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Design, development and characterization of Mouth dissolving films for better therapeutic efficacy

Mr. O. S. Kawarkhe[1], Prof. Dr. P. S. Kawtikwar[2], Ms. P. A. Mor[3], Dr. A. M. Mahale[4], Mr. N. D. Phupate[5]

1 Department of Pharmaceutics, S. N. Institute of Pharmacy, Pusad, Maharashtra 445204, India
2 Department of Pharmaceutics, S. N. Institute of Pharmacy, Pusad, Maharashtra 445204, India
3 Department of Pharmaceutics, S. N. Institute of Pharmacy, Pusad, Maharashtra 445204, India
4 Department of Pharmaceutics, S. N. Institute of Pharmacy, Pusad, Maharashtra 445204, India
5 Department of Pharmaceutical Chemistry, S. N. Institute of Pharmacy, Pusad, Maharashtra 445204, India

Abstract: The aim was Design, development and characterization of Mouth dissolving films for better therapeutic efficacy. A successful attempt was made to develop oral fast dissolving films of Losartan potassium. From the results it was observed that drug and different polymer combination ratio influence the thickness, folding endurance, drug content as well as the drug release pattern of fast dissolving oral film of Losartan potassium. Hence, the fast dissolving oral film of Losartan potassium are expected to provide clinician with a new choice of safe and more bioavailable formulations in the management of hypertension.

Keywords: Mouth dissolving film, Losartan potassium, HPMC, PEG.

Introduction:

Some patients have difficulty in swallowing or chewing solid dosage forms which risk or fear of chocking and thus is a major problem in the use of solid dosage forms. Fast dissolving film (FDF) is a new drug delivery system for oral drug delivered FDF is used in acute conditions such as pain, emesis, migraine, hypertension, congestive heart failure, asthma et. FDF has gained popularity due to its availability in various sizes and shapes. These are intended to disintegrate or dissolve within seconds. They offer advantages such as administration without water, ease of swallowing, rapid onset of action and convenience of dosing. For fast dissolving active pharmaceutical ingredients, absorption is possible through the oral mucosa and may improve bioavailability.

The advantages of oral film

- The film administered sublingually and buccally deliver the drug with high potential to improve the onset of action, lower the dose, and enhance the efficacy and safety profile of the medicament.
- All single unit dosage forms, soft gels and liquid formulations primarily enter the blood stream via the gastrointestinal tract, which subjects the drug to degradation from stomach acid, bile, digestive

enzymes and other first pass effects.

- Oral film is more stable, durable and quicker dissolving than other conventional dosage forms.
- Oral film enables improved dosing accuracy relative to liquid formulations since every strip is manufactured to contain precise amount of drug.
- Oral film ensures more accurate administration of drugs.
- Oral film can improves compliance due to the intuitive nature of dosage form and its inherent ease of administration. These properties are especially beneficial for pediatric, geriatric and neurodegenerative disease patients where proper and complete dosing can be difficult.

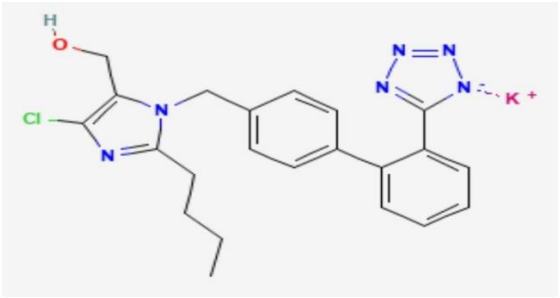
The disadvantages of oral film

- Oral disintegrating films have limitations in terms of the amount of drug that can be incorporates in each unit dose. For lyophilized dosage forms, the drug dose must generally be less than 400 mg for insoluble drugs and less than 60 mg for soluble drugs.
- Also, due to the nature of fast dissolving oral films, special packaging is needed for products that are fragile, which may add to the cost.
- Dose uniformity is a challenge.
- It takes moisture from atmosphere.

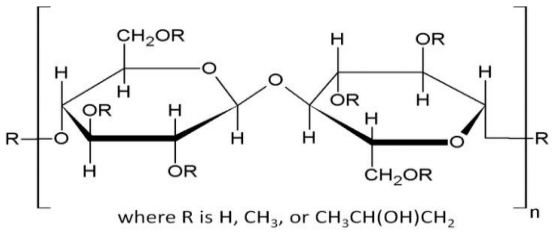
Methods of preparation

Following methods can be used for the preparation of fast dissolving oral films:

1. Solvent casting method
2. Semisolid casting method
3. Hot melt extrusion
4. Solid dispersion extrusion
5. Rolling method



(a)



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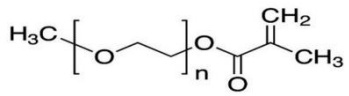


(c)

Figure 1 : Structure of (a)losartan potassium (b) HPMC and (c) PEG

2. PREPARATION :

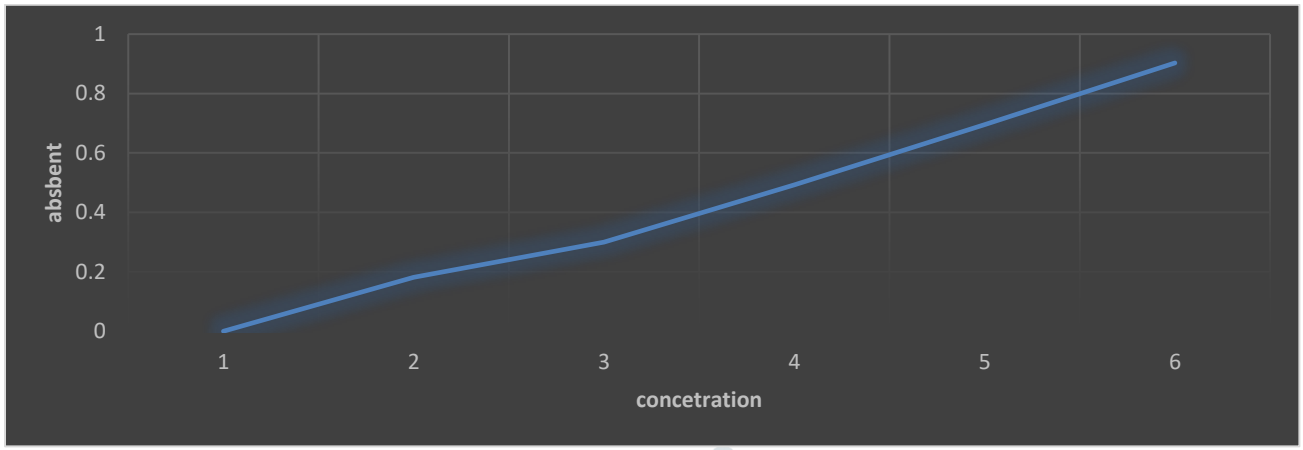
Oral fast dissolving film was prepared by solvent casting method. Aqueous solution I was prepared by dissolving film forming polymer, in specific proportion in distilled water and allowed to stirred for 3 hours and kept for 1 hour to remove all the air bubble entrapped or remove bubbles. Aqueous solution II was prepared by dissolving the pure drug, sweetener, and plasticizer in specific proportion in distilled water. The aqueous solution I and II were mixed and stirred for 1 hour. The solutions were cast on to 9cm diameter Petri dish and were dried in the oven at 45ºC for 12 hours. The film was carefully removed from surface of Petri dish and cut according to size required for testing (square film)

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Drug	150	150	150	150	150	150	150	150
HPMC	100	200	–	–	–	–	–	–
Carbopol	–	–	100	200	–	–	–	–
Ethyl cellulose	–	–	–	–	100	200	–	–
PVP	–	–	–	–	–	–	100	200
PEG	50	50	50	50	50	50	50	50
Saccharine	20	20	20	20	20	20	20	20
Citric acid	20	20	20	20	20	20	20	20
Methanol	5	5	5	5	5	5	5	5
Dis. Water	qs	qs	Qs	qs	Qs	qs	qs	qs

Table 1 : preparation of film

3. Results and discussion

Preformulation test :



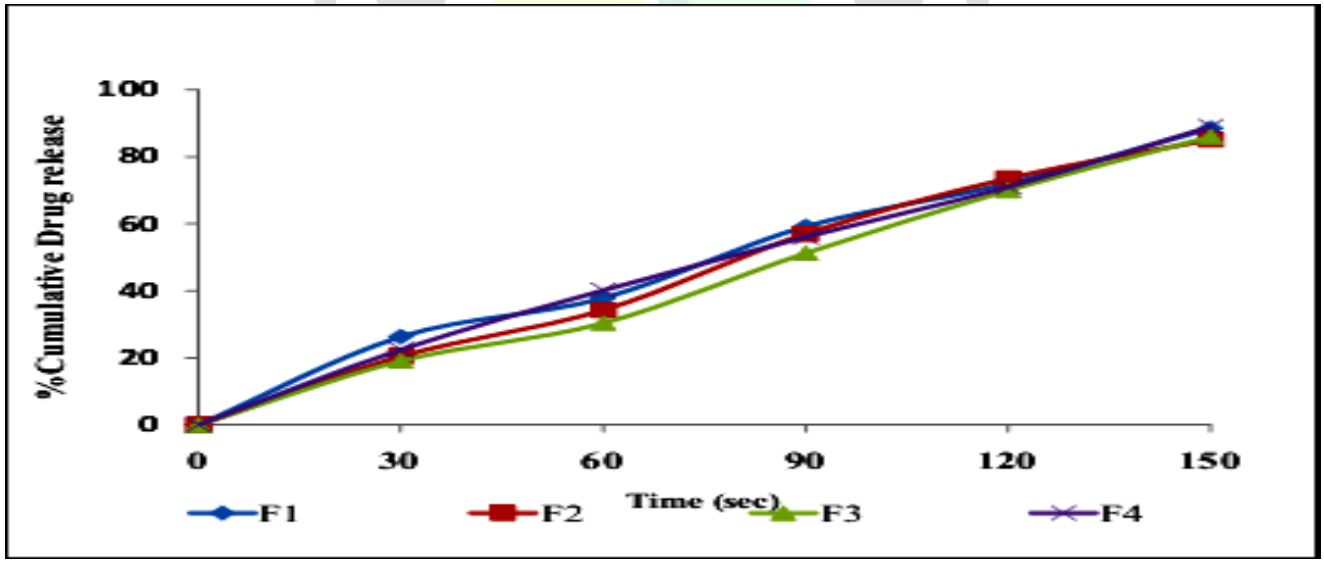
Standard calibration curve of Losartan potassium

Physcical evaluavtion results

Formulation code	Thickness (mm)	Weight variation (mg)	Folding endurance	%drug release	Surface PH	Disintegration time (sec)
F1	0.51	69	9	95.63209	6.14±0.05	20
F2	0.55	68	13	91.7261	6.25±0.10	28
F3	0.59	69	10	90.84418	6.35±0.02	25
F4	0.52	68.4	11	89.45821	6.5±0.08	31
F5	0.53	70	14	88.70223	6.45±0.05	27
F6	0.55	65	11	82.65435	6.65±0.02	36
F7	0.57	69.2	13	88.07224	6.23±0.06	32
F8	0.53	70.6	15	85.67829	6.36±0.03	39

Dissolution Result:

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8
1	15.2457	14.11172	13.22974	9.5758	9.323814	8.189836	8.567829	6.803864
2	20.66359	19.27761	24.9475	15.2457	12.97774	14.23772	14.74171	13.10374
3	23.05754	20.66359	32.25535	20.66359	20.66359	21.54557	25.57749	29.10542
4	24.69551	22.42755	39.68921	30.61739	29.48341	26.83746	37.92524	37.54725
5	34.14532	24.31751	45.98908	45.98908	44.72911	37.04326	49.769	39.68921
6	38.30323	33.38933	52.28895	48.38303	49.64301	43.46913	50.65099	51.65897
7	53.80092	57.70685	62.11676	51.91096	58.08484	51.91096	59.59681	61.86476
8	73.20454	70.93658	66.02268	62.24276	68.41663	63.25073	63.62873	64.63671
9	87.06426	85.42629	80.0084	77.23646	79.50441	75.0945	77.36245	75.72449
10	95.63209	91.72617	90.84418	89.45821	88.70223	82.65435	88.07224	85.67829



4. Conclusion

A successful attempt was made to develop oral fast dissolving films of Losartan potassium. From the results it was observed that drug and different polymer combination ratio influence the thickness, folding endurance, drug content as well as the drug release pattern of fast dissolving oral film of Losartan potassium. Hence, the fast dissolving oral film of Losartan potassium are expected to provide clinician with a new choice of safe and more bioavailable formulations in the management of hypertension.

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