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FORMULATION AND EVALUATION OF ESOMEPRAZOLE ORAL DISPERSIBLE TABLETS

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ABSTRACT
The aim of this study is to formulate and significantly improve the bioavailability and reduce the side effects of Mouth dissolving tablets Esomeprazole. The precompression blends of Esomeprazole were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend of all the batches indicates well to fair flowability and compressibility. Mouth dissolving tablets were prepared with various disintegrants like Primojel, Crospovidone and Sodium-starch glycolate at different concentration ratios and were compressed into tablets. The formulated tablets were evaluated for various quality control parameters. The tablets were passed all tests. Among all the formulations F3 formulation containing, drug and Primojel showed good result that is 98.12 % in 30 min. Hence from the dissolution data it was evident that F3 formulation is the better formulation. By conducting further studies like *invitro* studies, preclinical and clinical studies we can commercialize the product.

KEYWORDS: Esomeprazole, Primojel, Crospovidone, Sodium-starch glycolate and Mouth dissolving tablets.

INTRODUCTION
Oral solid dosage forms remain the most widely used drug delivery systems due to their convenience, stability, accurate dosing, and cost-effectiveness. Among them, tablets dominate global pharmaceutical markets. However, conventional tablets often fail to meet complex therapeutic requirements such as modified drug release, poor solubility enhancement, combination therapy, and patient-centric dosing. These challenges have stimulated the development of advanced tablet formulation technologies that integrate material science, process engineering, and digital manufacturing.

Recent advances include bilayer and multilayer tablets for dual-release profiles, multi-unit pellet systems to minimize dose dumping, hot melt extrusion for solid dispersions and continuous manufacturing, 3D printing for personalized dosage forms, and orally disintegrating tablets for improved patient compliance. This review integrates these technologies into a single scientific narrative, highlighting their principles, advantages, limitations, and industrial relevance.

EVOLUTION OF TABLET FORMULATION TECHNOLOGIES
Historically, tablet manufacturing relied on wet granulation, dry granulation, and direct compression. While effective, these methods offer limited flexibility in controlling drug release and formulation complexity. The evolution toward advanced systems was driven by:
Increasing prevalence of poorly water-soluble drugs
Need for fixed-dose combinations
Demand for patient-centric dosage forms
Regulatory emphasis on quality by design (QbD) and continuous manufacturing
Advanced techniques now enable precise modulation of drug release kinetics, improved bioavailability, and scalable production.

ORALLY DISINTEGRATING TABLETS (ODTS)

Concept

ODTs rapidly disintegrate in the oral cavity without the need for water, improving compliance in pediatric, geriatric, and dysphagic patients. In contrast to other traditional oral solid dosage forms, oral disintegrating tablets (ODTs) are a unique oral solid dosage form that quickly dissolves in the mouth (within seconds to minutes of oral administration) without chewing and without the need for water.[7] Orally disintegrating tablets offer benefits of easy swallowing, not requiring water, stability, accurate dosing, suitability to paediatrics and geriatrics, bedridden, mentally retarded, as well as bio-pharmaceutical advantages such as pre-gastric absorption. During the passage of saliva carrying the drug down to the stomach, some drugs are absorbed in the tract before the stomach leading to greater bio-availability than ordinary dosage forms. Compared to conventional disintegrants, super disintegrants are effective at lower concentrations and provide rapid tablet disintegration without compromising tablet hardness or stability. The development of orally disintegrating tablets using super disintegrants offers advantages such as rapid onset of action, improved bioavailability, ease of administration, and better patient acceptability. Therefore, the present project focuses on the formulation and evaluation of orally disintegrating tablets using super disintegrants to achieve fast disintegration and optimal drug release. Commonly used super disintegrants include croscarmellose sodium, sodium starch glycolate, and crospovidone.

Formulation Strategies

Use of super disintegrants such as croscarmellose sodium, crospovidone, and sodium starch glycolate is central to ODT design. Mechanism of action of super disintegrants

1. Capillary action
2. Swelling
3. Chemical reaction
4. Particle repulsive force
5. Deformation recovery
6. Enzymatic reaction
7. Combination reaction.

Evaluation Parameters

Disintegration time, wetting time, hardness, friability, and dissolution behavior are essential quality metrics.

DESIGN OF ORALLY DISINTEGRATING TABLETS (ODT's)

CRITERIA FOR SELECTION OF EXCIPIENTS IN ODTs

Formulation approaches for ODTs begin with selecting excipients to shorten the disintegrating time and comply with the pharmacopeia specifications. While selecting excipients, the following factors must be considered:

1. Rapid disintegration and dissolution
2. Good mouthfeel (no grittiness or bitterness)
3. Non-toxicity and GRAS status
4. Compatibility with drug
5. Adequate mechanical strength
6. Low hygroscopicity
7. Chemical and physical stability
8. Ease of processing (direct compression preferred)

PREPARATION OF POWDER BLEND FOR ORALLY DISINTEGRATING TABLETS

The performance of ODTs depends on the technology used in their manufacture. The orally disintegrating property of these tablets is attributable to the quick ingress of water into the tablet matrix, which creates porous structure and results in rapid disintegration. Hence, the basic approaches to develop ODTs include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water-soluble excipients in the formulation.

The **powder blend preparation** is a critical step in ODT formulation because it directly affects **blend uniformity, flowability, compressibility, tablet hardness, and disintegration time**.

1. Objectives of Powder Blend Preparation

- Ensure **uniform distribution of API** (especially low-dose drugs)
- Achieve **good flow properties** for uniform die filling
- Maintain **rapid disintegration** (≤ 30 seconds ideally)
- Prevent **segregation and content variability.**

Table 1: Typical Composition of Powder Blend for ODTs.

Component	Examples	Purpose
Active pharmaceutical ingredient (API)	Drug substance	Therapeutic effect
Diluent	Mannitol, lactose, MCC	Bulk, mouthfeel
Super disintegrant Binder (optional)	Croscarmellose sodium, PVP K30, MCC	Rapid tablet breakup Mechanical strength
Sweetener	Aspartame, sucralose	Taste masking
Flavor	Mint, orange	Patient acceptability
Glidant	Colloidal silicon dioxide	Improve flow
Lubricant	Magnesium stearate	Reduce friction

1. Step-by-Step Preparation of Powder Blend (Direct Compression Method)

Step 1: Sifting of Ingredients

- Sift **API, diluent, super disintegrant, sweetener, and flavor** through **#40 or #60 mesh**

 Purpose:
o Break agglomerates21
o Achieve uniform particle size
o Improve homogeneity

Step 2: Primary Blending
 Transfer sifted powders (except lubricant & glidant) into a **polybag, double cone blender, or V-blender**
 Blend for **10–15 minutes**
 Low shear mixing preferred to avoid:
o Loss of super disintegrant efficiency
o Electrostatic charging
Note: For low-dose drugs, apply **geometric dilution**.

Step 3: Addition of Super disintegrant (Optional Split Addition)
 Super disintegrant may be added:
o **Intra-granular (50–70%)**
o **Extra-granular (30–50%)**
 Blend gently for **5 minutes**
 Improves **wicking and swelling action**

Step 4: Addition of Glidant
 Add **colloidal silicon dioxide**
 Blend for **2–3 minutes**
 Improves powder flow and prevents segregation

Step 5: Lubrication
 Add **magnesium stearate (0.25–1%)**
 Blend gently for **1–3 minutes only**
 Over-mixing may:
o Reduce tablet hardness
o Delay disintegration
Avoid high-shear mixing during lubrication.

AIM OF THE WORK

Aim of the present work is to formulate Esomeprazole Mouth dissolving tablet by using Direct compression methd and different super disintegrants and evaluating its characteristics.

OBJECTIVE OF THE STUDY

Oral administration is the most popular route compared to other dosage forms due to ease of ingestion, pain avoidance, versatility and most importantly patient compliance but one important drawback of solid dosage form is the difficulty in swallowing (dysphasia) or chewing in patients particularly pediatric and geriatric patients.

The patient acceptability and compliance are important in design of the novel drug delivery system; one such drug delivery system is oral disintegrating tablets (ODTs) which has gained acceptance and popularity in the recent times.

Esomeprazole is a second generation proton pump inhibitor (PPI) medication intended for treatment of peptic ulcer.

The main objective of the study is to improve solubility and bioavailability of the Esomeprazole using various novel super disintegrants.

MATERIALS AND METHODS

Esomeprazole was Procured From Fenoza pharma, Hyderabad, India. Provided by SURA LABS, Dilsukhnagar, Hyderabad.as a gift sample from Matrix laboratories Ltd, hyd. Primojel, Crospovidone, Sodium starch glycolate Magnesium-stearate, AvicelPH102(MCC), Talc, Aspartame were obtained as a gift sample from Ozone International Pvt Ltd, Mumbai, India, and Merck Specialities Pvt Ltd, Mumbai, India. All other chemicals used were of analytical grade.

METHODOLOGY

Buffer preparation

Preparation of 0.2 M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.128 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 ml of distilled water and mixed.

Preparation of 0.2 M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed.

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of 0.2 M potassium dihydrogen orthophosphate and 112.5 mL of 0.2 M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

Analytical method development for Esomeprazole

a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400 nm against the reagent blank to fix absorption maxima. The λ_{max} was found to be 221 nm. Hence all further investigations were carried out at the same wavelength.

b) Construction of standard graph

100 mg of Esomeprazole was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1mg/mL (1000µg/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10µg/ml). From this stock solution aliquots of 0.5 ml, 1 ml, 1.5 ml, 2ml, 2.5 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 5, 10, 15, 20 and 25µg/ml respectively. The absorbance of each concentration was measured at respective (λ_{max}) i.e., 221 nm.

Formulation development

Drug and different concentrations of super disintegrants (Primojel, Crospovidone and Sodium starch glycolate) and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass motor for 15 min.

- The obtained blend was lubricated with magnesium

stearate and glidant (Aerosil) was added and mixing was continued for further 5 min.

- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table 2: Formulation table showing various compositions.

INGREDIENTS (MG)	FORMULATION CODES								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Esomeprazole	40	40	40	40	40	40	40	40	40
Primojel	25	50	75	-	-	-	-	-	-
Crospovidone	-	-	-	25	50	75	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	25	50	75
Mannitol	15	15	15	15	15	15	15	15	15
Aerosil	7	7	7	7	7	7	7	7	7
Sodium stearyl fumarate	6	6	6	6	6	6	6	6	6
Lactose	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Total Weight (mg)	200	200	200	200	200	200	200	200	200

Evaluation of tablets

Pre compression parameters

Measurement of Micromeritic properties of powders

1. Angle of repose

The angle of repose of API powder is determined by the funnel method. The accurately weighed powder blend is taken in the funnel. The height of the funnel is adjusted in a way that the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on o the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\tan \Theta = h/r \quad \text{..... (1)}$$

Where, h and r are the height and radius of the powder cone.

Table 3: Flow Properties and Corresponding Angle of Repose.

Flow Property	Angle of Repose (^{0})
Excellent	25-30
Good	31-35
Fair- aid not needed	36-40
Passable-may hang up	41-45
Poor-must agitate, Vibrate	46-55
Very Poor	56-65
Very, very Poor	>66

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in 100 ml graduated cylinder and the powder is leveled and the unsetled volume, V_0 is noted. The bulk density is calculated in g/cm^3 by the formula.

Bulk density = M/V_0 ..... (2)

V_0 = apparent unstirred volume

M= Powder mass

3. Tapped density

The powder sample under test is screened through sieve No. 18 and the weight of the sample equivalent to 25 gm filled in 100ml graduated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_0 is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, V_b is noted. The difference between two tapping volume is < 2%, V_b is considered as a tapped volume Vf. The tapped density is calculated in g/cm^3 by the formula.

Tapped density = M/Vf ..... (3)

M = weight of sample powder taken Vf = Tapped volume

4. Compressibility index

The compressibility index of the powder blend is determined by Carr's index to know the flow character of a powder. This formula for Carr's index is as below :

Carr's Index (%) = [(TD-BD)/TD] x100 ..... (4)

5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hausner's ratio. It is calculated by the following equation.

$H = Pt / \rho B$ ..... (5)

Where ρT= tapped density, ρB = bulk density

Table 4: Scale of Flowability.

Compressibility index (%)	Flow character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45

32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters

a) Thickness

The thickness of the tablets was determined by using Digital micrometer. 10 individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation 3 batches were calculated. It passes the test for weight variation test if not more than 2 of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the % shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-friabilator. Accurately weighed six tablets were placed in The Roche friabilator and rotated at 25 RPM for 4 min. Percentage friability was calculated using the following equation.

Friability = ([w0-w]/w0) x 100

Where w0 = weight of tablet at time zero before revolution. w = weight of the tablet after 100 revolutions

d) Drug content

The content of drug carried out by 5 randomly selected tablets of each formulation. The 5 tablets were grinded to get powder, this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analysed spectrophotometrically at 221 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 min. and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) WETTING TIME

- **Method:** A piece of tissue paper folded twice was placed in a small petridish containing 6ml of water. A water-soluble dye phenolphthalein was added to the petridish. The dye solution was used to identify the complete wetting of the tablet surface.
- A tablet was carefully placed on the surface of tissue paper in the petridish at room temperature.
- The time required for water to reach the upper surface of the tablets and completely wet them was noted as the wetting time. To check for reproducibility, the measurements were carried out in triplicates (n=3). The wetting time was recorded using a stopwatch.

g) WATER ABSORPTION RATIO (R)

- **Method:** The weight of the tablet before keeping in the petridish was noted (W_b) using digital balance. The wetted tablet from the petridish was taken and reweighed (W_a`) using the same. The Water absorption ratio, R, was determined according to the following equation:

$R = (W_a - W_b) / W_b * 100$

W_a= Weight of the tablet after absorption W_b= Weight of the tablet before absorption

h) IN VITRO DISPERSION TIME

- **Method:** *In vitro* dispersion time was determined by placing one tablet in a beaker containing 10 ml of pH 6.8 phosphate buffer at 37±0.5°c and the time required for complete dispersion was determined.
- To check for reproducibility, the measurements were carried out in triplicates (n=3). The dispersion time was recorded using a stopwatch.

i) Dissolution test of Esomeprazole

Drug release from Esomeprazole tablets was determined by using dissolution test USP 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at room temperature of 37˚ C and at a speed of 50 rpm.

5 ml aliquots of dissolution media were withdrawn each time intervals (5, 10, 15, 20, 30 min) and appropriate dilution by UV Spectrophotometer. The Concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies

Drug excipients compatibility studies were carried out by mixing the drug with various excipiennts in different proportions (in 1;1 ratio were to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly. Fourier Transform Infrared Spectroscopy (FTIR) studies were performed on drug, optimized formulation using Bruker FTIR. The samples were analyzed between wave numbers 4000 cm^{-1} and 550cm^{-1}.

RESULTS AND DISCUSSION

Preparation of Calibration Curve of Esomeprazole

The regression coefficient was found to be 0.999 which indicates a linearity with an equation of Y= 0.059 X-0.002. Hence Beer-Lambert's law was obeyed.

Table 8.1: Calibration curve data of Esomeprazole in pH 6.8 phosphate buffer.

Concentration(µg/mL)	Absorbance
0	0
5	0.121
10	0.214
15	0.321
20	0.449
25	0.555

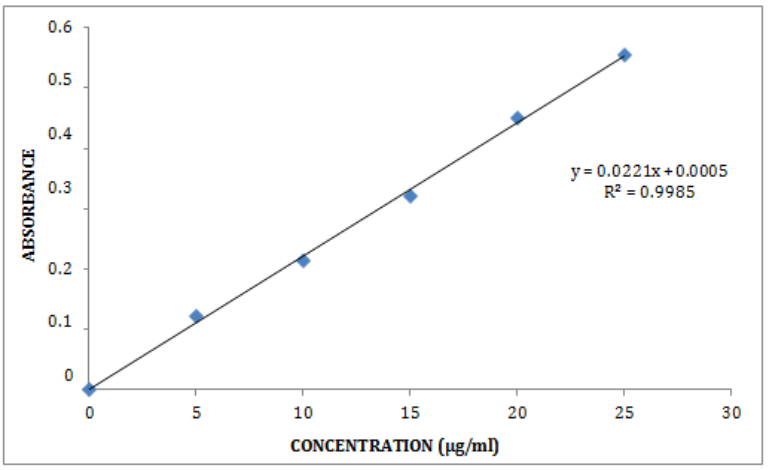


Fig 8.1: Standard curve of Esomeprazole.

Evaluation of pre-compression parameters of powder blend

Table 8.2: Evaluation of pre-compression parameters of powder blend.

Formulation Code	Angle of Repose	Bulk Density (gm/m L)	Tapped Density (gm/mL)	Carr's Index(%)	Hausner' s Ratio
F1	26.20±0.32	0.465±0.026	0.523±0.034	11.08±0.44	1.12±0.05
F2	21.77±0.34	0.492±0.038	0.585±0.042	15.89±0.36	1.18±0.06
F3	20.81±0.41	0.437±0.015	0.534±0.034	18.16±0.57	1.22±0.04
F4	23.25±0.53	0.435±0.042	0.526±0.021	17.30±0.46	1.20±0.11
F5	21.46±0.34	0.423±0.010	0.515±0.025	17.86±0.49	1.21±0.07
F6	25.78±0.32	0.474±0.042	0.554±0.041	14.44±0.65	1.16±0.08
F7	24.86±0.44	0.456±0.019	0.543±0.037	16.02±0.64	1.19±0.14
F8	25.60±0.32	0.461±0.026	0.565±0.023	18.40±0.76	1.22±0.004
F9	22.45±0.38	0.459±0.017	0.545±0.027	15.77±0.47	1.18±0.02

- For each formulation blend of drug and excipients were prepared and evaluated for various pre compression parameters described earlier in methodology chapter.
- The bulk density of all formulations was found in the range of 0.423±0.010 - 0.492±0.038 and tapped density was in the range of 0.515±0.025 - 0.585±0.042
- The Carr's index and Hausner's ratio was calculated from tapped density and bulk density.

Evaluations of post compression parameters of Esomeprazole mouth dissolving tablets

Table 8.3: Evaluation of post compression parameters of Esomeprazole Mouth dissolving tablets.

Formulation codes	Average weight (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	198.36	4.25	0.35	4.21	98.35
F2	200.15	5.01	0.56	4.82	99.47
F3	196.89	4.89	0.45	4.99	100.14
F4	199.75	5.14	0.54	4.81	99.25
F5	200.17	5.36	0.72	4.36	97.31
F6	197.42	4.87	0.28	4.55	100.10
F7	200.24	4.32	0.37	4.17	98.14
F8	198.73	4.56	0.52	4.97	97.35
F9	196.10	4.67	0.62	4.26	98.58

Weight variation and Thickness: All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown above. The average tablet weights of all the formulations were noted down.

Hardness and friability: All the Mouth Dissolving formulations were evaluated for their hardness using Monsanto hardness tester and the results are shown above. The average hardness for all formulations was found to be between (4.25 – 5.36) kg/cm^2 which was found to be acceptable. Friability was determined to evaluate the ability of the tablets to with stand the abrasion during packing, handling and transporting. All the Mouth dissolving formulations were evaluated for their percentage friability using Roche friabilator and the results are shown above. The average percentage friability for all the formulations was between 0.28 – 0.72 which was found to be within the limit.

Drug content: All formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown above. The assay values for all formulations were found to be in the range of (97.31 – 100.14). According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the Mouth dissolving formulation comply with the standards given in IP.

Table 8.4: Evaluation of post compression parameters of Esomeprazole mouth dissolving tablets.

Formulation	Disintegration time*(seconds)	Wetting time* (seconds)	*In vitro* dispersion time*(sec)	% Water absorption ratio*
F1	65	72	62	94
F2	45	63	34	98
F3	35	30	29	99
F4	72	56	73	96
F5	58	45	62	97
F6	50	34	53	98
F7	61	69	60	95
F8	51	41	52	97
F9	43	38	48	97

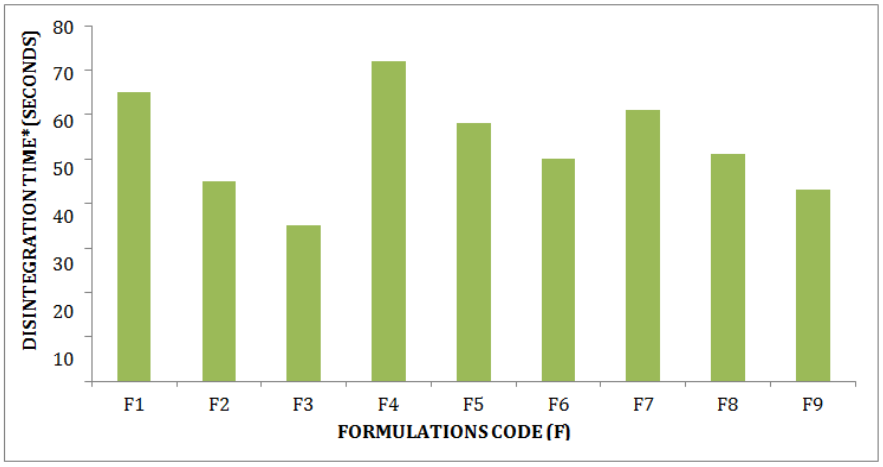


Figure 8.2: *In vitro* Disintegration time graph.

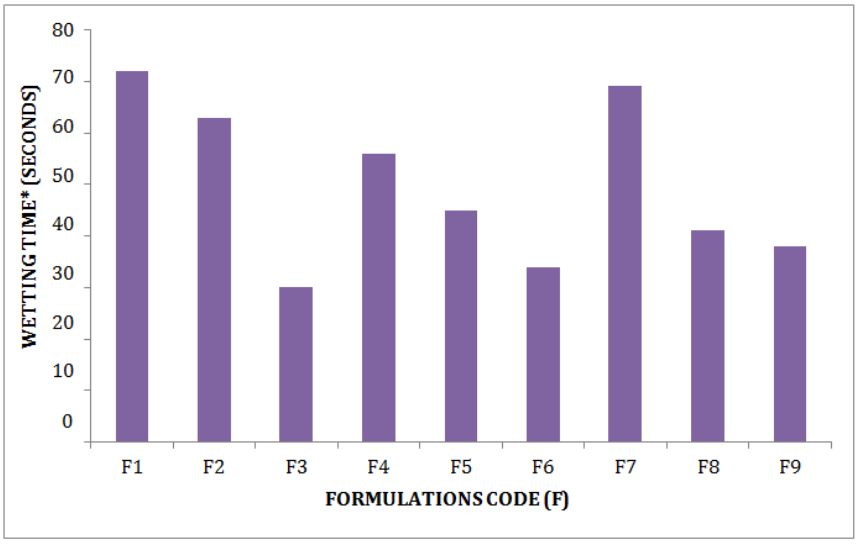


Figure 8.3: Wetting time graph.

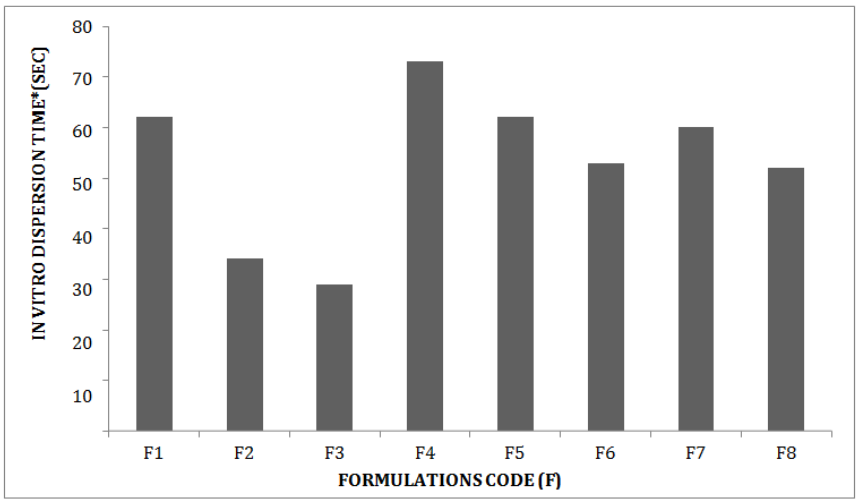


Figure 8.4: *In vitro* dispersion time.

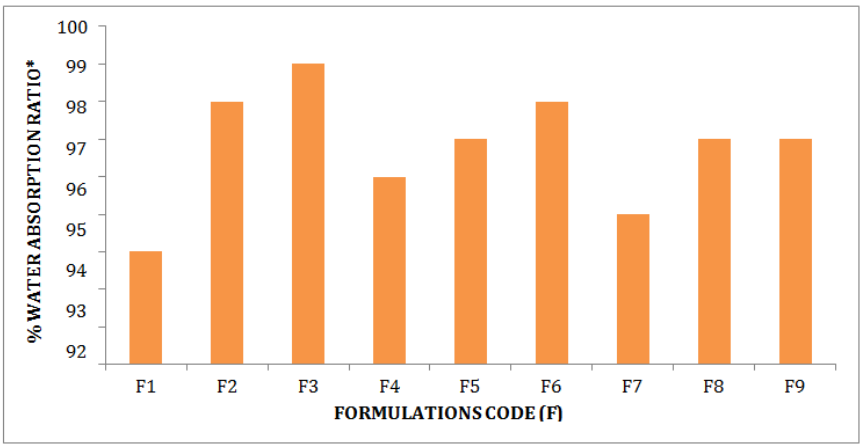


Figure 8.5: Water absorption ratio graph.

***In vitro* disintegration time:** *In vitro* disintegration studies showed from 35 to 72 secs. These results indicate that the F3 formulation which shown less disintegration time than remaining formulations.

Wetting time: Wetting time to the time required to wet completely when kept motionless on the tissue paper in a petridish.

- All the FDT formulations were evaluated for their wetting time as per the procedure described in the methodology section, and the results are shown in

table.

- The average wetting time for all the formulations was in the range of **(30 to 72)** seconds.
- It was also observed that formula F3 which had the least wetting time also had the minimum disintegration time showing a strong correlation between disintegration time and wetting time.

***In vitro* dispersion time**

Esomeprazole Mouth Dissolving Tablets F3 formulation dispersed time was 29 secs. It was known that less dispersion time than other formulation. The *In vitro* dispersion time for all formulation was found to be in a range of **29 to 73** seconds.

Water Absorption ratio: All the formulations were evaluated for water absorption ratio according to the procedure described in methodology section and the results are shown in table.

- The maximum water absorption ratio was shown by formulation F3 showed 99 %.
- Water absorption ratio is proportional to dissolution rate profile as higher the water absorption ratio Higher the dissolution.

***In vitro* drug release studies of Esomeprazole**

Table 8.5: Dissolution data of Esomeprazole.

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	47.25	54.28	53.75	38.92	45.81	45.20	46.75	45.32	56.94
10	59.41	65.15	75.85	46.58	58.99	57.38	67.28	63.79	68.66
15	67.37	68.82	82.54	58.28	67.38	79.82	73.41	78.34	82.24
20	73.85	73.65	88.76	65.96	74.87	86.73	79.63	82.47	87.11
30	76.65	84.56	98.12	72.48	86.56	95.19	83.82	89.68	93.23

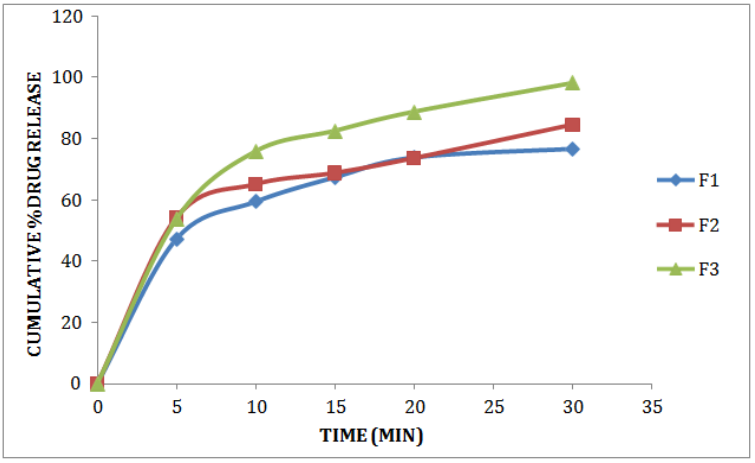


Fig 8.6: Dissolution profile of formulations F1, F2, F3.

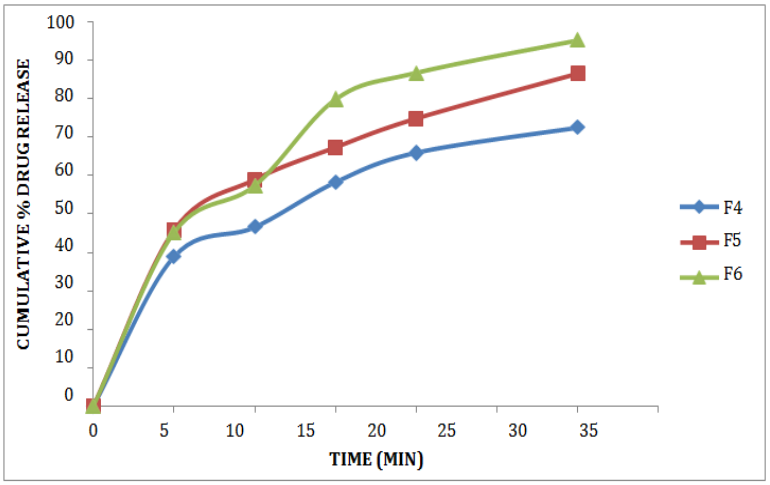


Fig 8.7: Dissolution profile of formulations F4, F5, F6.

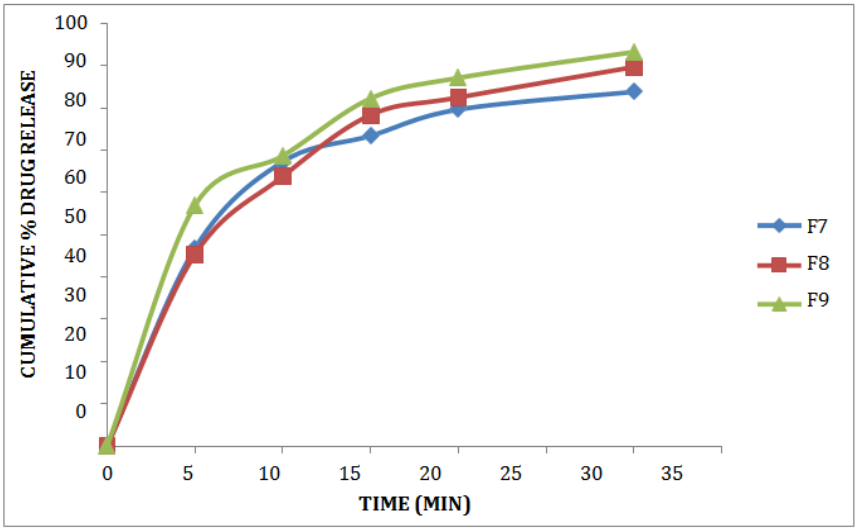


Fig. 8.8: Dissolution profile of formulations F7, F8, F9.

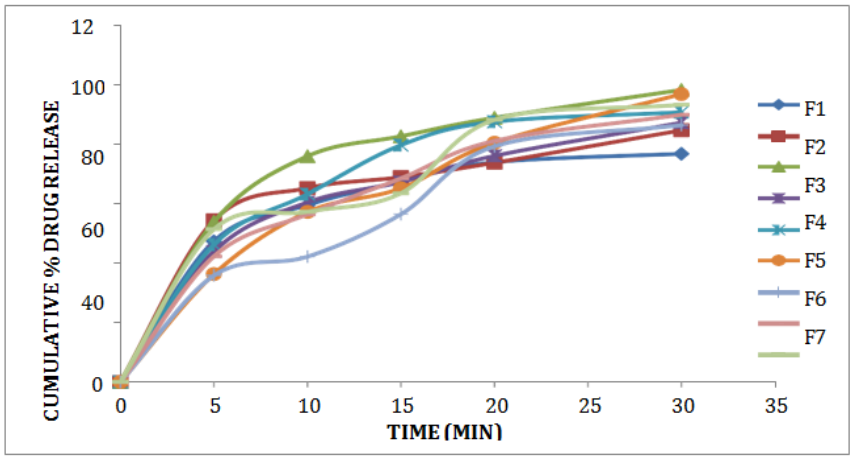


Fig. 8.9: Dissolution profile of all formulations F1-F9.

The F3 formulation shows 98.12 % drug release in 30 min while using 75 mg concentration of Primojel and disintegration time is 35 sec. In which increase of concentration of Primojel improved dissolution and decreased disintegration so it was optimized formulation. Finally Concluded that F3 formulation was the optimized Formulation.

FTIR RESULTS

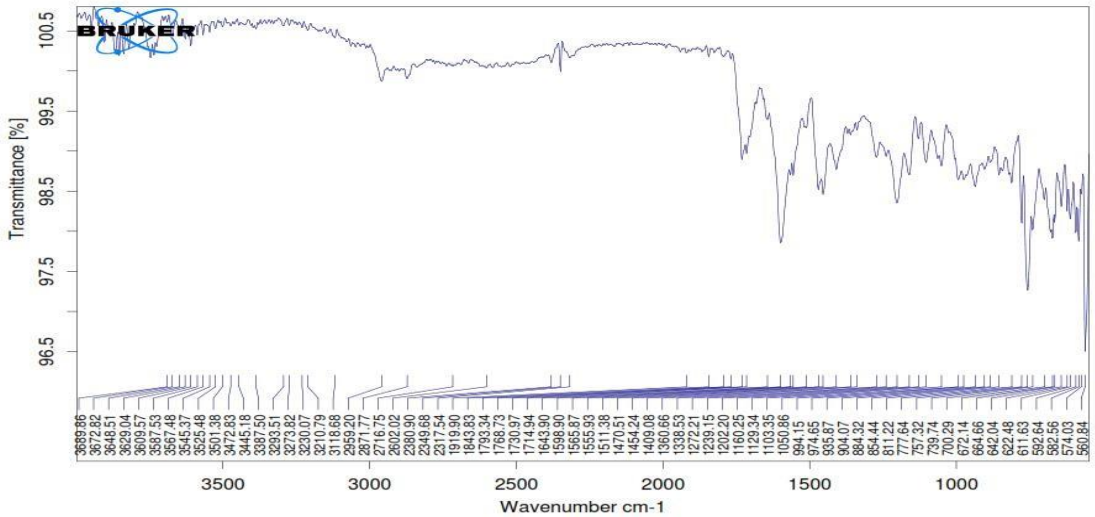


Fig. 8.10: FTIR of Esomeprazole Pure drug.

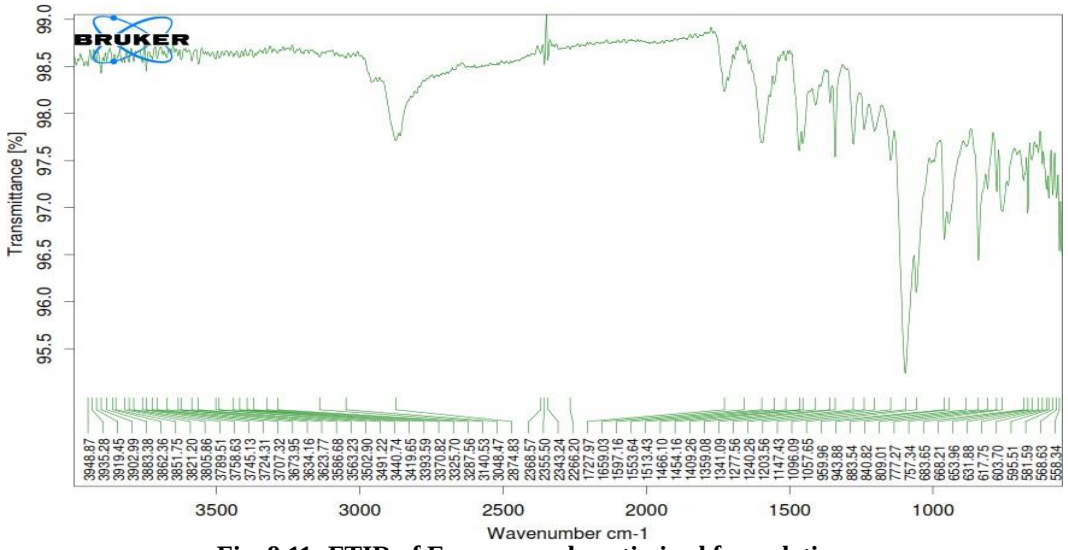


Fig. 8.11: FTIR of Esomeprazole optimized formulation.

Esomeprazole was mixed with proportions of excipients showed no colour change providing no drug-excipient interactions.

CONCLUSION

- The standard curve of Esomeprazole was obtained and good correlation was obtained with R^2 value of 0.998. The medium selected was pH.

6.8 Phosphate Buffer

- Esomeprazole was mixed with various proportions of excipients showed no colour change at the end of 2 months, proving no drug-excipient interactions.
- The pre compression blend of Esomeprazole mouth dissolving tablets using super disintegrants were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. The precompression blend or all batches indicating good to fair flowability and compressibility.
- Mouth dissolving tablets were prepared with various concentrations of super disintegrants and were compressed into tablets.
- The formulated tablets were evaluated for various quality control parameters. The tablets were passed all the tests.
- The formulations (F3) prepared with Primojel disintegrants showed drug release in increasing order. The formulation showed good drug release at 75 mg concentration.
- Among all the formulations F3 formulation containing drug and Primojel (75 mg concentration) showed maximum and good result that is 98.12% drug release in 30 min. Hence from dissolution data it was evident that F3 formulation is the better formulation.

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