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Development and evaluation of enteric coated tablet of Esomeprazole

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Abstract

Esomeprazole5-methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl)methylsulfinyl]-1H-benzimidazole is a proton pump inhibitor belongs to group of benzimidazoles . This compound inhabits gastric acid formation and thereby it is very efficient for the treatment of gastric and duodenum ulcers. In aqueous media more acidic than pH 4 it suffers a practically complete decomposition within a period shorter than 10 minutes. Even in solid state it is sensitive to heat, humidity, and light and especially to substances containing an acidic group. Esomeprazole which has an irritant effect on the stomach can be coated with a substance that will only dissolve in the small intestine. For such types of drugs, enteric coating added to the formulation tends to avoid the stomach's acidic exposure, delivering them instead to a basic pH environment (intestines pH 5.5 and above) where they do not degrade, and give their desired action. This stimulates us to formulate and evaluate esomeprazole as a enteric coated tablet.

Keywords: F Esomeprazole, Enteric Coated, Development and Evaluation

1. Introduction

The tablet coating is perhaps one of the oldest pharmaceutical processes still in existence [1]. It offers many benefits namely-improving the aesthetic quality of the dosage form, masking unpleasant order or test, easing ingestion, improving product stability and modified the release characteristic of the drug [2]. Enteric coating is a barrier applied to oral medication that controls the location in the digestive system where it is absorbed [3]. Enteric refers to the small intestine; therefore, enteric coatings prevent release of medication before it reaches the small intestine. Most enteric coatings work by presenting a surface that is stable at the highly acidic Ph found in the stomach,[4] but breaks down rapidly at a less acidic (relatively more basic) pH. Gastro-oesophageal reflux disease (GORD), peptic ulcers, non-ulcer dyspepsia or the use of NSAIDs, are very common. Among the drugs available [5] to inhibit acid secretion, proton pump inhibitors (PPI) have been shown to have the best efficacy-safety ratio [6]. Drugs such as esomeprazole which have an irritant effect on the stomach and must be absorbed in the gastrointestinal tract and because it is unstable under acidic conditions [7], enteric delivery systems are required. Similarly, certain groups of Azoles (Esomeprazole, Omeprazole, and all grouped azoles) are acid-unstable [8]. For such types of drugs, enteric coating added to the formulation tends to avoid the stomach's acidic exposure, delivering them instead to a basic pH environment [9] (intestines pH 5.5 and above) where they do not degrade, and give their desired action. The purpose of this study was to prepare and formulae the Enteric coated Esomeprazole tablets [10].The stomach is continuous with the esophagus at the cardiac sphincter and with the duodenum at the pyloric sphincter [11]. It has two curvatures. The stomach is divided into three regions: the fundus, the body and the antrum [12]. At the distal end of the pyloric antrum is the pyloric sphincter, guarding the opening between the stomach and the duodenum [13]. When the stomach is inactive the pyloric sphincter is relaxed and open and when the stomach contains food the sphincter is closed [14]. Temporary storage allowing time for the digestive, chemical digestion, preparation of iron for absorption, production of intrinsic factor needed for absorption of vitamin B12 in the terminal ileum regulation of the passage of gastric contents into the duodenum [15]. When the chyme is sufficiently acidified and liquefied, the pyloric antrum forces small jets of gastric contents through the pyloric sphincter into the duodenum [16]. The stomach secretes about 2.5 litres of gastric juice daily. The principal exocrine secretions are proenzymes such

as prorennin and pepsinogen elaborated by the chief or peptic cells and hydrochloric acid (HCl) and intrinsic factor secreted by the parietal or oxyntic cells [17]. Mucus-secreting cells abound among the surface cells of the gastric mucosa. ions are also secreted and are trapped in the mucus, creating a gel-like protective barrier that maintains the mucosal surface at a pH of 6-7 in the face of a much more acidic environment (pH 1-2) in the lumen [18].

Gastric acid secretion is a complex, continuous process in which multiple central and peripheral factors contribute to a common endpoint [19]: the secretion of H+ by parietal cells. Neuronal (acetylcholine, ACh), paracrine (histamine), and endocrine (gastrin) factors all regulate acid secretion. Their specific receptors (M_3, H_2, and CCK_2 receptors, respectively) are on the basolateral membrane of parietal cells in the body and fundus of the stomach. The H2 receptor is a GPCR that activates the Gs-adenylylcyclase-cyclic AMP-PKA pathway [20].

2. Materials and Method

2.1 Preformulation studies

2.1.1 Preparation of standard graph for Esomeprazole sodium using acidic buffer (pH 1.2) Determination of absorption maxima (λmax)

100 mg of Esomeprazole sodium sesquihydrate was weighed accurately and dissolved in 100 mL of pH 1.2 acidic buffer in 100 mL volumetric flask (stock solution). 2 mL was taken from the stock solution and transferred into 100 mL volumetric flask and diluted up to 100 mL with pH 1.2 acidic buffer. The resulting solution was labeled as standard working Solution. 2 mL of the working solution was withdrawn and diluted up to 10 mL with pH 1.2 acidic buffer in 10 mL volumetric flask. The spectrum of this solution was run in 200 to 400 nm range in UV-visible spectrophotometer. The λ max of the Esomeprazole sodium sesquihydrate was found to be 283 nm.

2.2.2 Preparation of standard graph

From above standard working solution, 1, 2, 3, 4, 5 and 7 mL was withdrawn and diluted up to 10 mL with pH 1.2 acidic buffer in 10 mL volumetric flask to get concentration of 2 µg, 4 µg, 7 µg, 8 µg, 10 µg and 12 µg respectively. The absorbance of each solution was measured by UV-visible spectrophotometer at 283 nm using the pH 1.2 acidic buffer as blank.

2.2.3 Preparation of standard graph for Esomeprazole sodium using phosphate buffer (pH 7.8)

Determination of absorption maxima (λ_{max})

100 mg of Esomeprazole sodium sesquihydrate was weighed accurately and dissolved in 100 mL of pH 7.8 phosphate buffer in 100 mL volumetric flask (stock solution). 2 mL was taken from the stock solution and transferred into 100 mL volumetric flask and diluted up to 100 mL with pH 7.8 phosphate buffer. The resulting solution was labeled as standard working Solution. 2 mL of the working solution was withdrawn and diluted up to 10 mL with pH 7.8 phosphate buffer in 10 mL volumetric flask. The spectrum of this solution was run in 200 to 400 nm range in UV-visible spectrophotometer. The λ max of the Esomeprazole sodium sesquihydrate was found to be 288 nm.

2.2.4 Preparation of standard graph

From standard working solution, 1, 2, 3, 4, 5 and 7 mL has withdrawn and diluted up to 10 mL with pH 7.8 phosphate buffer in 10 mL volumetric flask to get concentration of 2 µg, 4 µg, 7 µg, 8 µg, 10 µg and 12 µg respectively. The absorbance of each solution was measured by UV-visible spectrophotometer at 288 nm using the phosphate buffer (pH 7.8) as blank.

2.2.5 FTIR spectra study

This was carried out to find out the compatibility between the drug Esomeprazole sodium sesquihydrate and the croscarmellos sodium, MCC, manito and other exicipients. 10 mg of the sample and 400 mg of KBr were taken in a mortar and triturated. A small amount of the triturated sample was taken into a pellet maker and was compressed at10 Kg/cm2 using a hydraulic press. The pellet was kept on to the sample holder and scanned in Bruker FT-IR spectrophotometer. The spectra obtained were compared and interpreted for the functional group peaks

2.2 Evaluation

2.2.1 Precompression Parameters

Bulk density (Db)

Accurately weighed granules were carefully transferred into graduated measuring cylinder. The granules bed was then made uniform and the volume occupied by the granules was noted as per the graduation marks on the cylinder as mL. It is expressed in gm/mL and is calculated using the following formula

Tapped density (Dt)

It is the ratio of total mass of granule to the tapped volume of granule. The graduated measuring cylinder containing accurately weighed granule was manually tapped for 50 times. Volume occupied by the granule was noted. It is expressed in gram/mL and is calculated by following formula.

Compressibility index (I) and Hausner's ratio

Carr's index and Hausner's ratio measure the propensity of granule to be compressed and the flow ability of granule. Carr's index and Hausner's ratio were calculated using following.

$$I = \frac{D_t - D_b}{D_t} \times 100$$

Hausner's ratio = D_t / D_b

Where,

D_t –Tapped density of the powder

D_b–Bulk density of the powder

Angle of repose (θ)

The frictional forces in a loose powder can be measured by the angle of repose. This is the maximum angle possible between the surface of a pile of powder and the horizontal plane. Sufficient quantities of Esomeprazole granules were passed through a funnel from a particular height (2 cm) onto a flat surface until it formed a heap, which touched the tip of the funnel. The height and radius of the heap were measured. The angle of repose was calculated using the formula. Angle of repose (θ) = tan-1 (h/r) Where, h – Height of the pile in cm r – Radius of the circular base of the pile in cm

2.2.2 Formulation studies

Preparation of Esomeprazole sodium tablets

Preparation of powder blend

Esomeprazole sodium sesquihydrate powder blend for tabletting were prepared by direct compression method. Specified quantity of Esomeprazole, croscarmellos sodium, manitol, calcium phosphate, and MCC were weighed according to the formula (**Table 1**) and transferred in a mortar and pestle and mixed thoroughly. The powder was passed through sieve no 80 to obtain the granules. The specified quantity of magnesium stearate and talc were finally added and mixed for the compression of tablets.

Preparation of Esomeprazole sodium tablets

An ideal mixture of granules was directly punched into tablets weighing about 200 mg containing 40 mg of Esomeprazole sodium sesquihydrate, using rotary tablet compression machine (Riddhi 10 stn mini tablet press RDB4-10, Rimek, Ahmedabad, India), using 8 mm diameter concave punches. The different batches of Esomeprazole tablets were collected and stored in air tight containers.

Table 1. Composition of Esomeprazole sodium enteric coated sodium tablets

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Esomeprazole sodium (mg)	40	40	40	40	40	40	40	40	40
Croscarmellose sodium (mg)	2	4	6	2	4	6	2	4	6
Microcrystalline cellulose (mg)	27	25	23	27	25	43	80	50	23
Mannitol (mg)	50	75	100	40	85	80	43	50	75
Dicalcium phosphate (mg)	75	50	25	85	40	25	75	50	50
Talc (mg)	2	2	2	2	2	2	2	2	2
Magnesium stearate(mg)	4	4	4	4	4	4	4	4	4
Totalweight(mg)	200	200	200	200	200	200	200	200	200

2.3 Post compression parameters

Hardness test The prepared tablets were subjected to hardness test 28,38. It was carried out by using hardness tester and expressed in kg/cm2.

Friability test The friability was determined using friabilator and expressed in percentage (%). 20 tablets from each batch were weighed separately (Winitial) and placed in the friabilator, which was then operated for 100 revolutions at 25 rpm. The tablets were reweighed (Wfinal) and the percentage friability (F) was calculated for each batch by using the following formula.

$$F = \frac{(W_{initial}) - (W_{final})}{(W_{initial})} \times 100$$

Weight variation test

Twenty tablets were selected at random from the lot, weighed individually and the average weight was determined. The percent deviation of each tablets weight against the average weight was calculated. The test requirements are met, if not more than two of the individual weights deviate from the average weight by more than 5% and none deviates more than 10%. IP limit for weight variation in case of tablets weighing more than 80 mg but less than 250 mg is ± 7.5 %.

Drug content uniformity

The prepared Esomeprazole sodium sesquihydrate tablets were tested for their drug content. Three tablets of each formulation were weighed and finely powdered. About 40 mg equivalent of Esomeprazole sodium sesquihydrate was accurately weighed and completely dissolved in pH 7.8 phosphate buffer and the solution was filtered. 1 mL of the filtrate was further diluted to 100 mL with pH 7.8 phosphate buffer. Absorbance of the resulting solution was measured by UV spectrophotometer at 288 nm.

Disintegration time of Esomeprazole sodium core tablets

Disintegration test was carried out using the tablet disintegration test apparatus (Servewell Instruments pvt. Ltd., Electrolab ED-2L, India) pH 7.8 phosphate buffer at 37 ± 0.5 ºC was used as the disintegration media and the time in second taken for complete disintegration of the tablet.

Coating of compressed Esomeprazole sodium tablets

Preparation of enteric coating solution

The enteric coating solution was prepared by simple solution method. It was prepared by 7% w/w and 8% W/W of Eudragit L100 (E1 and E2) or cellulose acetate phthalate (C1 and C2) as an enteric polymer, PEG 1.5% w/w as plasticizer and acetone and isopropyl acetone was used as solvent. Diethyl phthalate was added and made up the volume with rest of the solvent mixture; this mixture was constantly stirred for 1h with paddle mechanical stirrer at the rate of 1000 rpm and the stirred coating solution was again filtered through muslin cloth, a coating solution was obtained.

Table 2: Composition of coating solution

Ingredients	Quantity(%)
Cellulose acetate phthalate/ EudragitL100	7.0 / 8.0
PEG	1.5
Acetone	59.4

Enteric coating of Esomeprazole sodium compressed tablets by dipping method

The compressed tablets were coated with enteric coating polymer (Eudragit L100 or cellulose acetate phthalate) solution by dipping method. Desired tablet coating continued the dipping and weight gain was achieved. The coated tablets were studied for its weight variation, thickness, uniformity of drug content and *in vitro* dissolution study.

Physicochemical evaluation of coating films

The same polymer solution was used to prepare the polymeric films and was subjected for film thickness, film solubility. The polymeric films were prepared by casting the acetone with PEG the polymer solution was poured on the glass plate. The film was dried for 24 h at room temperature under a special cover with reduced solvent evaporation to obtained smooth homogenous films. The dried films were cut in to 1cm2 area the prepared polymeric film was studied for film thickness, and film solubility. The thickness of dried films was determined by thickness Digital micrometer. The film solubility was studied with pH 1.2 and pH 7.8. The 1×1 cm2 coating film was selected, weighed and transferred in a beaker containing 20 mL of specified pH medium, which was mixed in a magnetic stirrer for 1 h at 37 ± 1°C and finally film solubility was examined.

***In vitro* drug release studies**

USP dissolution apparatus type II (Electrolab TDT-08L, Mumbai, India) was employed to study the *in vitro* drug release from various formulations prepared. The dissolution medium used was 900 mL of acidic buffer of pH 1.2 for 2 h and phosphate buffer of pH 7.8 for 1 hrs. The tablet was kept in to the basket. The temperature was maintained at 37 ± 0.5°C and the stirring rate was 100 rpm. Samples were withdrawn at regular time intervals and the same volume was replaced with fresh dissolution medium. The samples were measured by UV spectrophotometer at 283 nm (pH 1.2) and at 288 nm (pH 7.8) against a blank. The release studies were conducted in triplicate and the mean values were plotted versus time**.**

Stability studies

Stability studies were performed as per the ICH guidelines. Selected formulations of Esomeprazole sodium tablet were sealed in aluminum foil cover and stored at (40 ± 2 °C / 75 ± 5 % R.H) for a period of 3 months. Samples from each formulation which are kept for examination were withdrawn at definite time intervals. The withdrawn samples were evaluated for physical appearance, hardness, drug content.

3. Result and Discussion

Present study was done on enteric coating tablets with different formulation F1 to F9. Esomeprazole sodium sesquihydrate were prepared by direct compression method using different concentration of, microcrystalline cellulose, mannitol, dicalcium phosphate, croscarmellose sodium, magnesium stearate and talc, CAP and Eudragit L100 were used as enteric coating polymer, which prevent drug form gastric pH and release in intestinal pH.

3.1 Preformulation studies

Preparation of standard graphs

Standard graph for the drug Esomeprazole sodium was done separately in pH 1.2 acidic buffer and pH 6.8 phosphate buffer. Table 8.1and 8.2 show the concentrations of Esomeprazole sodium in pH 1.2 acidic and pH 6.8 phosphate buffers and the respective absorbance. The Figure 4 and 5 show the calibration curves of Esomeprazole sodium in pH 1.2 acidic buffer and pH 6.8 phosphate buffer respectively.

Table 3. Calibration data of Esomeprazole sodium in 0.1N HCl (pH 1.2)

Sl. No.	Concentration (mg/mL)	Absorbance* (nm)
1	0	0
2	2	0.082+0.0005
3	4	0.145+0.0015
4	6	0.231+0.0101
5	8	0.289+0.0023
6	10	0.361+0.0025
7	12	0.459+0.0047

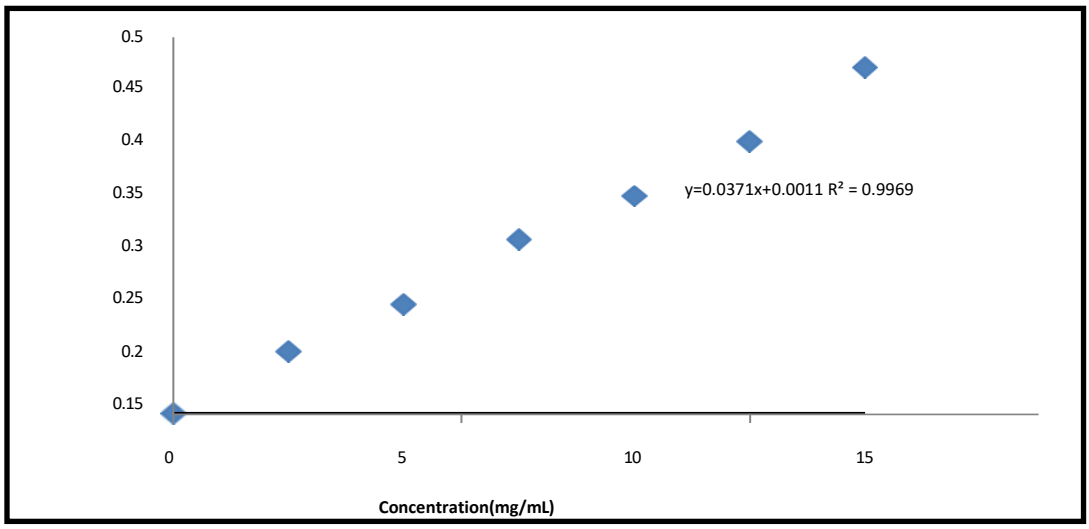

Figure 1. Standard graph of Esomeprazole sodium in 0.1N HCl (pH 1.2)

Table 4. Calibration data of Esomeprazole sodium in phosphate buffer (pH 6.8)

SL. NO.	Concentration (mg /mL)	Absorbance*(nm)
1	0	0
2	2	0.085±0.0040
3	4	0.149±0.0036
4	6	0.243±0.0015
5	8	0.305±0.0075
6	10	0.373±0.0051
7	12	0.468±0.0020

*Mean+SD, *n* = 3

FTIR Spectral Study

FT-IR spectroscopy study was carried out separately to find out the compatibility between the drug Esomeprazole and Microcrystalline cellulose, mannitol, dicalcium phosphate, croscarmellose sodium. The FT-IR was performed for drug, polymer and the physical mixture of drug-polymer. The spectral obtained from FT-IR spectroscopy studies shows in Table 8.2 and Figures 8.2The peaks obtained in the spectra of drug and polymers mixtures correlates with each other. This indicates that the drug was compatible with the formulation components. IR studies indicated no interaction between drug and polymers.

3.2 Evaluations

Precompression Parameters

The prepared Esomeprazole powder blend for tabletting was prepared by direct compression method. The prepared Esomeprazole powder blend were evaluated angle of repose, bulk density, tapped density, Hausner's ratio and compressibility index as given on Table 5.

The bulk densities of the granules were found to be in the range of 0.306 ± 0.03 to 0.384. ± 0.04 gm/mL, while the tapped densities were ranged between 0.313 ± 0.04 to 0.429 ± 0.05 gm/mL. The flow characteristics of the granules were assessed by determining their angle of repose and Carr's Index. The values of compressibility (5.74 ± 0.13 to 10.48 ± 0.20%) signify good flowability. The angle of repose of all formulation was less than 30 º (25.79 ± 0.24 to 29.52 ± 0.14) also indicate the good flowability of the prepared granules.

3.3 Formulation studies

Preparation of of Esomeprazole Sodium Tablets

The Esomeprazole sodium sesquihydrate tablets were prepared by direct compression method A total of nine formulations (F1-F9) by using a rotary tablet compression machine (8 mm diameter, Riddhi 10 stn mini tablet press RDB4-10, Rimek, Ahmedabad, India). Compositions of the Esomeprazole sodium sesquihydrate tablets are shown in Table 8.4

Post Compression Parameters of Esomeprazole Sodium Core Tablet

The Esomeprazole tablets were prepared by direct compression method and were evaluated for their hardness, weight variation, content uniformity, friability and *in vitro* drug release **(Table 9)**

Hardness has to be controlled to ensure that the product is firm enough to withand handling without breaking or crumbling and not so hard that the disintegration time is unduly prolonged. The average hardness of the tablets to be in range was found within 4.93 ± 0.15 to 6.20 ± 0.35 Kg / cm2. Friability value which also affected by the hardness value of tablets should be in the range 1% limits, which is the usual friability range of tablets. The friability of the prepared tablets was found less than 1% w/w. The drug content uniformity of Esomeprazole sodium present in tablets formulation ranged from 96.28 ± 0.15to 100.34 ± 0.13%. The average weight found 198 ± 0.15 to 206 ± 0.24 mg. Disintegration time varied between 11.48 ± 0.15 to 5.38 ± 0.23, hence all shows favorable result.

Table 5. Post compression parameters of Esomeprazole sodium core tablets

Formulation Code	Parameter				
	Hardness (Kg/cm^2)*	Friability (%)*	Weight variation (mg)*	Drug content (%)*	Disintegration time (min) *
F1	5.80± 0.12	0.69 ± 0.015	199± 0.12	96.28± 0.15	10.6± 0.62
F2	5.56± 0.24	0.51± 0.017	206± 0.24	97.62± 0.27	8.26± 0.56
F3	5.83± 0.08	0.48± 0.014	201± 0.17	99.51± 0.36	5.38± 0.23
F4	4.93± 0.15	0.64± 0.015	208± 0.20	98.17± 0.16	11.48± 0.15
F5	5.73± 0.25	0.71± 0.016	203± 0.16	98.92± 0.42	9.32± 0.18
F6	5.12± 0.34	0.68± 0.026	206± 0.14	100.34± 0.13	6.13± 0.25
F7	5.66± 0.17	0.54± 0.026	199± 0.22	98.50± 0.48	10.54± 0.43
F8	6.20± 0.35	0.49± 0.025	204± 0.18	98.41± 0.34	9.12± 0.71
F9	5.60± 0.24	0.42± 0.018	198± 0.15	99.08± 0.35	6.02± 0.21

* Mean ± SD, n=3

Physicochemical evaluation of coating films

Physicochemical evaluation of cellulose acetate phthalate, Eudragit L100 and were studied for different parameters such as film thickness, film weight and film solubility. The enteric polymer cellulose acetate phthalate, Eudragit L100 were found to be completely soluble in pH6.8 and insoluble in pH1.2 (Table 8.6)

Physicochemical evaluation of Esomeprazole sodium enteric coated tablets

The tablets which show most satisfactory result in disintegration, and drug content parameters (F3 and F9) coated by dip coating method. The results of physicochemical evaluation of prepared coated tablets are shown in Table 6. The weight variation was found to be between 0.211 ± 0.024 % to 214 ± 0.021 mg. The drug content was found to be between 93.47 ± 0.23% to 98.45 ± 0.12%. The hardness was found to be from 5.2 ± 0.11 to 6.5 ± 0.15 Kg / cm^2.

Table 6. Physicochemical evaluation of different polymer coating films

Polymer	Parameter		
	Film solubility		Film thickness (mm)*
	pH1.2	pH6.8	
CAP	Insoluble	Soluble	0.21± 0.07
EudragitL100	Insoluble	Soluble	0.24±0.08

*Mean+SD, *n* = 3

Table 7. Physicochemical evaluation parameters of enteric coated tablets

Polymer	Batch Code	Parameter		
		Weight Variation (mg) *	Hardness Kg/cm^2*	Drug content (%)*
CAP	**C1F3**	211± 0.035	6.5± 0.15	96.75± 0.14
	C2F3	214± 0.016	5.9± 0.24	93.65± 0.35
	C1F9	212± 0.006	5.4± 0.09	94.45± 0.26
	C2F9	210± 0.024	6.3± 0.14	98.54± 0.12
Eudragit L 100	**E1F3**	214± 0.021	5.5± 0.16	93.47± 0.23
	E2F3	213± 0.012	6.0± 0.06	94.56± 0.14
	E1F9	215± 0.015	6.5± 0.31	98.27± 0.45
	E2F9	211± 0.024	5.7± 0.20	96.35± 0.12

*Mean+SD, *n* = 3

***In vitro* drug release studies of enteric coated tablets**

The *in vitro* release of Esomeprazole sodium from the prepared tablets was studied in ph 1.2 for 2 h and in phosphate buffer pH 6.8 for 1 h. *In vitro* dissolution studies were performed using USP Type II rotating paddle dissolution apparatus (Electrolab TDT-08L, India) by using 1.2 N HCl and phosphate buffer (pH 6.8) as a dissolution medium. Formulation which shows most satisfactory result is C2F9, where drug release started after 2 hrs, and released maximum 99.72 by 3 hrs. Remaining were respectively, released started and reached maximum, CIF3-90 min and 96.42 in 3 hrs, C2F3-2 hrs and 94.59 in 195 min, E1F3-90 min and 98.15 in 165 min, E2F3-105 min and 97.54 in 3 hrs, C1F9-90 min and 99.79 in 165 min, EIF9-90 min and 97.97 in 165 min, E2F9-2 hrs and 97.39 in 3 hrs. The cumulative percentage releases of Esomeprazole sodium from the tablets were shown in Table 8.

Table 8. *In vitro* drug release of Esomeprazole sodium (C1F3)

Time (min)	Absorbance	Conc. (µg/mL)	Conc. in 900 mL (mg/mL)	Loss	Cumulative loss	Cumulative drug released	Cumulative percentage drug released*
0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0
105	0.024	0.6469	5.822	0	0	5.822	14.62±0.52
120	0.06	1.6172	14.555	0.0064	0.0064	14.561	36.58±0.40
135	0.091	2.3884	21.496	0.0161	0.0226	21.518	54.05±0.90
150	0.121	3.1758	28.582	0.0238	0.0465	28.629	71.91±0.39
165	0.142	3.7270	33.543	0.0317	0.0782	33.621	84.46±0.17
180	0.162	4.2519	38.267	0.0372	0.1155	38.383	96.42±0.40

Table 9. *In vitro* drug release of Esomeprazole sodium (E2F9)

Time (min)	Absorbance	Conc. (ug/ml)	Conc.in 900ml (mg/ml)	Loss	Cumulative loss	Cumulative drug released	Cumulative percentage drug released
0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0
120	0	0	0	0	0	0	0
135	0.054	1.417	12.755	0	0	12.755	32.18±0.34
150	0.098	2.572	23.149	0.0141	0.0141	23.163	58.44±0.58
165	0.139	3.648	32.834	0.0257	0.0398	32.874	82.94±0.18
180	0.167	0.038	0.043	39.448	0.0364	0.076	99.72±0.46

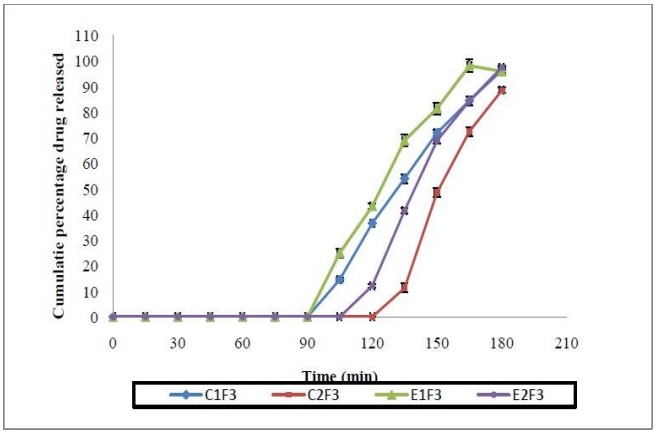

Figure 2. *In vitro* drug release of Esomeprazole sodium (C1F3 to E2F3)

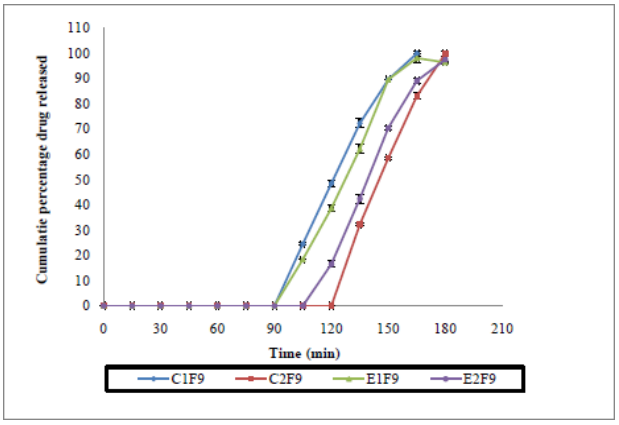

Figure 3. *In vitro* drug release of Esomeprazole sodium (C1F9 to E2F9)

Stability studies

Stability of a drug in a dosage form at different environmental conditions is important as it determines the expiry date of that particular formulation. Changes in the physical appearance, color, odor, taste or texture of the formulation indicate the drug instability. Among the three enteric coated Formulations, Formulation C2F9 was selected for stability studies based on the physicochemical characterization of coating films and release characteristics.

The stability studies were carried out at 40 ± 2 °C with 75 ± 5%% RH which shown in **Table 13**. There were no significant changes in their physical appearance, average weight of tablets and hardness. It was observed that the initial drug content and the drug contents of the samples analyzed after 1,2,3 month of storage were similar. The release profile also not showed any significant changes indicating that there were no significant changes in the physical as well as chemical characteristics of the formulation. Hence, it can be

concluded from the results that the developed tablets were stable and retain their pharmaceutical properties over a period of 3 month

Table 13.Stability studies of cellulose acetate phthalate coated tablet formulation C2F9

Evaluation parameters	Observation in month			
	Initial	1st month	2nd month	3rd month
Physical Appearance	White color tablets	No change	No change	No change
Hardness (Kg/ cm^2)*	6.3± 0.14	6.2± 0.56	6.2± 0.64	6.2± 0.26
Drug Content (%)*	98.54± 0.12	98.36± 0.52	98.16± 0.36	98.07± 0.28

4. Summary and Conclusion

The aim of the present study was to formulate and evaluate of enteric coated Esomeprazole sodium sesqui hydrate tablets by using manotol, dicalcium phosphate, microcrystalline cellulose, crossrmelose sodium, magnesium starate and talc.

FT-IR study was carried out to check any possible interactions between the drug and the excipients manotol, dicalcium phosphate, microcrystalline cellulose, crosscarmelose sodium, Esomeprazole sodium sesquihydrate were prepared by direct compression method using different concentration of, Avicel PH (MCC) as filler, mannitol and dicalcium phosphate as diluents, croscarmellose sodium as disintegrating agents, magnesium stearate and talc was used as a glidant and lubricant respectively. The granules were evaluated for the precompression parameters like angle of repose, bulk density, tapped density and compressibility index. The flow characteristics of the granules were assessed by determining their angle of repose and Carr's Index. The values of compressibility index and angle of repose signify good flowability of the granules for all the batches. This shows that the granules had smooth flow properties ensuring homogenous filling of the die cavity during the compression (punching) of tablets.

Coating has been done for the selected formulation from the proposed formulation 1- 9. Coating materials like CAP and Eudragit L100 with the difference concentration.

The *in vitro* dissolution studies were carried out for compressed and coated tablets using USP dissolution apparatus type II. The cumulative percentage of drug release from the tablets varied and depends on the type of polymer used and its concentration.

Formulation 3 and formulation 9 was selected for the coating. CAP and Eudragit L 100 was used for the coating polimer. In this present study coating material was used with 6 and 8 percentage on the above-mentioned formulation.

The stability study indicated that the prepared formulation was stable retained their pharmaceutical properties at room temperature and 40°C/75% RH over a period of 1 month. The coated tablets did not release the drug in hostile acidic environment (pH 1.2) due to protective polymer coating and released the drug in the intestinal environment (pH 6.8).

Formulation 9, coated with 8% CAP was found to be best formulation, based on release time of the drug in the intestine.

5. Conclusion

An attempt was made in this research work to formulate an oral enteric coating Esomeprazole sodium tablet and evaluate it. An ulcer is the disease caused by an imbalance between aggressive and defensive factors. Ulcer sarecrater-like sores which form in the lining of the stomach, just below the stomach at the beginning of the small intestine in the duodenum. Esomeprazole is a substituted benzimidazole derivative that targets gastric acid proton pumps, the final common pathway for gastric acid secretion. The drug covalently binding to the proton pumps, causing prolonged inhibition of gastric acid secretion.The stability of Esomeprazole is depending on pH and it rapidly degrades in acid medium of the stomach,but stable in alkaline conditions. Therefore, Esomeprazole should be delivered into the intestine. Hence, an attempt was made to formulate an enteric coated drug delivery system for Esomeprazole by using various enteric coating polymers.

From the reproducible results obtained from the executed experiments it can be concluded that CAP and Eudragit L 100 can be used as enteric coated polymer. Both the polymer can protect the drug from the acid environment that is in gastric pH and release the drug when it's reached in intestinal pH.

In this present research work, both the polymer have been used as an enteric coating polymer, with the best formulation. CAP and EudragitL100 have been used 6% and 8% with the best formulation. From the dissolution studies it was observed that, the enteric coated both polymer was intact for 2 hours in pH 1.2 buffer. The formulation which is said to the best formulation is C2F9, which is formulation no. 12 and coated with 8% CAP.

Therefore the study proved that the Esomeprazole enteric coated tablets can be used for ulcer and GERD disease.

Hence, formulation of Esomeprazole as an enteric coated tablet may solve the stability problem of drug in the stomach and release the drug in the intestine. After satisfied pre-compression and post compression result the of core tablets, tablets were coated with suitable coating material to develop the dosage form which is to overcome the drug

degradation by the gastric enzymes as well as the acidic environment of the stomach.

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