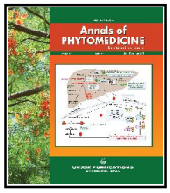
Annals of Phytomedicine 12(2): 963-971, 2023

DOI: http://dx.doi.org/10.54085/ap.2023.12.2.115

Annals of Phytomedicine: An International Journal

http://www.ukaazpublications.com/publications/index.php

Print ISSN : 2278-9839 Online ISSN : 2393-9885



Original Article : Open Access

Formulation and evaluation of esomeprazole magnesium trihydrate controlled release floating tablets

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Article Info

Article history

Received 10 November 2023

Revised 23 December 2023

Accepted 24 December 2023

Published Online 30 December 2023

Keywords

In vitro testing

Floating lag time

Floating duration time

Floating drug delivery system

Esomeprazole magnesium trihydrate

Abstract

The creation and evaluation of floating tablets for esomeprazole magnesium trihydrate, with a specific focus on investigating the influence of polymer types and concentrations. These tablets, designed for a floating drug delivery system, were manufactured by using the direct compression method. The key components employed in the formulation included polymers such as Carbopol 940P and hydroxyl propyl methyl cellulose, along with calcium carbonate serving as a gas-generating agent. The prepared tablets were assessed using FTIR spectroscopy, SEM, angle of repose, pre-formulation parameter, floating lag time, and floating duration time and release behavior. Pre-formulation and post-formulation evaluations are conducted for all the formulations F1-F7. Importantly, the post-formulation parameters of all formulations met the established criteria for quality. All formulations underwent pre-formulation studies, and all formulations were under the limits for each parameter discovered to be met successfully about angle of repose for all formulations F1-F7 in the range of 24.27 ± 0.25 to 26.78 ± 0.34, bulk density for all formulations F1-F7 0.320 ± 0.02 to 0.510 ± 0.01, for all formulations F1-F7 Carr's index values are 5.60 ± 0.01 to 10.65 ± 0.01 and tapped density for all formulations F1-F7 in the range of 0.370 ± 0.02 to 0.529 ± 0.01. One formulation, labeled as F7, stood out due to its remarkable extended floating duration of more than 24 h and drug release profile. The lag time for formulation F7 was found to be 3 sec, floating duration time was more than 24 h. The analysis indicated that the drug release mechanism from these formulations (F7) adhered to a nonfickian pattern, specifically following first-order release kinetics.

1. Introduction

Gastro retentive drug delivery systems are designed to be retained in the stomach for more time and release their active ingredients and thereby enable sustained and prolonged input of the drug to the upper part of the gastrointestinal tract (Chien,1992). A modified release drug delivery system with prolonged residence time in the stomach is of particular interest for drugs acting locally in the stomach; having an absorption window in the stomach or in the upper part of the small intestine; those unstable in the intestinal or colonic environments, or those having low solubility at high pH values (Caldwell *et al*.,1988).

These tablets, designed for a floating drug delivery system, were manufactured by using the direct compression method. The key components employed in the formulation included polymers such as Carbopol 940P and hydroxyl propyl methyl cellulose, along with calcium carbonate.

2. Materials and Methods

Esomeprazole magnesium trihydrate, an active pharmaceutical ingredient was procured from a local vendor. Carbopol 940P (Loba Chemie Pvt. Ltd., Mumbai, India), and HPMC (Qualigens Fine Chemicals, Mumbai, India), were procured and used in this investigation. The entire chemicals of analytical grade and double distilled water were used throughout the experiment.

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2.1 Development of standard calibration curve

2.1.1 Determination of λmax of esomeprazole magnesium trihydrate solution

Using a UV spectrophotometer, a drug solution of 10 µg/ml was produced and scanned against 0.1N HCl as a reference solution over the wavelength range of 200 - 400 nm. A graph was created by taking X axis and Y axis for concentration and absorbance. The graph's tallest peak was designated as ''max''(Chen and Park, 2000).

2.1.2 Preparation of standard stock solution of drug

Esomeprazole magnesium trihydrate should be carefully weighed and dissolved in 100 ml of ethanol. This results in a standard stock solution concentration of 1000 µg/ml.

2.1.3 Preparation of working stock solution

10 ml of esomeprazole standard stock solution was taken and diluted up to 100 ml with 0.1N HCl. It will give a 100 µg/ml concentration of working esomeprazole standard stock solution (Subramanyam, 2000).

2.1.4 Preparation of working dilutions

1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5 and 5 ml are taken from the working standard stock solution and 10 ml of 0.1N HCl was added to make up the solution to produce 10, 15, 20, 25, 30, 35, 40, 45, and 50 µg/ml concentrations, respectively, to produce 10, 15, 20, 25, 30, 35, 40, 45 and 50 µg/ml concentrations, respectively (Choi *et al*., 2002).

2.2 Formulation of esomeprazole magnesium trihydrate controlled release floating tablet

2.2.1 Formulation design

Esomeprazole magnesium trihydrate floating tablets are prepared by direct compression method using two different types of polymers that is Carbopol 940P and HPMC. Calcium carbonate is used as a gas forming agent, PVPK 30 is used as a binder, and talc and magnesium stearate were used as a glidant and lubricant composition of formulations shown in Table 1 (Chowdary and Srinivasan, 2003).

2.3 Procédure

40 mg of esomeprazole was weighed and taken in mortar and pestle and the other entire ingredients were also weighed separately and passed through sieve no # 25. Esomeprazole magnesium trihydrate, Carbopol 940P, HPMC, calcium carbonate, lactose, and PVPK 30 were weighed and mixed to get a homogeneous powder. Then, the homogeneous mixture is allowed to pass with sieve no # 40 (Davis, 2005).

The sieved mixture was mixed with magnesium stearate and talc for lubrication. After lubricating, the powder was passed through sieve no # 100. Then, the powder equivalent to 200 mg was weighed separately and was directly compressed into tablets using a tablet compression machine (Dusel, 2008) (Table 1).

Table 1: Formulation trials of esomeprazole magnesium trihydrate controlled release floating tablets

Formulation code	Esomeprazole magnesium trihydrate (mg)	Carbopol 940P(mg)	HPMC (mg)	Calcium carbonate (mg)	Lactose (mg)	Pvpk30 (mg)	Talc (mg)	Magnesium stearate (mg)
F1	40	60	-	25	50	15	5	5
F2	40	60	-	20	50	20	5	5
F3	40	-	65	10	60	15	5	5
F4	40	-	65	20	50	15	5	5
F5	40	40	50	15	35	15	5	5
F6	40	60	40	25	10	15	5	5
F7	40	65	35	25	10	15	5	5

3. Results

3.1 Pre formulation studies

3.1.1 Solubility

For pre formulation investigations, solubility is a crucial factor since it impacts how well the drug dissolves in the body. Both oral administration and medication dissolution have a direct impact on medicine's bioavailability. Because particle size, shape, and surface area may affect how a medicine dissolves, it should be decided upon before preformulation (Deepaa and Karthikeyanb, 2009).

3.1.1.1 Method

Take an adequate amount of esomeprazole magnesium trihydrate and add it to an appropriate amount of solvent. Then, it was observed as follows shown in Table 2 (Dave *et al*., 2014).

Table 2: Esomeprazole magnesium trihydrate solubility

S. No.	Solvents	Observed
1	0.1N HCl	Soluble freely
2	Dichloromethane	Soluble freely
3	Ethanol	Soluble freely

3.1.2 Melting point

The substance which transfers from a solid to a liquid state is known as the melting point. In the case of pure crystals, this transition occurs at a distinct and well-defined temperature.

The melting point of the drug was determined by taking a small amount of drug in a capillary tube closed at one end and placed in a melting point apparatus and the temperature at which the drug melts was recorded in Table 3 (El-Kamal, 2021).

Table 3: Melting point of esomeprazole magnesium trihydrate

Trials	Melting point observed	Average melting point	Reference melting point
1.	181	184	182-191^{0}C
2.	184		
3.	188		

3.1.3 Analytical methodology

3.1.3.1 Determination of absorption maximum (λ) of esomeprazole magnesium trihydrate

Using a UV spectrophotometer, a drug solution of 10 µg/ml was produced and scanned against 0.1N HCl as a reference solution in the wavelength range of 200-400 nm. By taking concentration and absorbance on the X axis and Y axis, a graph was created. The graph's highest peak was observed at 301 nm.

3.1.3.2 Development of calibration curve

5, 10, 15, 20, 25, 30, 35, 40, 45 and 50 µg/ml concentrations of esomeprazole magnesium trihydrate solutions were scanned against reference solution as 0.1N HCl at 301 nm using UV spectrophotometer absorbance are shown in Table 4, by taking concentration and absorbance on the X axis and Y axis a graph was created. This gives a graph of standard calibration esomeprazole magnesium trihydrate solutions. These are scanned at 301 nm for their absorbance by UV spectrophotometer.

Table 4: Standard graph of esomeprazole magnesium trihydrate in 0.1N HCl

S.No.	Concentration (µg/ml)	Absorbance
1	10	0.057
2	15	0.086
3	20	0.115
4	25	0.144
5	30	0.173
6	35	0.202
7	40	0.231
8	45	0.261
9	50	0.292

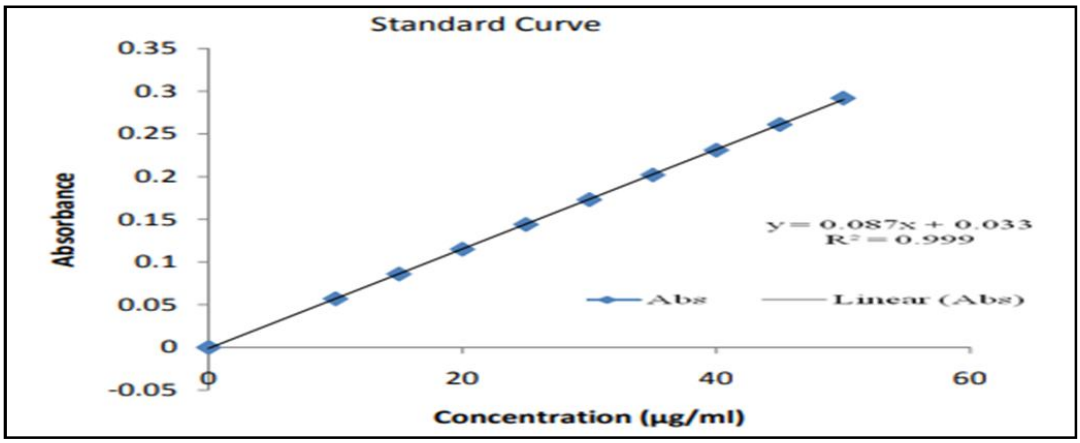

Figure 1: Standard graph of esomeprazole magnesium trihydrate.

3.2 Compatability studies

3.2.1 Drug excipient compatability study

To know the chemical interaction between esomeprazole magnesium trihydrate and excipients, an esomeprazole magnesium trihydrate excipient compatibility study was performed by FTIR. FTIR spectra of pure drug and optimized formulation were analyzed in the range of 400 to 4000 cm^{-1} (Aarati Patil, 2022).

Table 5: Esomeprazole magnesium trihydrate and excipients interpretation

S. No.	Functional group identification	Theoretical IR absorbance (cm^{-1})	Observed IR absorbance (cm^{-1})
1	S=O	980-1225	1077.80
2	C-N	1250-1335	1271.28
3	C-H	675-900	808.51

3.3 Pre formulation studies

Table 6: Pre formulation studies of different formulation of esomeprazole magnesium trihydrate

Formulation	Angle of repose (λ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Carr's index (I)%
F1	25.47 ± 0.23	0.510 ± 0.01	0.529 ± 0.01	6.34 ± 0.04
F2	26.78 ± 0.34	0.320 ± 0.02	0.370 ± 0.02	7.50 ± 0.05
F3	24.85 ± 0.32	0.455 ± 0.3	0.406 ± 0.01	8.70 ± 0.02
F4	26.47 ± 0.25	0.466 ± 0.01	0.518 ± 0.03	10.65 ± 0.01
F5	24.27 ± 0.28	0.459 ± 0.02	0.505 ± 0.04	8.92 ± 0.02
F6	25.68 ± 0.31	0.455 ± 0.03	0.482 ± 0.05	5.60 ± 0.01
F7	25.58 ± 0.36	0.456 ± 0.04	0.505 ± 0.01	8.91 ± 0.4

3.4 Evaluation of esomeprazole magnesium trihydrate controlled release floating tablets

Esomeprazole magnesium trihydrate controlled release floating tablets were evaluated for their uniformity of weight, thickness, hardness, % friability, disintegration, floating studies, *i.e.*, lag time and duration time of floating, *in vitro* dissolution studies. All evaluations were done in triplicate and average values were reported (Aarati Patil, 2022)

3.4.1 Thickness

Table 7: Thickness of different formulation of esomeprazole magnesium trihydrate

Formulation code	Thickness in (mm)
F1	4.52 ± 0.21
F2	4.52 ± 0.21
F3	4.78 ± 0.32
F4	4.76 ± 0.15
F5	4.88 ± 0.63
F6	4.83 ± 0.51
F7	4.98 ± 0.22

3.4.2 Weight variation

Irregular die cavity filling, unequal distribution of ingredients during compression, and variations in compressional pressure cause tablets to vary in weight. Although, the weight of each formulation will not be constant, weight variance is within a ± 5% weight-per-weight range, demonstrating adequate control of the compression process.

Table 8: Weight variation of different formulations of esomeprazole magnesium trihydrate floating tablets

Formulation code	Weight variation
F1	193.5 ± 3.84
F2	192.2 ± 2.73
F3	195.5 ± 2.13
F4	196.3 ± 2.73
F5	184.5 ± 2.27
F6	185.4 ± 2.31
F7	200.1 ± 3.45

3.4.3 Hardness

Table 9: Hardness of different formulation of esomeprazole magnesium trihydrate floating tablets

Formulation code	Hardness (kg/cm^2)
F1	5.3 ± 0.7
F2	5.0 ± 0.6
F3	5.0 ± 0.7
F4	5.3 ± 0.6
F5	5.1 ± 0.1
F6	5.3 ± 0.6
F7	5.1 ± 0.1

3.4.4 Friability

Table 10: Friability of different formulation of esomeprazole magnesium trihydrate floating tablets

Formulation code	Friability
F1	0.52
F2	0.61
F3	0.55
F4	0.59
F5	0.54
F6	0.56
F7	0.51

3.4.5 Drug content

Table 11: Drug content of different formulation of esomeprazole magnesium trihydrate floating tablets

Formulation code	Drug content
F1	98.6%
F2	94.5%
F3	95.6%
F4	94.6%
F5	92.4%
F6	96.6%
F7	99.8%

3.4.6 Floatingstudies

Table 12: Floating studies of different formulation of esomeprazole magnesium trihydrate floating tablets

Formulation code	Floating lag time	Total floating time
F1	3 sec	>24 h
F2	69 sec	>12 h
F3	Not floated	-
F4	20 min	>8 h
F5	Not floated	-
F6	3 sec	>24 h
F7	3 sec	>24 h

3.5 *In vitro* dissolution studies of esomeprazole magnesium trihydrate controlled release floatingtablets

Table 13: Esomeprazole magnesium trihydrate floating tablets of all formulation F1 - F7 *in vitro* dissolution studies

Time (h)	F1	F2	F3	F4	F5	F6	F7
30 min	81.04 ± 0.22	80.4 ± 0.89	8.65 ± 0.65	2.16 ± 0.54	4.87 ± 0.54	4.47 ± 0.76	8.65 ± 0.45
1 h	94.20 ± 0.32	90.62 ± 0.76	10.82 ± 0.54	17.31 ± 0.67	9.57 ± 0.76	12.98 ± 0.34	10.82 ± 0.56
2 h	100.4 ± 0.76	95.11 ± 0.76	35.05 ± 0.76	28.45 ± 0.34	13.91 ± 0.34	19.94 ± 0.22	21.23 ± 0.76
4 h	-	100.8 ± 0.56	50.34 ± 0.45	44.53 ± 0.45	29.37 ± 0.76	48.44 ± 0.89	30.52 ± 0.34
8 h	-	-	88.44 ± 0.98	81.38 ± 0.32	67.88 ± 0.32	82.10 ± 0.67	50.52 ± 0.45
12 h	-	-	100.5 ± 0.45	97.72 ± 0.12	98.98 ± 0.43	95.52 ± 0.45	60.34 ± 0.65
16 h	-	-	-	-	-	-	74.84 ± 0.56
20 h	-	-	-	-	-	-	84.32 ± 0.87
24 h	-	-	-	-	-	-	99.98 ± 0.89

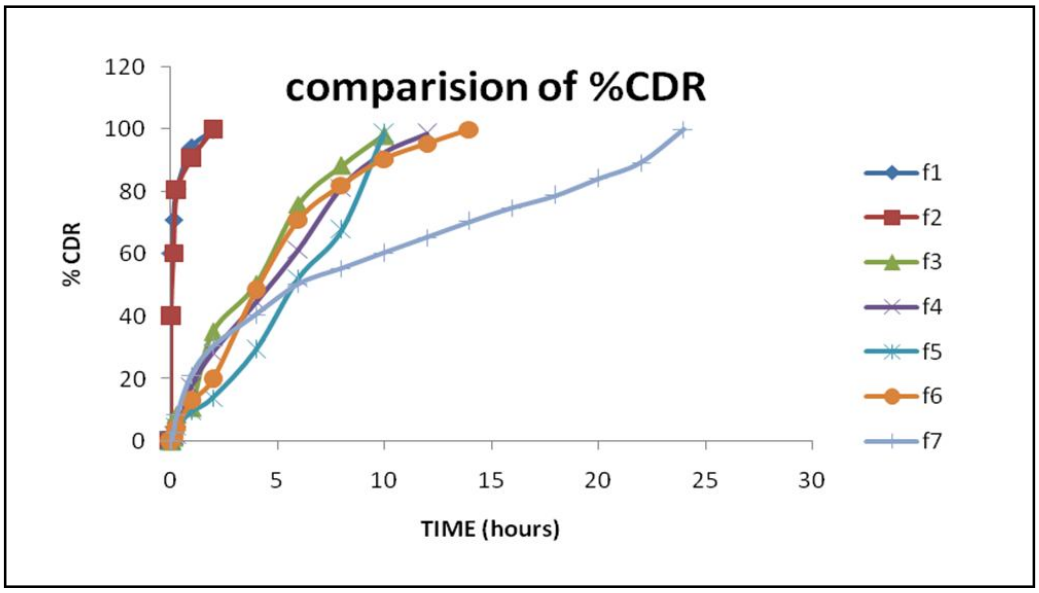

Figure 2: *In vitro* % drug release of esomeprazole magnesium trihydrate floating tablets of all formulation F1-F7.

3.6 Model dependent kinetics

Release kinetics of the formulation F7 esomeprazole magnesium trihydrate floating tablets, *in vitro* dissolution study data of optimized formulation was plotted in all kinetic models. It follows the Korsmeyer-peppas model.

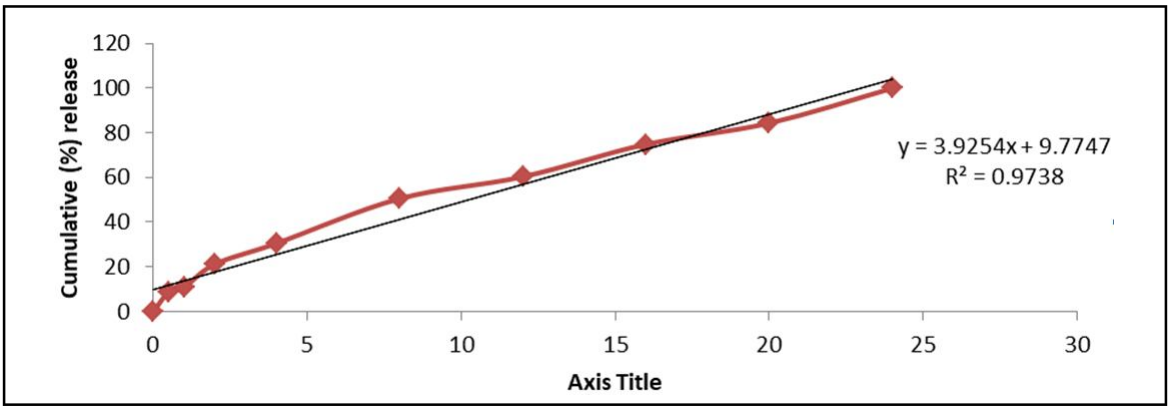

Figure 3: Zero order kinetics.

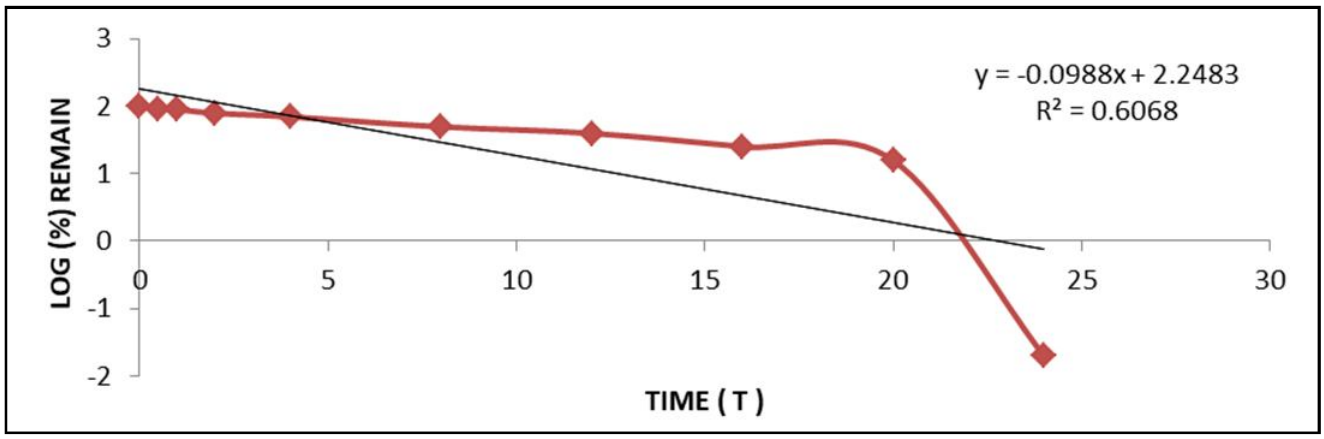

Figure 4: First order release kinetics.

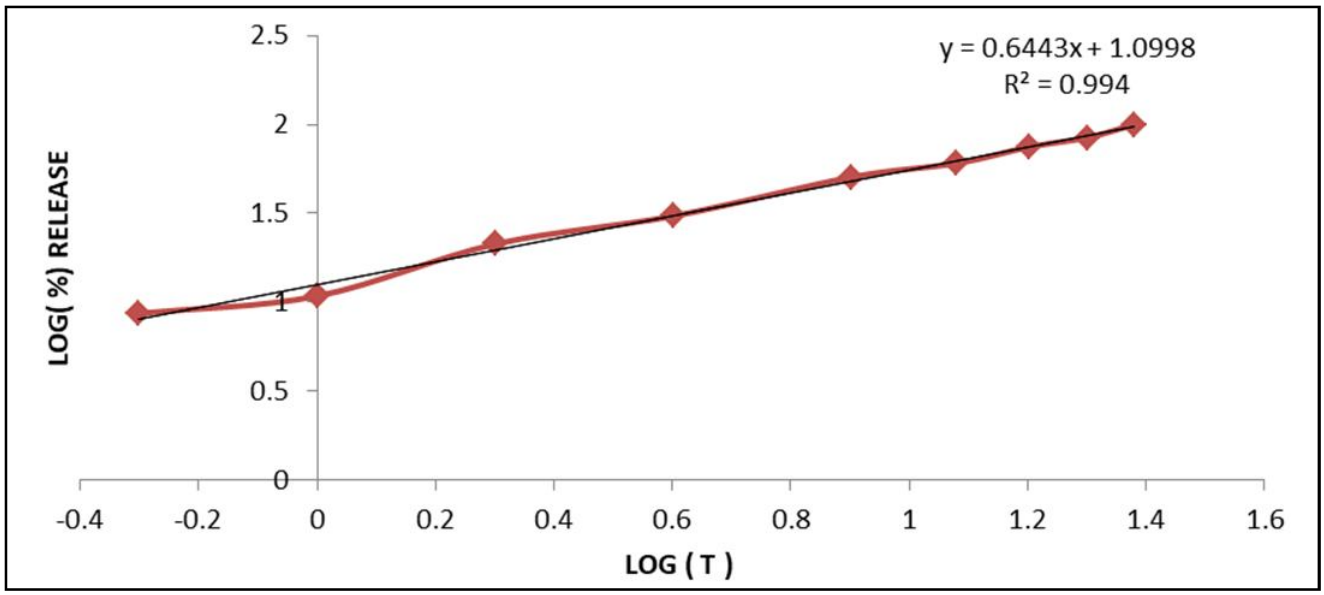

Figure 5: Korsmeyer peppas model.

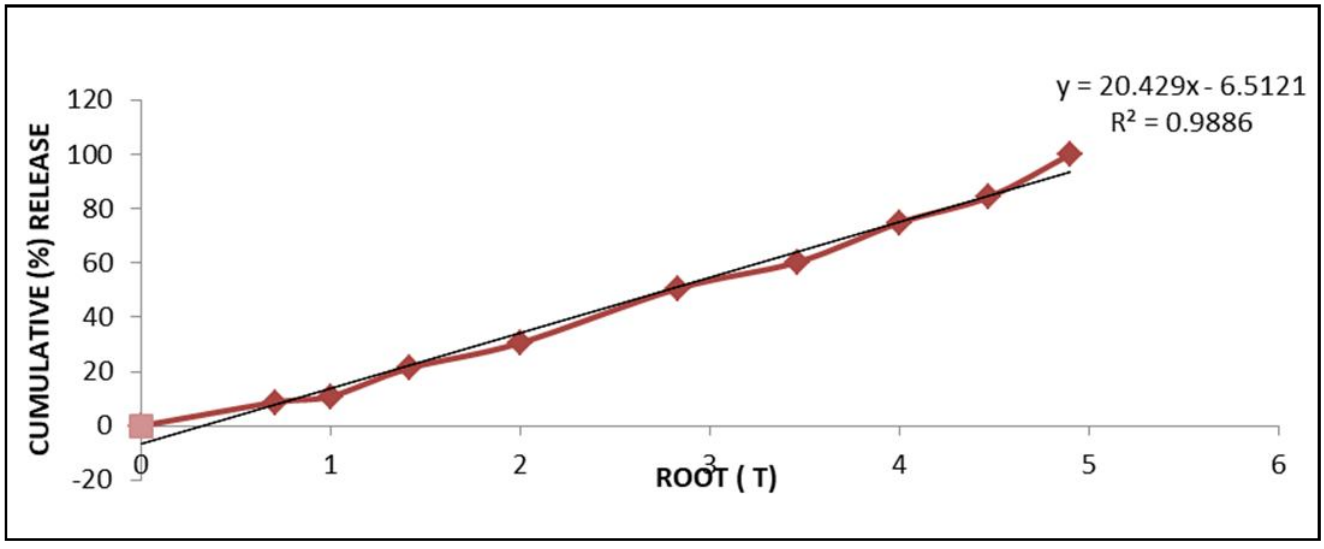

Figure 6: Higuchi model.

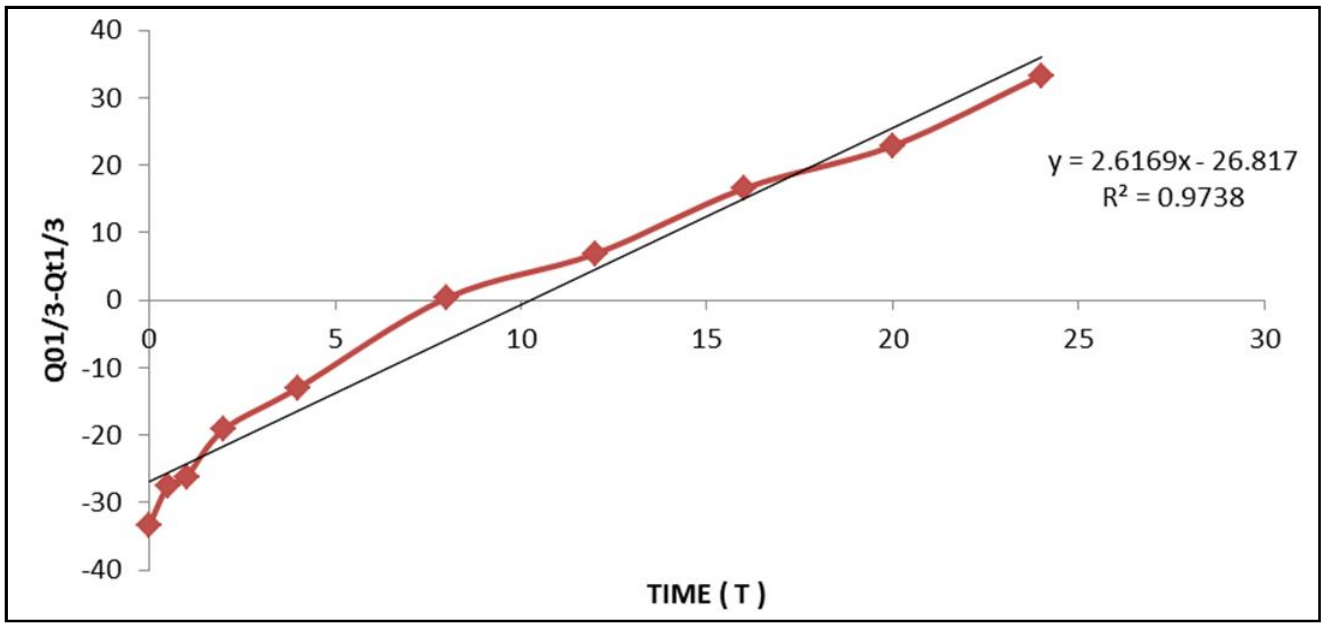

Figure 7: Hixson crowell.

3.7 Surface morphology.

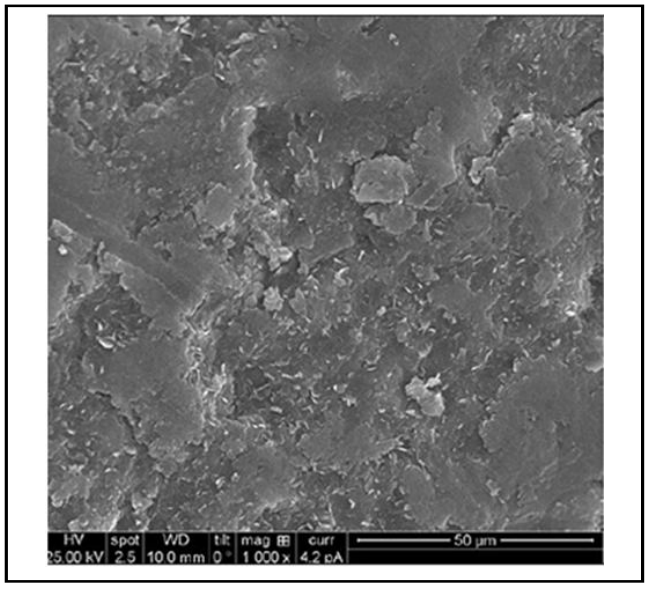

Figure 8: SEM analysis of optimized formulation F7.

4. Discussion

4.1 Development of standard calibration curve

The esomeprazole magnesium trihydrate calibration curve is determined by 0.1N HCl in the range which is 10-50 µg/ml. Esomeprazole magnesium trihydrate exhibits good linearity with $R^2 = 0.999$.

4.1.1 Drug excipient compatibility study

The FTIR spectra of the pure drug esomeprazole and pure drug with excipients were conducted. The FTIR spectral analysis showed that the peaks observed were S = O, C - N, and C - H which are similar to pure drug and drug with excipients which has shown in the figures. This indicates no drug excipient interaction shown in Table 5.

4.2 Preformulation studies

All formulations underwent pre formulation studies, (Kapil Thakur, 2020) and all formulations were under the limits for each parameter discovered to be met successfully about angle of repose for all formulations F1-F7 in the range of 24.27 ± 0.25 to 26.78 ± 0.34, bulk density for all formulations F1-F7 0.320 ± 0.02 to 0.510 ± 0.01, for all formulations F1-F7 Carr's index values are 5.60 ± 0.01 to 10.65 ± 0.01 and tapped density for all formulations F1-F7 in the range of 370 ± 0.02 to 0.529 ± 0.01 shown in Table 6.

4.3 Evaluation of esomeprazole magnesium trihydrate controlled release floating tablets

4.3.1 Weight variation

All formulations F1-F7 esomeprazole magnesium trihydrate floating tablets F1-F7 in the range of 184.5 ± 2.27 to 200.1 ± 3.45 which are within the pharmacopoeial limits shown in Table 8.

4.3.2 Friability

This term refers to the percentage weight loss of tablets during manufacture, jacking, shipment, and consumer use. Friability is a strength metric that indicates a tablet's capacity to withstand shock and abrasion without crumbling. All formulations of esomeprazole magnesium trihydrate floating tablets F1-F7 in the range of 0.51 to 0.61 which are within the pharmacopoeial limits shown in Table 10.

4.3.3 Thickness

A screw gauge is used to measure the tablet's thickness. It provides tablet's weight variation over the period. All formulations F1-F7 in the range of 4.52 ± 0.21 to 4.98 ± 0.22 are shown in Table 7.

4.3.4 Hardness

Using a hardness tester Monsanto, measures the strength necessary to break the tablets that are arranged at right angles to one another by applying pressure to a coiled spring, the hardness was determined. All formulations of esomeprazole magnesium trihydrate floating

tablets F1-F7 in the range of 5.0 ± 0.6 to 5.0 ± 0.1which are within the pharmacopoeial limits shown in Table 9.

4.3.5 Drug content

Take 20 tablets, and then crushed to make powder and one dose's worth of powder is placed in a 100 ml volumetric flask and 0.1N HCl is added volume was made up with 0.1N HCl. about 1 ml of sample is diluted to 10 ml and absorbance was measured at 301 nm by UV spectrophotometer, of all the various formulations F1-F7 Drug content is in the range of 92.4% to 99.8% shown in Table 11.

4.3.6 Floating studies

F7 was best among other formulations because of its floating time which is more than 24 h compared to other F1-F5 and F6 formulations, floating lag time was 3 sec and has a better release of drug in a controlled manner for more than 24 h shown in Table 12.

4.4 *In vitro* dissolution studies of esomeprazole magnesium trihydrate controlled release floating tablets

In vitro, percentage drug release studies were done by using 0.1N HCl for formulations F1-F7 of esomeprazole magnesium trihydrate floating tablets formulated by using Carbopol 940P and HPMC. *In vitro* drug dissolution studies are done by paddle type which is USP type II apparatus, 0.1N HCl is used as dissolution media maintaining temperature at 37^0C ± 0.5^0C and rotated at a 75 rpm. Percentage drug release for formulations F1 and F2 which contains 60 mg of Carbopol 940P as polymer and calcium carbonate 25 mg added as gas forming agent in F1 and 20 mg of calcium carbonate added in F2 as gas forming agent but the drug release was within 4 h, if we use Carbopol 940P as polymer. Percentage drug release for formulations F3 and F4 which contain 65 mg of HPMC as polymer and calcium carbonate 10 mg added as gas forming agent in F3 and 20 mg calcium carbonate added in F4 as gas forming agent but the drug release was within 12 h, if we use HPMC as polymer. Percentage drug release for formulations F5, F6 and F7 which contain 40, 60 and 65 mg of Carbopol 940P and 50, 40, 35 mg of HPMC as polymers and calcium carbonate 15, 20 and 25 mg is added as gas forming agent in F5, F6 and F7 but the drug release was within 12 h in F5 and F6, by using 65 mg Carbopol 940P and 35 mg HPMC there was controlled percentage of drug release up to 24 h and by using 25 mg calcium carbonate as gas forming agent, the tablet was floated for 24 h.

So F7 formulation was considered an optimized formulation because the tablet was released in a controlled manner for up to 24 h shown in Table 13.

4.5 Model dependent kinetics

The results of the R^2 value for the Korsmeyer-peppas model were obtained as 0.994 which is close to '1' based on that we confirm the optimized formulation F7 follows the Korsmeyer-peppas model.

For the Korsmeyer-peppas model, the release component 'n' value was found to be 0.99 which is greater than <0.89, the release of drug from the formulation was non fickian diffusion.

4.6 Surface morphology

The surface morphology (Devina Vaidya, 2021) of esomeprazole magnesium trihydrate floating tablets was examined by scanning electron microscopy. The surface morphology of optimized formulation F7 was showing in the 50 µ range.

5. Conclusion

In this present work, esomeprazole magnesium trihydrate is used for preparing floating tablets, it is used in treating ulcers and prevention. Esomeprazole magnesium trihydrate floating tablets are to increase gastric residence time and avoid gastric irritation. Floating tablets of esomeprazole magnesium trihydrate are prepared with a single polymer and with different polymers. Different amounts of HPMC and Carbopol 940P were used to generate different formulations (F1-F7). A total 7 formulations that are from F1-F7 were prepared. The flow properties are tested for bulk density, tapped density, angle of repose, Carr's index and Hausner's ratio. Floating tablets are prepared by direct compression method, which is a convenient approach. Various formulations (F1-F7) are evaluated for post compression parameters like weight variation, hardness, friability, content uniformity, *in vitro* dissolution studies, lag time and duration time of floating conducted, which give satisfactory results. The lag time of the formulation showed that they can be used for floating systems. Formulation F7, containing hydroxypropyl methylcellulose (HPMC) and Carbopol 940P, demonstrated the best drug release profile, releasing approximately 98.4% of the drug over 24 h. The study was successful in formulating esomeprazole magnesium trihydrate floating tablets, but further research is needed to validate their efficacy in clinical applications.

Conflict of interest

The authors declare no conflicts of interest relevant to this article.

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Citation **Rohini Reddy Shimmula, Vishnu Priya Atla, Srinivas Nimmagada, Haarika Balusu and Shanthi Priya Chinthala (2023). Formulation and evaluation of esomeprazole magnesium trihydrate controlled release floating tablets. Ann. Phytomed., 12(2):963-971. http://dx.doi.org/10.54085/ap.2023.12.2.115.**