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Formulation And Evaluation of Buccal Patch For Peptic Ulcer Management

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ABSTRACT: The current study attempted to formulate and evaluate an omeprazole magnesium buccal patch for the treatment of peptic ulcers. Buccal Drug Delivery System (BDDS) offers an advantageous route for acid-labile drugs such as Omeprazole Magnesium by providing direct absorption through the buccal mucosa while avoiding gastric degradation and hepatic first-pass metabolism. In this study, buccal patches were developed using the solvent-casting method employing HPMC as the primary film-forming polymer, SCMC as a swelling and release-modifying agent, PEG and glycerol as plasticizers, and PVP K30 as a solubilizing/wetting agent. The prepared formulations were evaluated for thickness, weight variation, surface pH, moisture content, folding endurance, swelling index, drug content uniformity and *in-vitro* drug release studies. FT-IR analysis confirmed the compatibility of Omeprazole Magnesium with all polymers and absence of drug–excipient interaction. Among all the formulations, F5 showed the highest cumulative drug release due to its higher SCMC content and presence of PVP K30, followed by formulation F2. The overall results indicate that Omeprazole Magnesium can be successfully incorporated into a buccal patch system and that formulation F5 may serve as a promising controlled drug-delivery approach for the effective management of peptic ulcer disease.

KEY WORDS: Peptic ulcer, omeprazole magnesium, Buccal patch.

I. INTRODUCTION

Peptic ulcer disease is a gastrointestinal issue that causes mucosal injury as a result of pepsin and stomach acid secretions. It typically occurs in the stomach and proximal duodenum, but it can also occur in the lower oesophagus, distal duodenum, or jejunum in unopposed hypersecretory states like Zollinger-Ellison syndrome, hiatal hernias (Cameron ulcers), or ectopic gastric mucosa (e.g., Meckel's diverticulum). [1]

Peptic ulcer disease is caused by an imbalance between substances that protect and destroy the mucosa of the stomach and duodenum. Patients with gastric and duodenal ulcers present similarly. Patients may experience epigastric or retrosternal pain, early satiety, nausea, bloating, burp, or postprandial misery. These symptoms are nonspecific and may be difficult to distinguish clinically from functional dyspepsia.[2]

Helicobacter pylori, a Gram-negative bacterium, lives between the mucous layer and the gastric epithelium and is specifically suited to survive in the stomach's harsh environment. Helicobacter pylorus is initially found in the antrum, but it eventually migrates to the stomach's more proximal regions.

Peptic ulcer is one of the world's most common gastrointestinal illnesses, impacting 10% of the global population. Duodenal peptic ulcers account for approximately 19 out of every 20 cases. Every year, an estimated 15000 people die from peptic ulcers. The annual incidence rates of peptic ulcer bleeding and perforation were 19.4-57 and 3.8-14 per 100,000 people, respectively. The average 7-day recurrence of bleeding was 13.9%, while the average long term recurrence of perforation was 12.2%.[3] Ulcer Index Ulcers were scored as follows: no ulcer = 0, superficial ulcer = 1, deep ulcer = 2, and perforation = 3. The mean ulcer score for each animal will be reported as an ulcer index.[4]

The aim is the primary goal of the study is to develop and evaluate an omeprazole magnesium buccal patch for peptic ulcers using various ingredients and the solvent casting method. The primary goal is to improve patient compliance and bioavailability by avoiding first pass metabolism of the drug.

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Types of peptic ulcer

1) Gastric Ulcer

Gastric is a word that means "related to the stomach'. Gastric ulcers, as the name implies, are found in the stomach. They can occur when stomach acid used to digest food irritates the stomach lining, resulting in an open sore.

2) Duodenal Ulcer

After leaving the stomach and passing through the digestive tract, food enters the duodenum. This is the first section of the small intestine, which continues the digestion process. Peptic ulcers that form on the lining of the duodenum are known as duodenal ulcers.[5]

Symptoms

Many people with peptic ulcers don't have symptoms. If there are symptoms, they may include:

• Dull or burning stomach pain.
• Feeling of fullness or bloating.
• Belching.
• Heartburn.
• Nausea.[6]

BUCCAL PATCH

DEFINITION: Buccal patches are non-dissolving thin matrix modified release dosage forms made up of one or more polymer films or layers containing the drug and/or other excipients.

The patch may have a mucoadhesivepolymer layer that attaches to the gingiva, teeth, or oral mucosa to regulate the release of the medication into the oral mucosa (unidirectional release), oral cavity (unidirectional release), or both (bidirectional release). After a predetermined amount of time, the patch is removed from the mouth and discarded.[7]

Advantages of buccal patches

- The buccal mucosa is highly vascularized, allowing medications to be swallowed quickly.
- Prevents drugs from entering the gastrointestinal fluids, bypassing the first pass effect.
- Close contact with the mucosa improves the drug's efficacy.
- Increased patient compliance when compared to other administration methods.
- Patients who are unconscious can accept it with ease.[8]

II. MATERIALS AND METHODS

The following materials are used for the studyOmeprazole Magnesium (Embiotic laboratories Pvt.Ltd), HPMC (Loba chem Pvt.Ltd), Sodium carboxy methyl cellulose (SD fine chem.Ltd), Polyethylene glycol (SD fine chem.Ltd), Polyvinylpyrrolidione (LobachemPvt.Ltd), Glycerine (Moly chem.Ltd).

The following equipments are used for the study screw gauge (Dhananjaiequipmentspvt.ltd,), Incubator (Labpro international), UV-Visible spectrophotometer (ShimadzuUV1900), Magnetic Stirrer (Remi equipment's Pvt.Ltd., Mumbai), Digital pH meter (Optics Technology, NewDelhi), Electronic Weighing Balance (Shimadzu), Dissolution apparatus (Microsil India), Magnetic beads (Tarsons products Ltd), Desiccator (Rising Sun Enterprises).

PREFORMULATION STUDIES

It is the first step in the rational development of a dosage form, and the goal of this study is to look into the properties of a drug alone as well as the properties of the drug when combined with various excipients. Pre-formulation studies are the process of characterizing various properties of drugs and excipients, such as physical, chemical, and mechanical properties, in order to develop a safer, more effective, and stable dosage form.

The overall goal of this study is to generate data that will assist formulators in developing a stable dosage form with high bioavailability that can be mass produced in batches.

a) Determination of solubility

To determine the solubility of a little amount of omeprazole magnesium, several solvents such as water, ethanol, and HPLC grade methanol were taken individually.

b) UV absorption maxima of omeprazole magnesium

10mg of omeprazole magnesium was dissolved in HPLC grade methanol and diluted to 100ml with solvents. Dilute 2ml of solution with 50ml of solvent, and examine the sample between 200nm and 400nm to determine the absorption maximum.

Selection of Solvent: According to the drug's solubility characteristics, HPLC grade methanol was chosen for analysis. The wavelengths for estimating Omeprazole magnesium at 302nm were chosen from scanning the UV spectra of both drugs.

Preparation of Standard Stock Solution: To prepare a standard solution with a concentration of 100 µg/ml, 10mg of each drug was accurately weighed and dissolved in a small amount of HPLC grade methanol. The volume was adjusted to 100ml. The standard solutions for these drugs were obtained by diluting the respective stock solution with HPLC grade methanol. This stock solution was used to prepare aliquots at 2, 4, 6, 8 and 10 µg/ml.

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Preparation of sample stock solutions: Diluting 1ml (100µg/ml) of standard stock solution with 100ml HPLC grade methanol resulted in a sample stock solution with a concentration of 1µg/ml. Dilute the sample stock solution to desired concentrations (2, 4, 6, 8, 10µg/ml).

Determination of λ max: Omeprazole magnesium standard solutions were scanned at different concentrations between 200-400 nm to determine the λmax. The wavelengths for estimating Omeprazole magnesium at 302nm were chosen from scanning the drug with UV spectra.

c) Drug excipient compatibility study (FT-IR Studies)

IR spectroscopy of Omeprazole magnesium, HPMC, SCMC, PEG, and PVP was performed using an FT-IR spectrophotometer.[9]

Procedure:

The sample disc was prepared by triturating approximately 1 or 2 mg of the sample substance with around 10 - 20 mg of KBr / Potassium bromide and compressing the triturate with a hydraulic press to form a thin disc of around 10-15mm diameter, which will be sufficient to give an IR spectrum of a suitable intensity.

This disc is then placed in a sample holder and scanned in the range of 4000-400cm-1 in an FTIR spectrophotometer to obtain a spectrum.

The obtained spectra of the drug and excipients were compared and interpreted for functional group peaks in order to detect any significant interactions.

FORMULATION TABLE FOR OMEPRAZOLE MAGNESIUM BUCCAL PATCH

Table 3: Formulation table

INGREDIENTS	F1	F2	F3	F4	F5
Omeprazole magnesium (mg)	20	20	20	20	20
HPMC(mg)	100	90	110	100	100
SCMC(mg)	10	10	5	10	20
PEG(mg)	0.02	0.02	0.02	0.02	0.02
PVP K30(mg)	-	5	-	5	5
Glycerol (ml)	0.02	0.02	0.02	0.02	0.02
Water (ml)	q. s	q. s	q. s	q. s	q. s

PREPARATION OF OMEPRAZOLE MAGNESIUM BUCCAL PATCH

The buccal patches were created using the solvent casting method. To make the patch liable, various polymers were used (HPMC K100M, SCMC), as well as plasticizer (PEG 400) and a hydrophilic polymer (PVP K30).

The quantity of various polymers was optimized as specified. The dose of omeprazole magnesium was kept constant at 20mg. We weighed the polymer, plasticizer, and hydrophilic polymer. The drug and polymer were gradually added to 20 ml of distilled water (at 90 °C) while constantly stirring. After cooling the polymer solution to room temperature, the plasticizer and hydrophilic polymer were added separately according to the formula. The solution was then poured into glass Petri dishes. The Petri dishes were placed in an incubator at 37 °C, and patches were obtained by evaporating the solvent.

EVALUATION PARAMETERS OF BUCCAL PATCHES

a) Physical appearance

The drug sample was evaluated for its organoleptic properties

b) Thickness of patch

- A micrometre screw gauge was used to measure three patches of each formulation from three different locations.
- The mean value was then determined.

c) Folding endurance

- Three larger patches of each formulation, measuring 2 x 2 cm, were cut with a sharp blade.
- Folding endurance was tested by repeatedly folding a small patch at the same location until it ruptured.
- The folding endurance value was calculated based on how many times the patch could be folded in the same location without breaking.
- The mean value was calculated and recorded.

d) Weight uniformity of the patches

To assess patch weight, three patches of each formulation were individually weighed on a digital balance. The mean weight of each formulation was then calculated.

e) Surface pH of patches

To determine surface pH, three patches of each formulation were allowed to swell on an agar plate's surface for two hours. Surface pH was measured using pH paper placed on the swollen patch's surface, as described in the report. The average of three readings was recorded.

f) Swelling Index

- The swelling index was determined using the diameter method.
- To prepare the agar solution, 0.2 g of agar was dissolved in 10 mL of warmed simulated saliva fluid at pH 6.8 (50-70°C).
- The solution was then poured into a Petri dish and left to cool.
- After determining the initial patch diameter, each patch was allowed to swell on its designated gel surface.
- The diameters of the patches were measured after 2, 5, and 7 hours, and the results were recorded as the average of three readings. Swelling studies lasted 7 hours because a 7-hour residence time was recommended.

g) Drug content uniformity

- The drug content of patches was assessed without the backing membrane.
- Hydrochloric acid (0.008 ml) was added to a beaker and diluted with distilled water to make 10 ml.
- The patch was dispersed in 5 ml of the above solution, and the volume was increased to 10 ml with pH 6.8 simulated saliva fluid.
- An analysis of 1 ml of this solution was performed using UV spectroscopy to determine drug content.[10]

h) Moisture content

- The buccal patches were weighed precisely and stored in desiccators containing anhydrous calcium chloride.
- The patches were removed and weighed three days later.
- Moisture content (%) was calculated by applying the formula to moisture

Moisture content (%) = <u>Initial weight – Final weight</u> × 100

Initialweight[11]

i) *In-vitro* drug release

The dissolution study was conducted using a USP Type-2 rotating paddle dissolution test apparatus. To provide sink conditions, 100 ml of HPLC grade methanolwas used as the dissolution medium in a 250 ml glass beaker maintained at 37 ± 0.5 0 C and stirred at 50 rpm. A cyanoacrylate adhesive was used to fix the 2 cm diameter film to the glass disk. The disk was kept at the bottom of the dissolution vessel, with the film on the upper side. At predetermined intervals, 5 ml samples are withdrawn and replaced with the same volume of dissolution medium. The samples were filtered through a 0.45 µm filter, diluted with HPLC grade methanol, and measured spectrophotometrically at 302nm.[12]

III. RESULTS AND DISCUSSION

PREFORMULATION STUDIES

- **API CHARACTERIZATION OF THE DRUG**

Table 4: Organoleptic properties of omeprazole magnesium

PROPERTY	SPECFICATION	OBSERVATION
COLOUR	White to off-white crystalline powder	White powder

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ODOUR	Odourless	Odourless
TASTE	Tasteless to slightly bitter	Slightly bitter

- **SOLUBILITY**

Table 5: Solubility studies were carried out in different solvents

SOLVENTS	SOLUBILITY
Water	Practically insoluble
Ethanol	Slightly soluble
HPLC grade methanol	Freely soluble

Standard calibration curve of Omeprazole magnesium by using HPLC-grade methanol

Table 6: Standard calibration curve of Omeprazole magnesium with HPLC-grade methanol

S.NO	CONCENTRATION (µg/ml)	ABSORBANCE AT 302nm
1	2	0.120
2	4	0.241
3	6	0.361
4	8	0.480
5	10	0.602

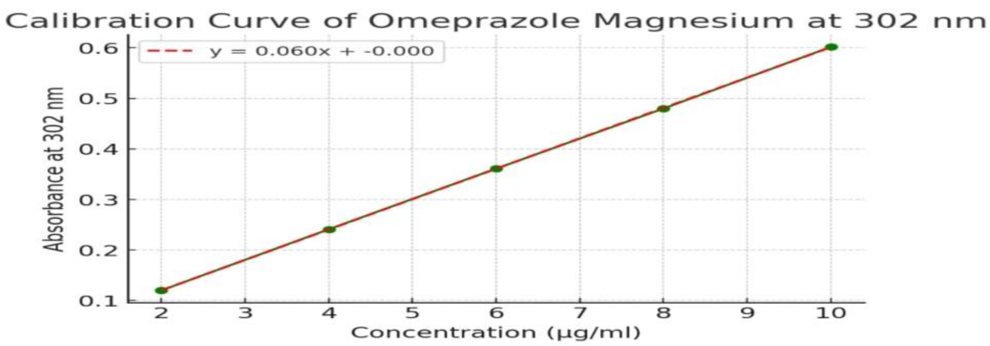

Fig 1: Estimation of Omeprazole magnesium using UV-spectrometer

Estimation of Omeprazole magnesium was carried out at wavelength 302 nm in HPLC-grade methanol**.** The value of regression coefficient (R^2) was found to be 1.000, which showed an excellent linear relationship between concentration and absorbance. The regression equation generated was y = 0.060x. By using the value of regression co-efficient % CDR was calculated. The standard calibration curve obeyed Beer's law at the given concentration range of 2 - 10µg/ml.

DRUG EXCIPIENT COMPATIBILITY STUDY

The compatibility study between drug and the carriers was carried out using FTIR spectrometer.

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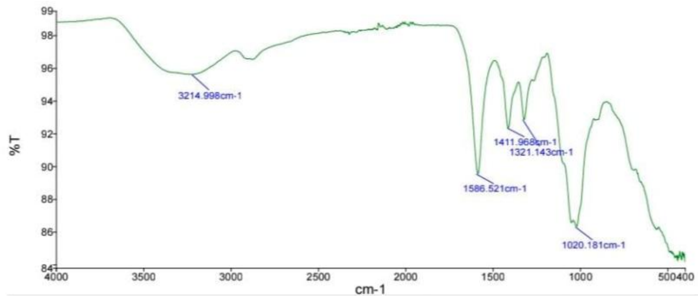

Fig 2: FT-IR Spectrum of Omeprazole magnesium

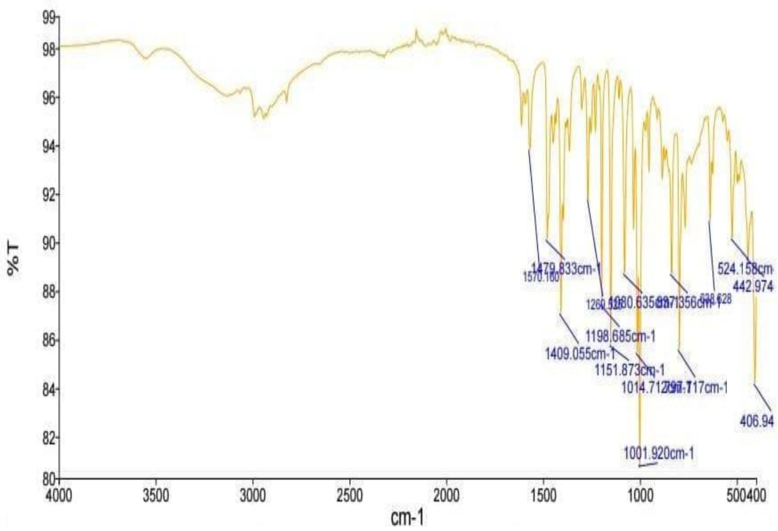

Fig 3: FT-IR spectrum of Drug and polymers

The physical mixture ofOmeprazole magnesium and excipients was analyzed using FT-IR to determine any interactions between them. When Omeprazole magnesium is mixed with excipients, the IR spectra show major peaks at cm^{-1},1570.15 cm^{-1},1409.05 cm^{-1} and 1001.92 cm^{-1}. As a result, no specific interaction was detected between the drug and the polymers used in the formulations.

EVALUATION OF BUCCAL PATCH

Table 7: Evaluation of thickness uniformity

FORMULATION CODE	THICKNESS (cm)
F1	0.14±0.024
F2	0.13±0.038
F3	0.16±0.042
F4	0.15±0.023
F5	0.12±0.034

The thickness test of the formulation was carried out to ensure consistency, comfort and efficacy. The range of thickness should fall within the limit that is 0.05 – 0.18cm ±0.03 and the thickness of the formulation F1- F5 ranges from 0.12 – 0.17cm±0.03.

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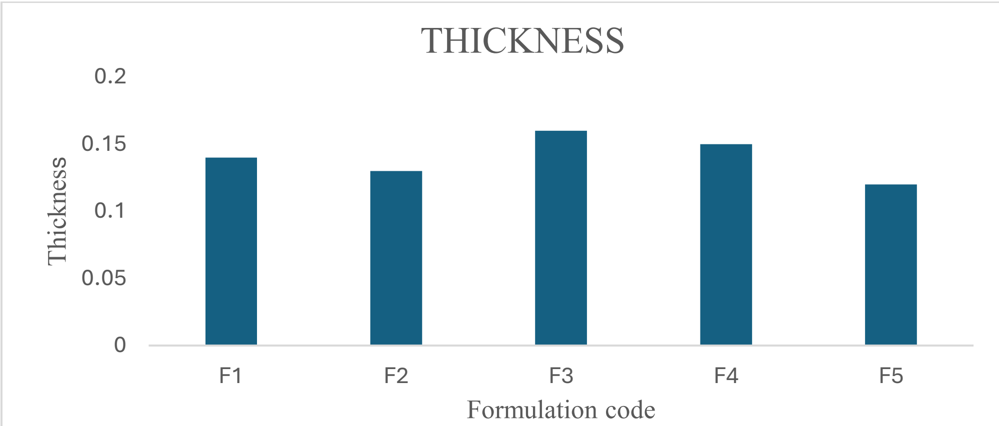

Fig 4: Thickness uniformity

Table 8: Evaluation of folding endurance

FORMULATION CODE	FOLDING ENDURANCE
F1	528±11.2
F2	455±19.3
F3	395±21.5
F4	610±13.4
F5	430±33.8

The folding endurance test was done to ensure the patches mechanical strength and durability while handling, storage and use. Its limit ranges ≥ 200 and the folding endurance of the F1-F5 formulations was found from 395 – 610. Hence the formulated patches ensures the mechanical strength and durability.

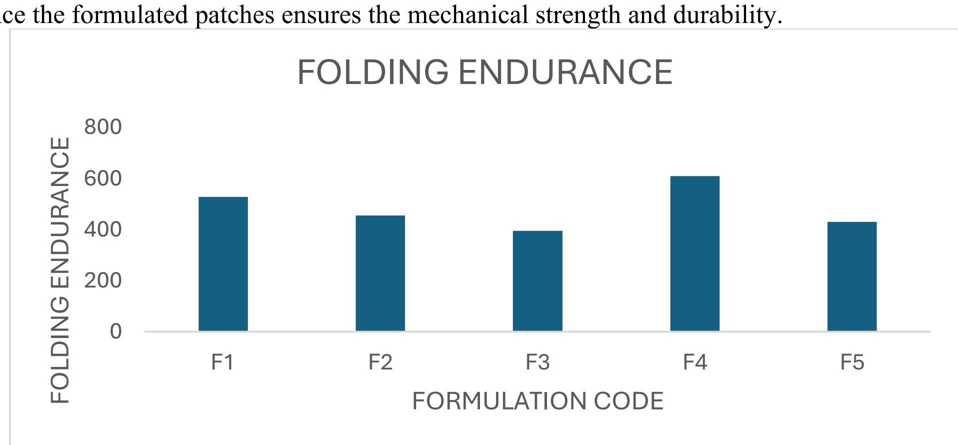

Fig 5: Folding endurance

Table 9: Evaluation of weight variation

FORMULATION CODE	WEIGHT VARIATION (cm)
F1	0.172±0.029
F2	0.181±0.027
F3	0.152±0.031
F4	0.149±0.024
F5	0.163±0.030

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The weight variation of formulation is crucial to ensure consistency and accuracy of the dosage form, and limit ranges from 0.1– 0.3±0.02 cm, the weight variation of the formulation F1- F5 ranges from 0.149-0.181cm±0.02.

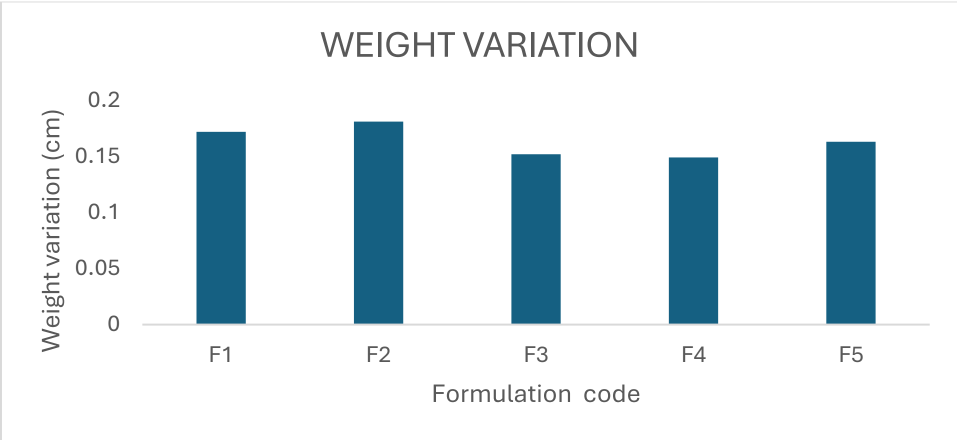

Fig 6: Weight variation

Table 10: Evaluation of surface pH

FORMULATION CODE	SURFACE pH
F1	6.4±0.4
F2	6.6 ±0.3
F3	6.8±0.5
F4	7.0±0.2
F5	7.1±0.3

The surface pH of the buccal patch was determined to optimize both drug permeation and mucoadhesion. Attempts were made to keep the surface pH as close as to salivary pH. The pH values the formulations F1-F5 were within the range of salivary pH 6.4 to 7.1

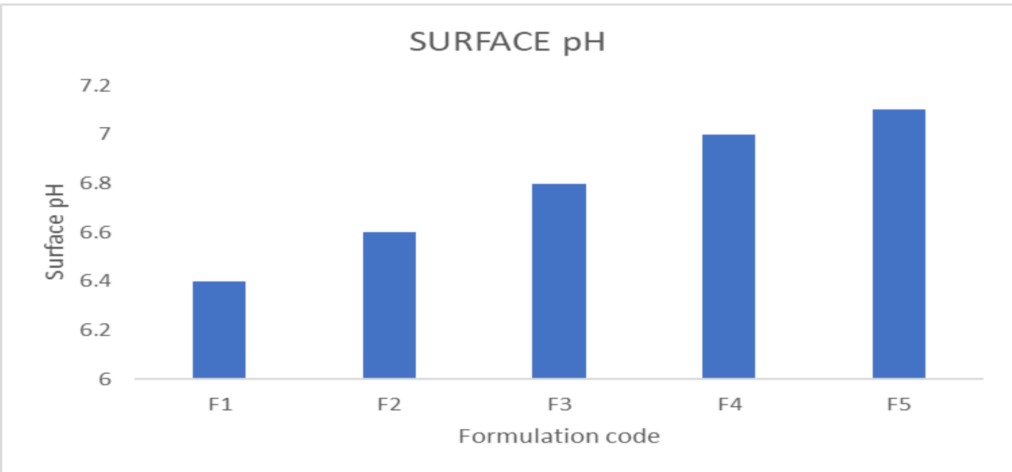

Fig 7: Surface pH

Table 11: Evaluation of swelling index

Time (Hr)	F1	F2	F3	F4	F5
2	36±0.04	21±0.06	29±0.03	26±0.05	30±0.03
5	50±0.08	34±0.10	33±0.07	43±0.06	56±0.09
7	74±0.10	68±0.12	65±0.08	54±0.07	69±0.11

The swelling index of formulation is critical to ensure physical integrity, adhesion and release characteristics and its limit ranges from 50-200% and the swelling index of the formulation F1-F5 was ranges from 54-74%

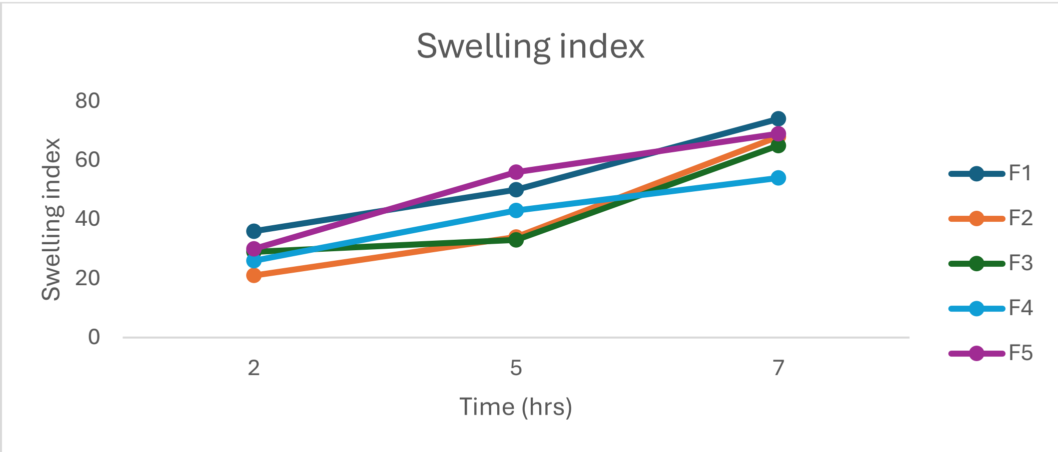

Fig 8: Swelling index

Table 12: Evaluation of drug content uniformity

FORMUATION CODE	DRUG CONTENT UNIFORMITY (%)
F1	98.6±0.9
F2	97.9±1.1
F3	99.4±0.8
F4	100.2±0.6
F5	99.0±0.7

The drug content uniformity is carried out to ensure the safety, efficacy and quality of the formulation and its limit ranges from 90-110% ± 10%, it was found that the formulation F1-F5 ranges from 97.9 – `100.2%.

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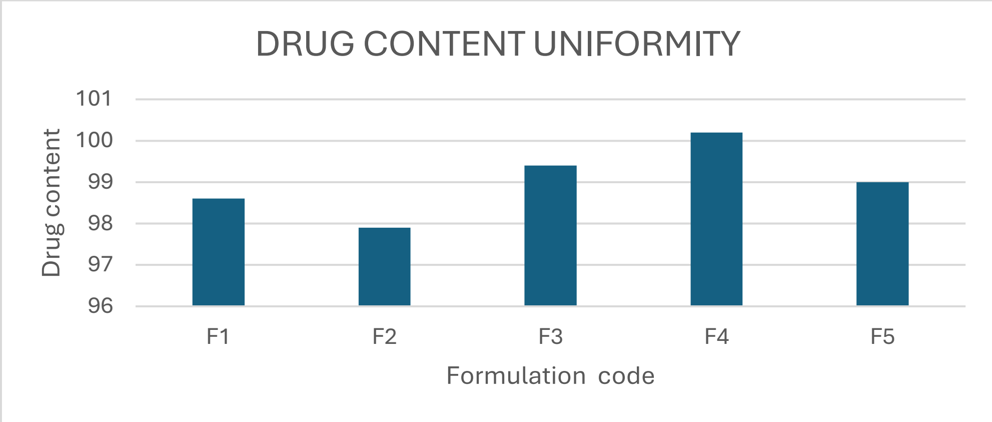

Fig 9:Drug content uniformity

Table 13: Evaluation of moisture content

FORMULATION CODE	MOISTURE CONTENT (%)
F1	12.8±0.42
F2	11.6±0.38
F3	13.2±0.51
F4	14.1±0.47
F5	13.6±0.33

The moisture content for buccal patch is done to ensure product stability, efficacy and shelf life and limit ranges from 10-15%±2.5%, the moisture content of the formulations F1-F5 ranges from 11.6 – 14.1 %.

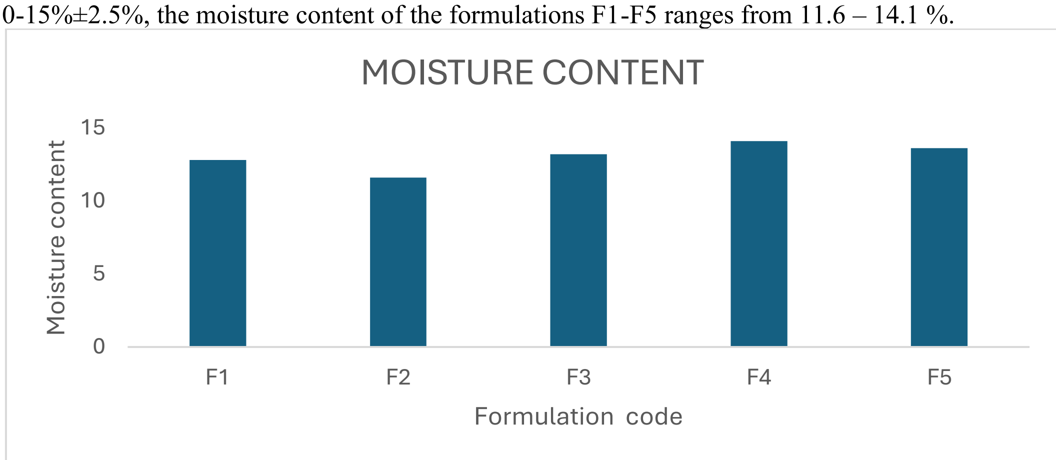

Fig 10:Moisture content

Table 14: *In-vitro* Dissolution studies

TIME (Hrs)	F1	F2	F3	F4	F5
0	0	0	0	0	0

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2	37.4	34.1	18.1	16.3	8.5
4	57.1	50.1	26.1	24.2	18.6
6	76.4	51.6	42.1	39.3	24.7
8	80.1	62.3	57.9	47.9	37.2

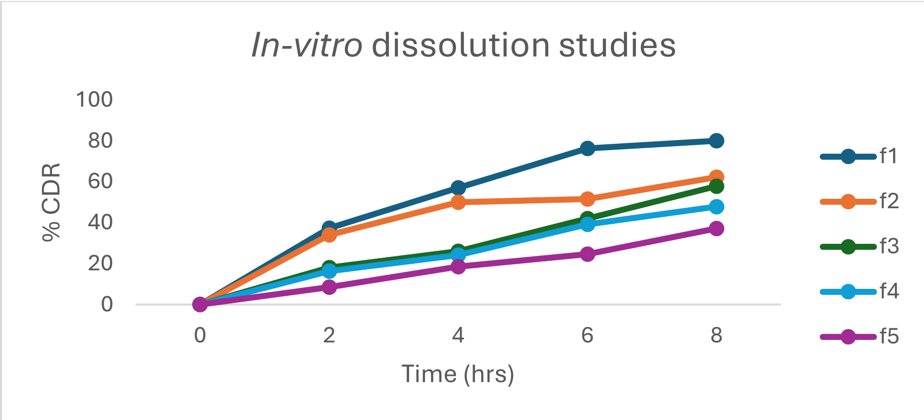

Fig 11: *In-vitro* dissolution studies

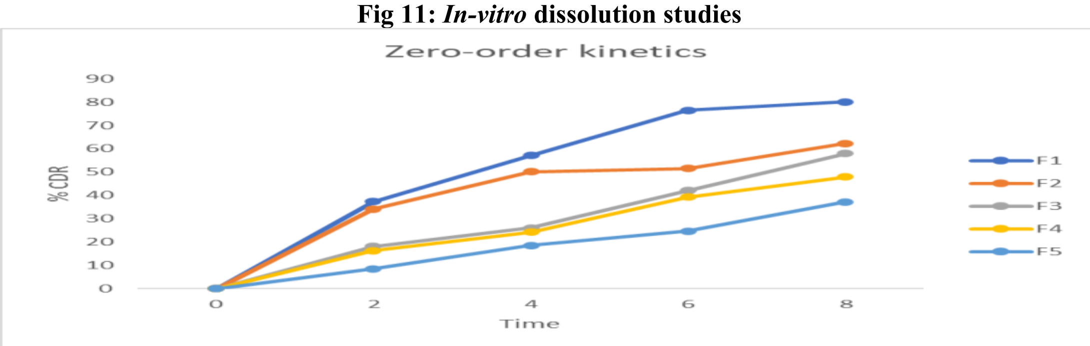

Fig 12: Zero-order kinetics

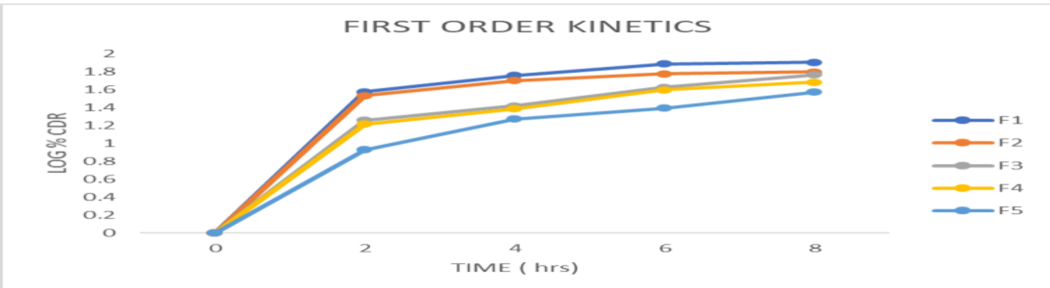

Fig 13: First order kinetics

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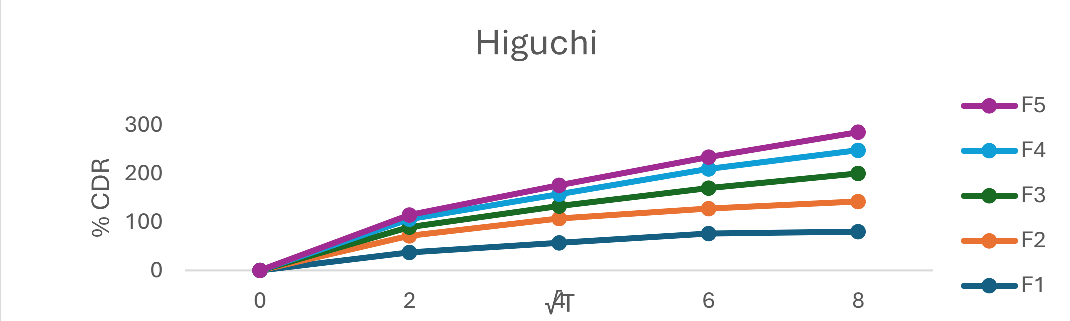


Fig 14: Higuchi release kinetics

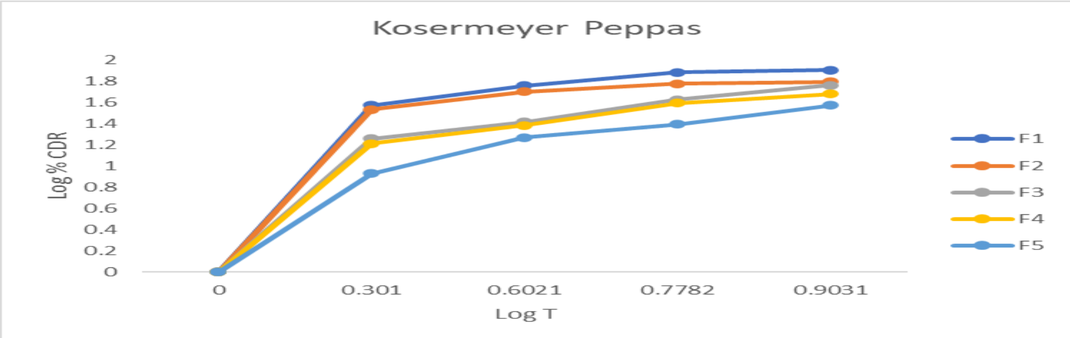


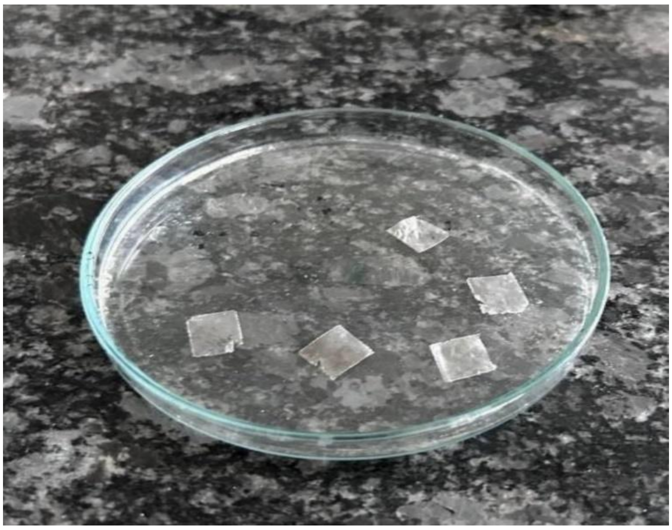
Fig 15: KosermeyerPeppas release kinetics

Table 15: *In-vitro* drug release kinetics studies of Omeprazole magnesium buccal patch

Formulation	Zero order	First order	Higuchi	Kosermeyer- Peppas		Best fit model
	r^2	r^2	r^2	r^2	N	
F1	0.9203	0.9808	0.9896	1.0000	0.6105	Kosermeyer- Peppas Non fickian diffusion
F2	0.8527	0.9244	0.9824	0.9071	0.3963	Higuchi Fickian diffusion
F3	0.9896	0.9674	0.9152	0.9609	0.8372	Zero order Non fickian diffusion
F4	0.9878	0.9902	0.9439	0.9754	0.7983	First order Non fickian diffusion
F5	0.9914	0.9789	0.8959	0.9909	1.0317	Zero order Non fickian diffusion

The *In- vitro* dissolution studies was carried out for 8 hrs. The regression co-efficient for F3 and F5 formulations follows zero order kinetic type of drug release, F2 formulation follows the Higuchi kinetic type of drug release, F1 formulation follows the kosermeyerpeppas type of drug release and F4 formulation follows first order kinetic type of drug release. The 'n' value obtained from peppas equation were more than 0.5. which indicated that all formulations showed drug release by fickian and non fickian diffusion mechanism.

FORMULATED OMEPRAZOLE MAGNESIUM BUCCAL PATCHES



IV. CONCLUSION

The current study has been successful to formulate the buccal patches of omeprazole magnesium for the treatment of peptic ulcer, when applied to the buccal mucosa, deliver the drug at a controlled rate to the systemic circulation. Buccal patches of omeprazole magnesium were formulated using the solvent casting method in order to develop controlled release formulations with polymers such as HPMC K100M, SCMC, PEG, and PVP. Pre-formulation studies showed satisfactory results for drug description, solubility, pH, melting point, and λ max. The compatibility of drugs and excipients was investigated using FTIR. The results showed that there was no interaction between the drug and the excipient. All formulations physicochemical parameters were evaluated including thickness, weight variation, % moisture content, folding endurance, surface pH, swelling index drug content, and *in-vitro* drug release studies. Formulation F1, which contains HPMC, SCMC, PEG, and PVP was selected as best formulation because of its highest drug release rate (80.1%) and follows thekosermeyerpeppas type of drug release. Hence it can be concluded that buccal patch of Omeprazole magnesium offers a promising alternative to conventional oral dosage form by improving bioavailability and enhancing patient compliance.

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