5 % RH. Three tablets samples were withdrawn periodically, after 30 days, 60 days and 90 days, and the release profile was obtained. Average of three readings was noted and SD was computed. The drug release profiles obtained after stress was compared with the profiles of normal profiles.

RESULTS AND DISCUSSION

Treatment of peptic or gastric ulcer disease requires an antibacterial agent like Roxithromcin, an broad spectrum antibacterial agent, which is effective against bacteria, *H.pylori*, and an acid suppressing drug like Omeprazole, a proton pump inhibitor. Roxithromycin has its absorption window in stomach and whereas Omeprazole is absorbed from small intestine. Also, Omeprazole is not stable in gastric pH, but stable in intestinal pH. In this light of information, roxithromycin was aim to be dissolved in stomach and Omeprazole in small intestine. Study of core tablets containing 20 mg of Omeprazole (tablet weight 70 mg) and coat formulation containing 200 mg Roxithromycin (the coat weight is 330 mg) and the total weight of core in coat tablet containing two drugs is 400 mg. well formulated added developed. Further the core in coat tablets were formulated as floating drug delivery, by incorporating gas forming agents. The core tablets were initially punched using 6 mm punches and later coat formulation was manipulated in 10 mm die cavity so as to surround the core tablet and was then punched in a 10 station tablet press Machine.

Roxithromycin has been reported to be highly helpful in treating patients suffering with peptic ulcer disease. It is a low molecular weight, BCS class II drug. With recommended dose of 150 mg twice a day or 300 mg once daily may be prescribed**.** Omeprazole has been also reported to be highly helpful in treating patients suffering with PUD. It is a low molecular weight, BCS class II drug, with recommended dose of 20 to 40 mg orally once a day for 4 to 8 weeks may be prescribed**.**

Preparation of Calibration Curves

1. Standard calibration curve for Roxithromycin:

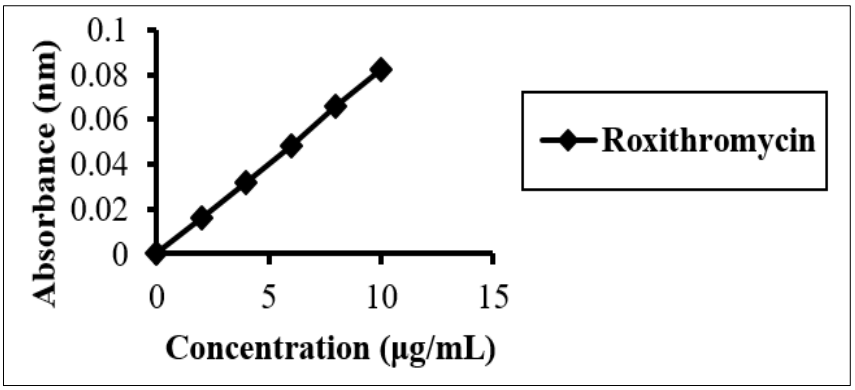

Fig: 2 Calibration curve of Roxithromycin in distilled water.

From the standard curve of Roxithromycin, it was observed that, the drug obeys beer's law between 0– 10 µg/mL at 300.4 nm in distilled water. From the raw data the regression equation was obtained with the slope value of 0.0082 and an intercept of -0.0005.The curve exhibited high coefficient of correlation (r^2= 0.9996) indicating the curve is straight with a slope of 0.0082. The linear regression equation computed was used for the quantitation of drug, y = 0.0082*X - 0 .0005 with a correlation coefficient r= 0.9996.

2. Standard calibration curve for Omeprazole:

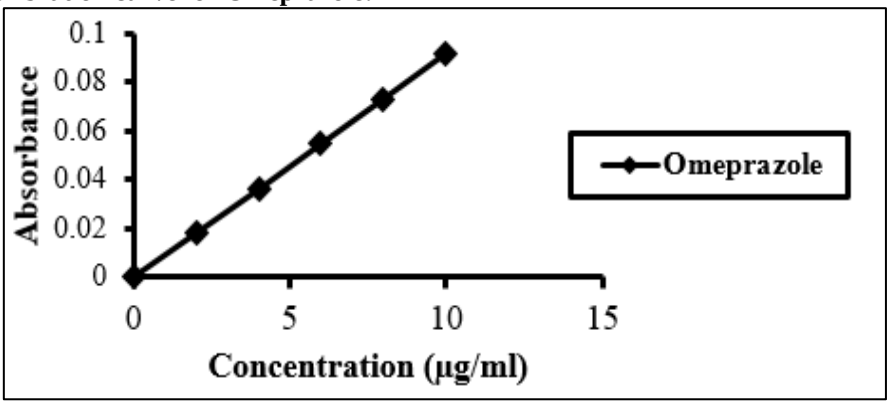

Fig: 3 Calibration curve of Omeprazole in distilled water.

From the standard curve of Omeprazole, it was observed that, the drug obeys beer's law between 0– 10 µg/mL at 370.4nm in distilled water. From the raw data the regression equation was obtained with the slope value of 0.0092 and an intercept of -0.0003.The curve exhibited high coefficient of correlation (r^2= 0.9999) indicating the curve is straight with a slope of 0.0092. The linear regression equation computed was used for the quantitation of drug, y = 0.0092*X - 0 .0003 with a correlation coefficient r= 0.9999.

Drug study by FTIR spectroscopy

a) Omeprazole with excipient study by FTIR spectroscopy

FTIR spectra of drug in combination with excipients in 1:1 ratio were used to study compatibility between drug and excipients and between excipients, using a FTIR spectrophotometer. (Variancary, Model-640). FTIR spectra of Omeprazole, physical mixtures shown in Figures 4, 5. The characteristic absorption peaks of Omeprazole were found at 2970 cm^{-1} (C-H stretching of aliphatic), 2970cm^{-1}(-C-H aliphatic in stretching), 1734 cm^{-1}(C=O stretching), 1570 cm^{-1}(C=C stretching of aromatic ring), 3421 cm^{-1} (O-H deformation of aromatic ring),3441cm^{-1} (N-H stretching).

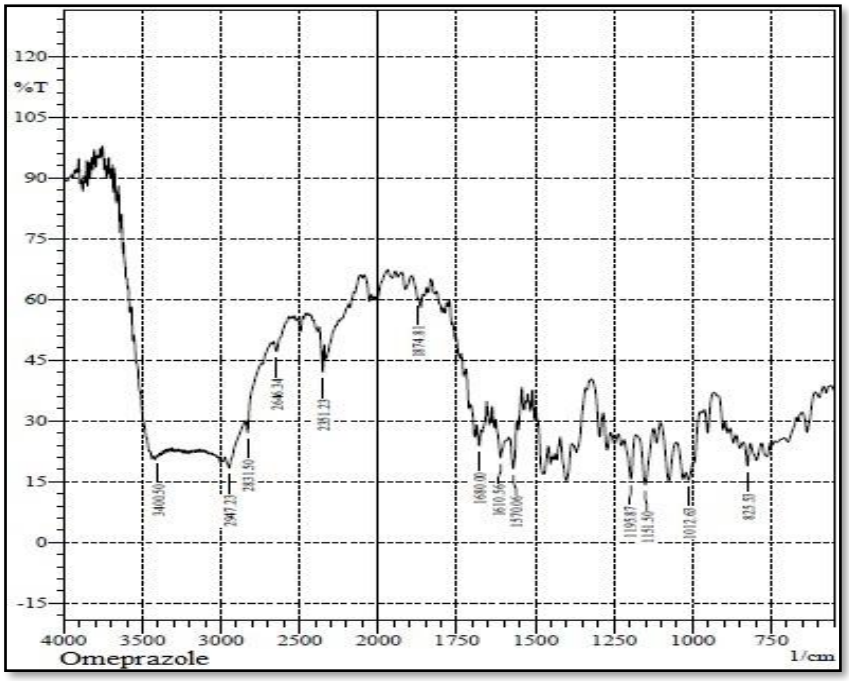

Figure No. 4 FTIR Spectrum of the Omeprazole

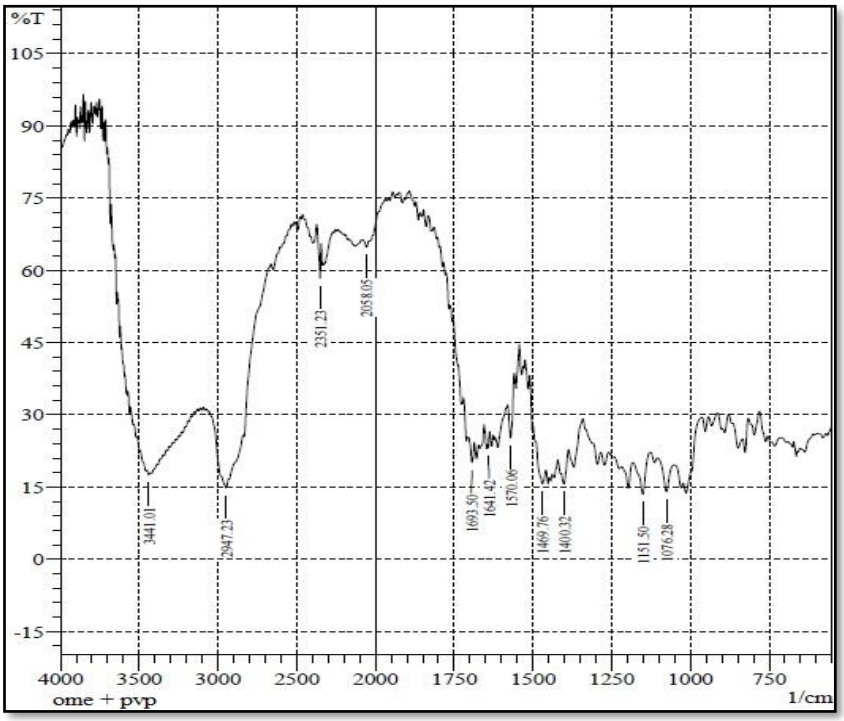

Figure No. 5 FTIR Spectrum of Omeprazole with PVP K30

b) Roxithromycin with excipient study by FTIR spectroscopy

FTIR spectra of drug in combination with excipients in 1:1 ratio were used to study compatibility between drug and excipients and between excipients, using a FTIR spectrophotometer. (Varian cary, Model-640).FTIR spectra of Roxithromycin, physical mixtures shown in Figures 6 and 7. The characteristic absorption peaks ofRoxithromycinwere found at 3010 cm^{-1} (C-H stretching of aromatic), 2947 cm^{-1}(-C-H aliphatic in stretching), 1734 cm^{-1}(C=O stretching), 1570 cm^{-1} (C=C stretching of aromatic ring), 3421 cm^{-1} (O-H deformation of aromatic

ring),3400 cm^{-1} (N-H stretching).

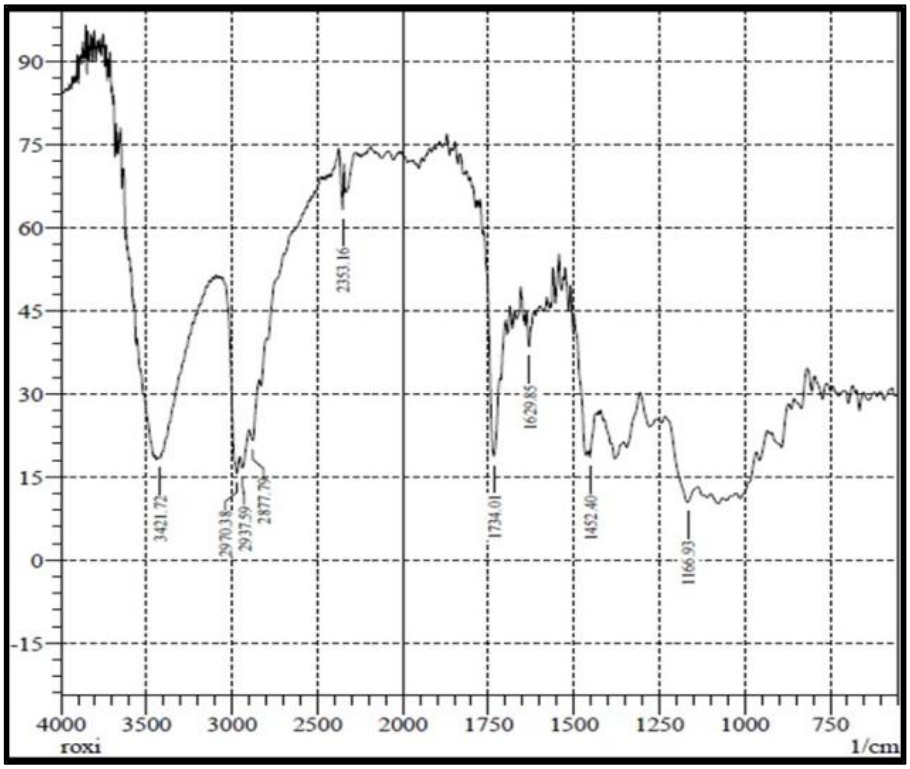

Fig. 6 FTIR Spectrum of the Roxithromycin

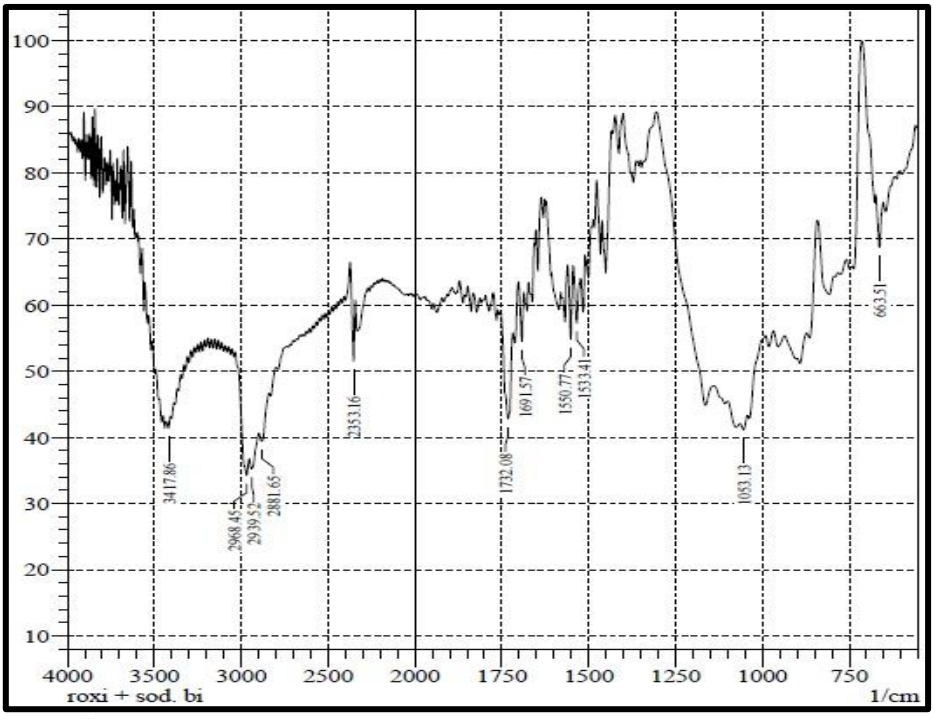

Fig. 7 FTIR Spectrum of Roxithromycin with Sodium bicarbonate

Table No. 3 Rheological properties of powder blends of Core formulations and also Core in Coat formulations (n=3)

Batch code	Bulk density (gm./mL) ±SD	Tapped density (gm./mL)±SD	Carr's index % ±SD	Hausner's ratio ±SD	Angle of repose(⁰0) ±SD
Cr	0.3092± 0.01	0.5347± 0.08	13.37± 0.01	1.57 ± 0.06	28^0.40'± 0.58
F1	0.2130± 0.01	0.2708 ± 0.01	11.93± 0.01	1.26 ± 0.02	28^0.97'± 0.43
F2	0.2206 ± 0.01	0.2765 ± 0.01	12.05± 0.006	1.33 ± 0.05	30^0.12'± 0.35
F3	0.210 ±0.008	0.2696± .009	10.90± 0.01	1.24 ± 0.02	28^0.38'± 0.48
F4	0.2082± 0.04	0.2765 ± 0.01	15.64± 0.02	1.36 ± 0.005	28^0.85'± 0.25
F5	0.2130± 0.01	0.2765± 0.01	14.90± 0.01	1.35 ± 0.02	29^0.70'± 0.34
F6	0.2206± 0.01	0.3006± .001	12.48± 0.03	1.29 ± 0.12	30^0.08'± 0.55

Cr→ Core tablet; F → Core in Coat formulation

Table No. 4 Evaluation data of Post-Compression characteristics of Core tablets of Omeprazole (n=3).

Formulation code	Average weight of Tablet (mg) ±SD	Hardness (kg/cm2) SD	Diameter (mm)±SD	Thickness (mm)±SD	Friability ±SD %	Disintegration time (min)
Cr	0.683±0.02	3.13 ±0.23	6.00 ±0.008	2.28 ±0.01	0.666±0.08	9.33 ±0.05

Table No. 5 Evaluation data of Post-Compression characteristics of Core in Coat Tablets of Roxithromycin and Omeprazole (n=3).

Formulation code	Weight of Tablet (mg) ±SD	Hardness (kg/cm2) ±SD	Diameter (mm)±SD	Thickness (mm)±SD	Friability ±SD %	Disintegration time (min)
F1	0.398 ± 0.001	4.2 ± 0.20	10.09 ± 0.01	4.491± 0.001	0.33± 0.145	13:17± 0.001
F2	0.399 ± 0.001	4.1± 0.23	10.08 ±0.003	4.489± 0.006	0.37± 0.106	13:11 ± 0.004
F3	0.398 ±0.002	4.5 ± .030	10.03 ± 0.02	4.484± 0.003	0.42± 0.137	12:54± 0.002
F4	0.397 ± 0.002	4.2± 0.20	10.03 ±0.002	4.490± 0.005	0.61± 0.08	13:19 ± 0.003
F5	0.398 ± 0.002	4.2± 0.11	10.04 ± 0.01	4.484± 0.008	0.57± 0.105	13:07 ± 0.001
F6	0.399± 0.001	4.0± 0.11	10.00 ±0.004	4.490± 0.004	0.33 ± 0.145	13:04 ± 0.003

In vitro dissolution studies:

Dissolution of Omeprazole and Roxithromycin core in coated floating tablets was performed according to USP dissolution method 1, basket method, (Electrolab TDT- 08L Plus, Dissolution tester USP Mumbai, India). The actions mimicked the gastro intestinal transit time. The dissolution media consisted of 900 ml of either 0.1 N hydrochloric acid (first 2 h) or phosphate buffer of pH6.8 (next 3 h)or phosphate buffer of pH 7.4 (for remaining 3 h) at a temperature of 37±0.5ºC and the media was stirred at 50 rpm. Samples of 1 ml were withdrawn periodically and the same volume of respective buffer was replaced into the dissolution jar. The sample was suitably diluted and analyzed at a λ_{max}of370.4nmfor quantitation of Omeprazole and similarly quantitation of Roxithromycin was carried out at 300.4 nm using UV spectrophotometer (Jasco, Japan).The physical changes occurring in tablet during dissolution was observed by naked eye and the observations were noted periodically.

Dissolution profile of optimizedformulation F6

The results of F6, containing Core formulation (Xanthan gum) and Coat containing Sodium bicarbonate 8 % w/w, Tartaric acid 2% w/w were tabulated as in Table

Table No. 6 a): Dissolution profile of Roxithromycin from formulation F6

Time (h)	Amount	Cum Amount eleased (mg)	% Cum Drug Released	Cum % Drug Remaining	Log % Cum Drug Remaining
0	0	0	0	100	2
0.5	10.4073	93.6658	47.5268	52.473	1.7993
1	14.1056	126.951	64.4160	35.583	1.5512
1.5	17.3089	155.780	79.7392	20.955	1.3066
2	19.5146	175.631	89.0240	10.883	1.0404
2.5	20.8670	187.803	95.2931	4.7068	0.7727
3	21.1560	190.404	96.6129	3.3870	0.5298
4	21.4406	192.965	97.9124	2.0875	0.1196
5	21.8165	196.348	99.6288	0.3711	-0.4304

Table No. 6 b): Dissolution profile of Omeprazole from formulation F6

Time (h)	Amount	Cum Amount Released (mg)	% Cum Drug Released	Cum % Drug Remaining	Log % Cum Drug Remaining
0	0	0	0	100	2
1	0.0369	0.8653	0.8653	99.136	1.9962
1.5	1.8647	0.1980	1.0040	98.995	1.9956
2	1.9677	0.1990	1.0091	98.990	1.9956

2.5	1.9960	0.2736	1.3876	98.612	1.9943
3	2.0235	0.3086	1.5653	98.434	1.9937
4	2.0449	0.3289	1.6682	98.331	1.9926
5	2.0641	0.3764	1.9090	98.090	1.9912
6	2.1532	86.2003	80.5356	19.464	1.2892
7	2.1608	92.3527	92.3527	7.6472	0.7042
8	2.1797	99.4796	99.4796	0.5203	-0.2837

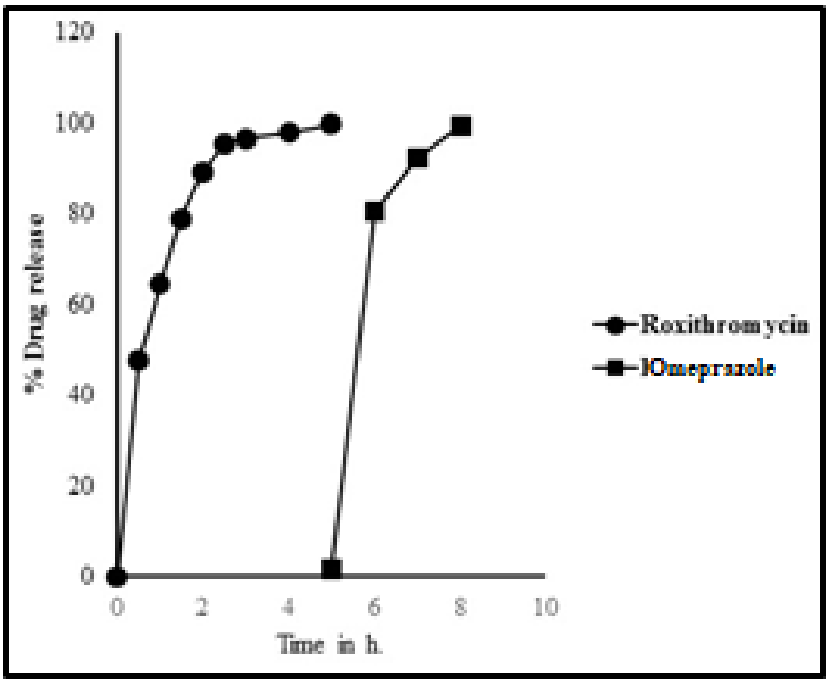

Fig 8 a: Cum. % drug released of Roxithromycin and Omeprazole core in coatformulation of F6

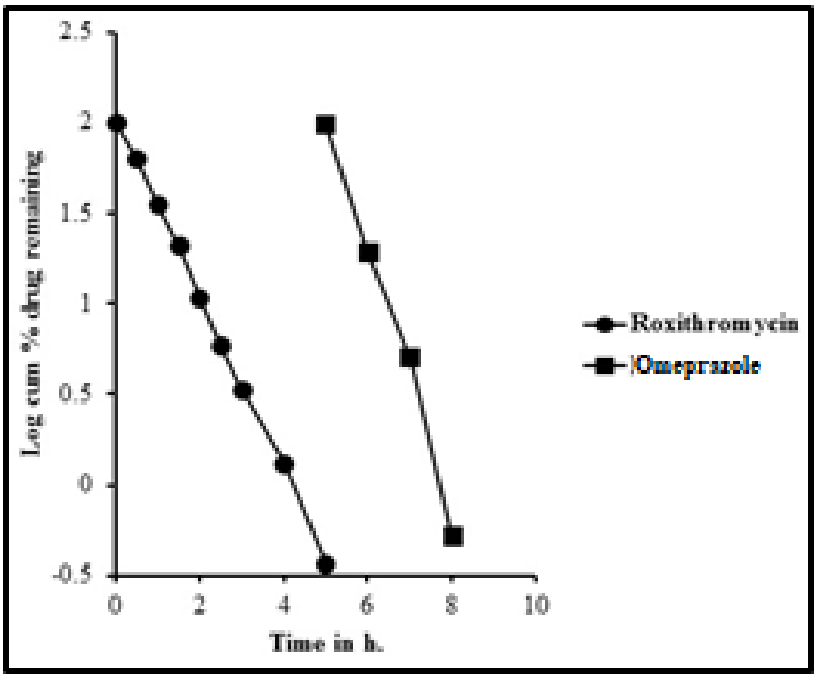

Fig 8 b: Log cum.% drug remaining of Roxithromycin and Omeprazole core in coatformulation Of F6

Stability Studies of F6 Formulation:

The stability of Roxithromycin and Omeprazole in the core in coat floating tablets was assessed according to ICH guidelines. Arrangements were made inside a stability chamber to induce a stress of temperature and humidity simultaneously and uniformly an all the tablets kept for study. A temperature of 40^0C and a relative humidity of 75%RH was selected, and F6 formulation was selected as a model dosage form. Nearly 50 tablets of F6 were placed inside the stability chamber so that, each tablet is separately exposed to 40^0C/75% RH. At the end of 24 h, 30 days, 60days and 90 days, 3 tablets were removed randomly, inspected visually for any changes and later subjected to dissolution studies.

The dissolution profiles were obtained and the results of these formulations were compared with the dissolution profile of the tablet which was no exposed to stress. The profiles of the formulation F6 was seen to remain similar, indicated by slope, visual inspection showed that, there was no apparent effect of temperature/humidity, color, odor. Therefore it could be understood that, the core in coat floating tablets are capable of protective both the days for a long period. Further, studies up to 6 month could not be conducted because of time constraint of this dissertation; however the results of this study will be reported elsewhere.

CONCLUSIONS:

The treatment of peptic ulcer disease currently is multi drug therapy with one or more antibiotics and one or more acid release suppressing agents like proton pump inhibitors or H2 receptor antagonists. There is hardly any oral dosage form which combines both an antibiotic and a proton pump inhibitor. Based on the literature surveyed, it may be concluded that floating drug delivery offers various potential advantages for drug with poor bioavailability due their absorption is restricted to the upper gastrointestinal tract (GIT) and they can be delivered efficiently thereby maximizing their absorption and enhancing absolute bioavailability. Hence, it can be concluded that these dosage forms serve the best to deliver anti secretory and antibiotic agents for the treatment of diseases like peptic ulcer related to the GIT.

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