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"FORMULATION AND EVALUATION OF ALMOTRIPTAN ORAL FILM DELIVERY SYSTEM"

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Abstract

The present study was undertaken to formulate and evaluate Almotriptan oral/buccal fast-dissolving films as a patient-friendly dosage form for migraine management. Almotriptan is a selective serotonin 5-HT1B/5-HT1D receptor agonist used in the acute treatment of migraine. Films were prepared by the solvent-casting method using Eudragit L100, HPMC K4M and HPMC K15M as film-forming polymers. Propylene glycol and Tween 80 were incorporated as plasticizer and permeation enhancer, respectively. Twelve formulations (F1–F12) were prepared by varying polymer composition. The films were evaluated for physical appearance, flatness, thickness, folding endurance, drug content, moisture uptake, moisture content and in-vitro permeation through a dialysis membrane. All formulations exhibited acceptable physical characteristics. Formulation F6, containing HPMC K4M 300 mg and Eudragit L100 60 mg, showed the highest cumulative drug release, 94.7% at 12 h. Release-kinetic analysis indicated that the Korsmeyer–Peppas model provided the best fit (R^2 = 0.9892), with an n value of 0.6203, suggesting non-Fickian diffusion. The developed Almotriptan buccal film system may provide a convenient alternative to conventional oral dosage forms.

Keywords: Almotriptan; oral film; buccal film; solvent casting; HPMC K4M; Eudragit L100; dialysis membrane; Korsmeyer–Peppas.

1. Introduction

Conventional tablets and capsules may be difficult to administer to patients experiencing nausea, vomiting or swallowing difficulties during migraine attacks. Oral thin films are thin, flexible polymeric dosage forms that hydrate and disintegrate rapidly in the oral cavity and can be administered without water. They offer portability, ease of administration, accurate dosing and the possibility of improved patient compliance. Buccal delivery may also reduce exposure to gastrointestinal degradation and partially avoid hepatic first-pass metabolism. Almotriptan, a triptan used for acute migraine, was selected as a model drug for the development of a polymeric buccal film delivery system.

Migraine is a common and disabling neurological disorder characterized by recurrent attacks of moderate-to-severe headache, often accompanied by nausea, vomiting, and increased sensitivity to light and sound. The episodic nature of migraine and the rapid onset of symptoms necessitate drug-delivery systems that can provide prompt therapeutic action while improving patient convenience and compliance. Conventional oral dosage forms such as tablets and capsules may present limitations during acute migraine attacks because nausea and vomiting can interfere with swallowing and gastrointestinal drug absorption.

Almotriptan is a selective serotonin **5-HT₁B/5-HT₁D receptor agonist** belonging to the triptan class of antimigraine agents. It exerts its therapeutic effect primarily through constriction of dilated cranial blood vessels and inhibition of the release of vasoactive neuropeptides, thereby reducing migraine-associated pain and other symptoms. Although conventional oral almotriptan formulations are effective, the requirement for swallowing a solid dosage form may be inconvenient for patients experiencing nausea, vomiting, or difficulty swallowing during a migraine attack. Therefore, the development of an alternative oral dosage form capable of rapid administration may provide potential advantages in terms of convenience and patient acceptability.

Oral films are thin, flexible polymeric dosage forms designed to rapidly disintegrate or dissolve when placed on the tongue or within the oral cavity. They offer several advantages over conventional solid dosage forms, including ease of administration without water, improved patient convenience, reduced risk of swallowing difficulties, and the potential for rapid drug release. Depending on the formulation and drug properties, oral films may facilitate drug dissolution in the oral cavity and can potentially provide a faster onset of action compared with conventional tablets. Their low dose requirement, large surface area, and ability to incorporate suitable film-forming polymers make them particularly attractive for drugs intended for acute therapy.

The solvent casting method involves dissolving water-soluble polymers in water while the drugand other excipients are dissolved in a compatible solvent. These two solutions are thencombined and stirred thoroughly to create a uniform mixture. The resulting homogeneoussolution is poured into a Petri dish and left to dry.

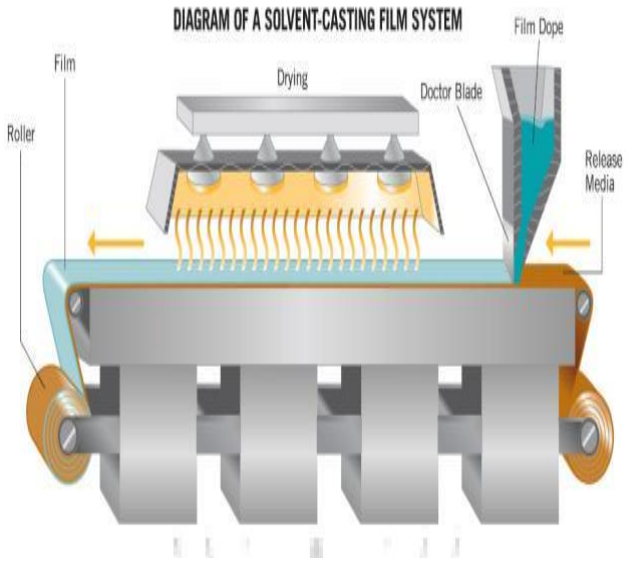


Fig 1.1 Instrumentation Of Solvent Casting System.

The formulation of an almotriptan oral film requires careful selection and optimization of film-forming polymers, plasticizers, superdisintegrants, sweeteners, and other excipients to achieve desirable mechanical strength, flexibility, uniformity, rapid disintegration, and drug-release characteristics. Parameters such as film thickness, folding endurance, tensile strength, surface pH, drug content uniformity, disintegration time, dissolution profile, and stability are important considerations in the development and evaluation of the formulation.

In view of these considerations, the present study is aimed at the **formulation and evaluation of an almotriptan oral film drug-delivery system** to provide a convenient, rapidly disintegrating dosage form with satisfactory physicochemical and drug-release characteristics. The developed formulation may offer a patient-friendly alternative to conventional oral dosage forms for the management of acute migraine attacks.

2. Materials and Methods

2.1 Materials

Table 2.1 List Of Materials

Material	Function
Almotriptan	Active pharmaceutical ingredient
Eudragit L100	Film-forming polymer
HPMC K4M	Film-forming polymer
HPMC K15M	Film-forming polymer
Dichloromethane and ethanol	Solvent system
Propylene glycol	Plasticizer/permeation enhancer
Tween 80	Permeation enhancer/surfactant
Methanol	Solvent for standard preparation

2.2 Formulation of buccal films

Eudragit L100, HPMC K4M and HPMC K15M were weighed in the required ratios and dissolved or dispersed in dichloromethane and ethanol under magnetic stirring. Almotriptan (40 mg per formulation), propylene glycol and Tween 80 were added with continuous stirring to obtain auniform dispersion. The dispersion was poured into a Petri plate, and solvent evaporation was controlled by placing an inverted cut funnel over the films. After 24hrs, the dried films are stored in a desiccator.

Table 2.2.1Formulations of Almotriptan Buccal Film

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Almotriptan (mg)	40	40	40	40	40	40	40	40	40	40	40	40
Eudragit L100 (mg)	200	250	300	–	–	–	–	–	–	150	150	–
HPMC K4M (mg)	–	–	–	200	250	300	–	–	–	150	–	150
HPMC K15M (mg)	–	–	–	–	–	–	200	250	300	–	150	150
Dichloromethane (mL)	8	8	8	8	8	8	8	8	8	8	8	8
Ethanol (mL)	8	8	8	8	8	8	8	8	8	8	8	8
Propylene glycol (mL)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Tween 80 (mL)	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3

- **Preparation of StandardCalibration Curve ofAlmotriptan:**

100mg of Almotriptan was accurately weighed and dissolved in little amount of pH phosphatebuffer(pH1.2) in 100ml to get 100µg/ml (working standard). Then 0.2, 0.4, 0.6, 0.8 and 1ml of working standard was taken in 10 ml standard volumetric flask and made up thevolume with 6.8 pH phosphate buffer to prepare 2µg, 4µg, 6µg, 8µg and 10µg drug per mlsolution.Methanoland make up the final volume up to 100ml with 6.8pH phosphate buffer to prepare stocksolution. The 10ml of stock solution was further diluted with 6.8 pH.

3.1 Calibration curve

The calibration data for Almotriptan in pH 6.8 phosphate buffer showed a linear relationship in the tested concentration range. The regression equation reported in the study was y = 0.0636x + 0.0751.

Table 3.1Standard Calibration curve of Almotriptan:

Concentration (µg/mL)	Absorbance at 258 nm
2	0.128
4	0.267
6	0.456
8	0.589
10	0.762
12	0.963

Physical evaluation:

- **Thickness:**This thickness of the films was assessed at 3 different points using screw gauze.For each formulation, three randomly selected films were used.

- **Folding endurance:**The folding endurance was measured manually for the preparation film.A strip of the films (4x3 cm) was cut evenly and repeatedly folded at the same place till it isbroken.

- **Moisture uptake:**The films were placed in the desiccators containing 200 ml saturatedsolution of potassium chloride, to get the humidity inside the desiccators at 84%RH. After3days the films were taken and weighed the percentage moisture absorption of the film wasfound.

- **Moisture content:**The films were placed in the desiccators containing 200 ml saturatedsolution of potassium chloride, to get the humidity inside the desiccators at 84%RH. After3days the films were taken and weighed the percentage moisture absorption of the film wasfound.

- **Drug content determination:**The film of area 3.83cm 2 was cut and dissolved in PBS pH7.4. Then solvent ethanol and dichloromethane, to make polymer soluble, were added tothe mixture and the remaining volume was made up with PBS pH 7.4 to 100 ml in 100 mlvolumetric flask. Then 1 ml was withdrawn from the solution and diluted to 10 ml. Theabsorbance of the solution was taken at 258nm and concentration was calculated. Bycorrecting dilution factor, the drug content was calculated.

All prepared films were reported to be flat, smooth and flexible. The results of thickness, folding endurance, drug content, moisture uptake and moisture content are presented below.

Formulation	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)
F1	0.3569	20	45	7.98	3.77
F2	0.352	25	65	25.05	9.2
F3	0.347	27	57.5	13.09	5.16
F4	0.3496	24	60	15.63	5.66
F5	0.346	30	67.5	11.73	4.87

F6	0.3517	32	92.5	19.65	12.67
F7	0.3478	40	101.7	9.42	3.43
F8	0.3437	37	85	10.87	4.72
F9	0.3503	34	55	16.44	6.62
F10	0.3532	29	62.5	13.08	6.17
F11	0.3546	26	85	20.63	7.94
F12	0.3503	31	82.5	15.73	6.55

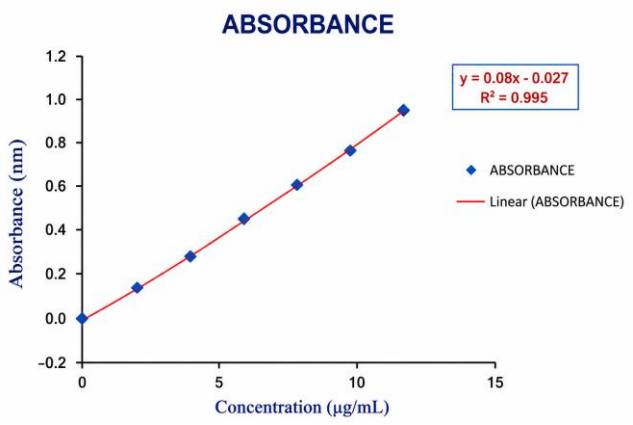
3.3 In-vitro permeation

Formulation F6 showed the highest cumulative release among the twelve formulations, reaching 94.7% at 12 h. The HPMC K4M-containing formulations generally showed a better release profile than the HPMC K15M- containing formulations under the reported test conditions.

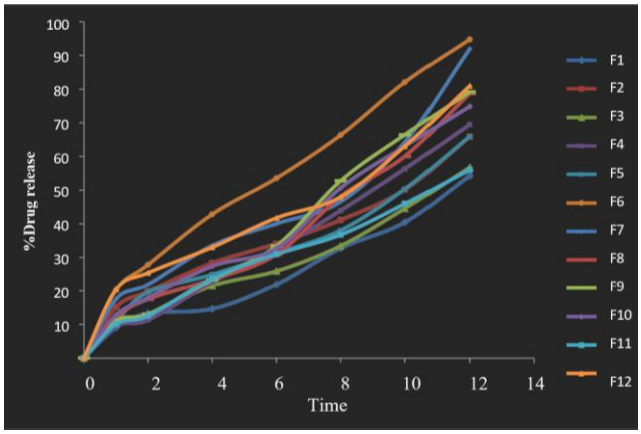
Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1	9.05	15.1	10.1	9.49	10.9	20.2	17.5	12.0	11.1	12.7	10.0	20.4
2	13.3	19.8	12.8	11.3	19.6	27.8	21.9	17.5	13.0	17.9	12.5	25.4
4	14.6	28.3	21.5	22.6	24.9	42.8	33.5	23.4	23.3	27.4	23.6	33.0
6	21.9	34.1	25.9	32.3	31.2	53.5	40.0	30.9	33.4	32.7	30.9	41.7
8	32.7	41.1	33.4	43.9	38.0	66.3	46.5	48.1	52.7	50.6	36.7	47.9
10	40.4	50.1	44.5	56.3	50.3	82.0	64.2	60.0	66.4	63.0	45.9	63.0
12	54.2	65.8	56.7	69.4	65.9	94.7	91.9	78.7	79.1	74.8	56.0	80.9

Results and discussions:

I. Standard graph of almotriptan in pH 6.8 phosphate buffer.



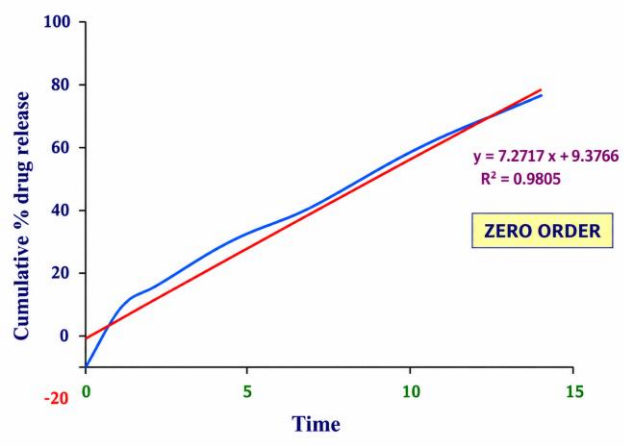
II. Release Profile Of In-Vitro Permeation Studies Using Dialysis Membrane



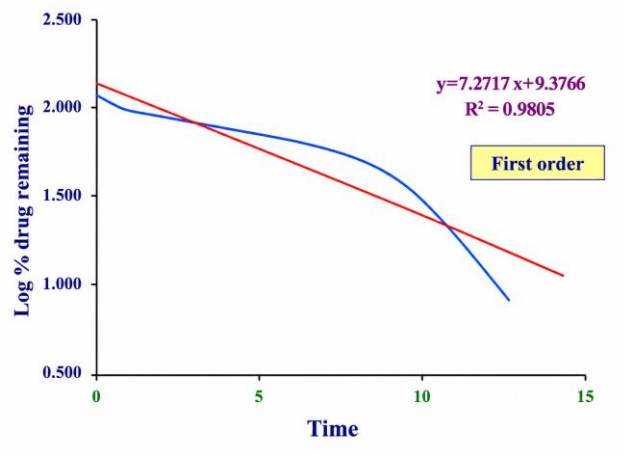
III. Kinetics Of In-Vitro Permeation Studies Using Dialysis Membrane

Cumulative (%) release Q	Time (T) min	Root (T) min½	Log (%) release	Log (T)	Log (%) remain	Release rate (cumulative % release/t)	Peppas log Q/100	%drug remain
0	0	0	-	-	2.000	-	-	100
20.236	1	1.000	1.306	0.000	1.902	20.236	-0.694	79.7644
27.80759	2	1.414	1.444	0.301	1.858	13.904	-0.556	72.19241
42.87958	4	2.000	1.632	0.602	1.757	10.720	-0.368	57.12042
53.59293	6	2.449	1.729	0.778	1.667	8.932	-0.258	46.40707
66.38743	8	2.828	1.822	0.903	1.527	8.270	-0.178	33.61257
82.0877	10	3.162	1.914	1.000	1.253	8.209	-0.086	17.9123
94.7055	12	3.464	1.976	1.079	0.724	7.892	-0.024	5.294503

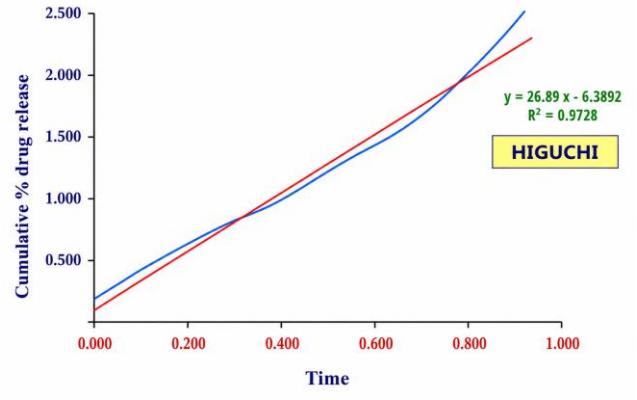
IV. Zero order kinetics



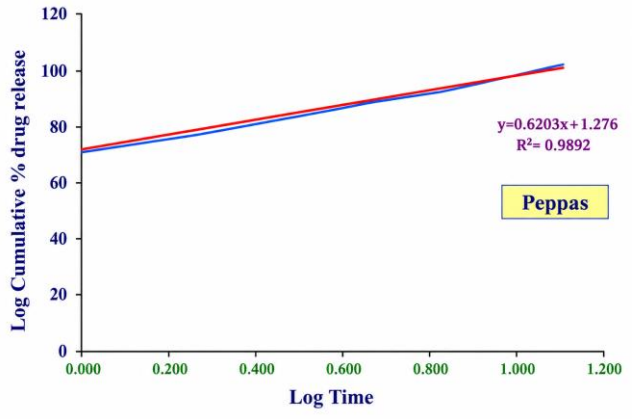
V. First order



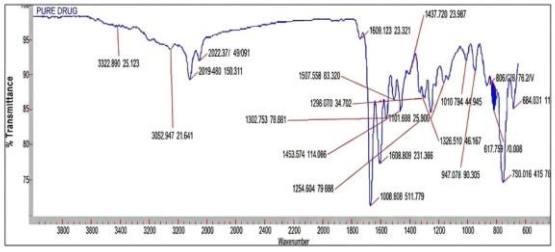
VI. Higuchi plot



VII. Peppas plot



VIII. Fourier Transform Infrared Spectroscopy Spectrum Of Pure Drug



IX. Fourier Transform Infrared Spectroscopy Spectrum Of Optimized Formulation



SUMMARY

The present study focused on the formulation and evaluation of Almotriptan oral films for rapid and effective migraine treatment. The films were prepared by the solvent-casting method using Eudragit L100, HPMC K4M, and HPMC K15M as film-forming polymers, with propylene glycol and Tween 80 as excipients. Twelve formulations (F1–F12) were prepared and evaluated for physical appearance, thickness, folding endurance, drug content, moisture properties, disintegration time, and in-vitro drug release.

Among the formulations, F6 was selected as the optimized formulation and showed approximately 94% drug release within 12 minutes. Drug-release kinetics indicated that the Korsmeyer–Peppas model provided the best fit (R^2 = 0.9892), with an n-value of 0.6203, indicating non-Fickian diffusion. FTIR studies showed no significant drug–excipient interactions, confirming formulation compatibility. Overall, the study demonstrated that Almotriptan oral films can provide rapid drug release and may be a suitable patient-friendly dosage form for migraine management.

CONCLUSION

Conclusion

The study successfully developed **Almotriptan oral films** using the solvent-casting method. Among the twelve formulations, **F6 was selected as the optimized formulation**, showing approximately **94% drug release within 12 minutes**. The **Korsmeyer–Peppas model** showed the best fit with **R^2 = 0.9892** and an **n-value of 0.6203**, indicating **non-Fickian diffusion**. FTIR studies confirmed the compatibility of Almotriptan with the excipients. Overall, the developed oral film demonstrated **rapid drug release and potential for effective migraine management**.

Conflict of Interest

The authors declare that there is no conflict of interest.

Almotriptan Oral Film Delivery System

Author Contributions

Divya Nemani: experimental work, data collection, analysis and manuscript preparation.
Dr. M. Gayatri Devi: supervision, guidance and review of the manuscript.

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