Research Article
CODEN (USA): IJPLCP

ISSN: 0976-7126
Hardiya & Mann, 12(9):1-4, 2021

International Journal of Pharmacy & Life Sciences
Open Access to Researcher

Formulation and Evaluation of mouth dissolving film of Carbamazepine

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Article info

Received: 29/07/2021

Revised: 18/08/2021

Accepted: 21/09/2021

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Abstract

The current approaches in novel drug delivery system main aims to achieve enhanced efficacy and safety of drug molecule by formulating a convenient dosage form for administration and to achieve enhanced patient compliance. One such approach is Oral Films. The present study was an attempt to develop MDF for Carbamazepine, for the prevention of complications of cardiovascular disease. The main interest in such a dosage form was to avoid extensive first pass metabolism, degradation in stomach and for prolonged effect or sustained release profile. The Mouth Dissolving Films were formulated in five different batches F1 to F6 by using hydrophilic polymers HPMC E5, Salivary Stimulating Agent citric acid and PEG. All the formulations were prepared by Solvent casting method. The in vitro drug release profiles obtained for films made with combinations of HPMC E5 gives immediate release in 3-6 min. Preformulation studies were carried out by determining physical appearance, UV and FT-IR spectra of drug. Which identify the sample Solubility of Carbamazepine was determined in various aqueous and non aqueous solvent. Finally it can be concluded that selected drug and polymers fulfill the all parameters which can be required for the optimized Mouth Dissolving Films.

Keywords: Oral Films, Carbamazepine, Evaluation

Introduction

Current advances in Novel drug delivery systems main aim to improve safety and efficiency of drug molecule by formulating a convenient dosage form of drug to attain higher patient compliance. Fast dissolving oral dosage form that gives higher compliance among oral forms like ensuring dose delivery due to the immediate dissolution in the oral cavity.

- Better compliance compared to other oral formulations.
- No need to swallow.
- Avoid first pass metabolism so increase bioavailability.
- Beneficial for traveling patients who do not have access to water.
- Should be flexible, easy for transportation and handling and storage.
- Decrease in side effects related with the drug.
- Precision in administration of dose.

One such approach is formulation of mouth dissolving tablets. A major drawback of a mouth dissolving tablet is its poor mechanical strength. Most of the methods used for manufacturing of mouth dissolving tablets aim at decreasing the disintegration time, but doing this the mechanical strength is always compromised.[1-2]

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Technologies like Zydis and Orasolv need special packaging and patient counseling for removing the tablet from the strip. Thus, most important aspect of formulation of a mouth dissolving tablet is to maintain the mechanical strength of the tablet with rapid disintegration. Also grittiness is the problem associated with mouth dissolving tablets.
In the present work, we have attempted to formulate Oral Film of Carbamazepine with special emphasis on, increasing bioavailability of drug by avoiding first pass metabolism and improving dissolution and disintegration of drug. [3-4]

Material and Methods

Films will prepared by Solvent Casting Method
The different compositions of six films were prepared having same dose of Nitroglycerin Shown in table No. 10 and the concentrations of film are mentioned in Table No.1, HPMC-E5 is soaked for overnight in distilled water and stirred for 30 minutes then 5 ml of distilled water was added to PVA and heated up to 80°C. Then the polymeric solutions were mixed thoroughly. Sucrose and citric acid were added to the polymeric solution and stirred for 15 minutes. Drug, tween 80, menthol were dissolved in 5 ml of methanol and sonicated for 30 minutes. Polymeric solution was added to the drug solution and PEG-400 was added, again stirred for 15 minutes. The resulting solution was poured into the petridish and dried in hot air oven at 40°C.After drying film were removed with the help of sharp blade and kept in desiccators for 24 hrs then cut into small sizes. Piece having area of 2×2 cm^2 these films were subjected for different evaluation parameters. [5-7]

Table 1: Composition of film

Formulation Code	Amount of Carbamazepine	Amount of Polymer	Amount of PEG
F 1	0.4 mg	100 mg	25 mg
F 2	0.4 mg	150 mg	50 mg
F 3	0.4 mg	200 mg	50 mg
F 4	0.4 mg	250 mg	100 mg
F 5	0.4 mg	250 mg	100 mg
F 6	0.4 mg	300 mg	250 mg

Evaluation of Oral Film [6-7]

Physical appearance
Physical appearance was checked by visual inspection through naked eye.

Thickness
As the thickness of film is directly concern with drug content uniformity, it is necessary to ascertain uniformity in the thickness of the film. It can be measured by micrometer screw gauge or calibrated digital Screw gauge at different strategic location [(1).]

Weight variation test
The 4cm2 film was cut at three different places in the cast film. The weight of each strip was taken and then the weight variation was observed.

Surface pH
The surface pH of the film was determined in order to investigate the possibility of any side effects in vivo. As an alkaline or acidic pH may origin of irritation to the buccal mucosa, it was determined to become the surface pH as close to neutral as possible. for this purpose combined glass electrode is used. The film is allowed to swell by keeping it in contact with 1 ml of water at room temperature. The pH is identified by bringing the electrode into contact with the film surface and allowing equilibrating for 1 min.

In-vitro disintegration time
In-vitro disintegration time is determined visually in a petridish of 20 ml distilled water with swirling for every 10 seconds. The disintegration time is the time when the film starts to break or disintegrates. Disintegration time will vary depending on the formulation but typically the disintegration range from 5 to 30 seconds. Although, no official guidance is available for oral fast disintegrating films

Folding endurance
Folding endurance is determined by folding repeatedly of the film at the same place till the film breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

Drug content
A film of area 2×2cm^2 was placed in a volumetric flask containing 50 ml of phosphate buffer of pH-6.8 and kept aside for some time to release the total drug present in the film and the volume was made up to 100 ml with the same buffer. Then the absorbance was measured after suitable dilution at

210 nm against drug devoid polymer blank solution in phosphate buffer of pH-6.8, and the content of Carbamazepine was calculated using standard graph.

In - vitro drug release

Determination of dissolution profile of films was carried out in a beaker containing 30 ml phosphate buffer (pH 6.8) at 37 ± 0.50 °C. Whole assembly was then placed on a shaker. Sample aliquot (1.0 ml) was withdrawn at different time intervals and replaced with same fresh media. Samples were filtered and diluted with phosphate buffer (pH 6.8) and analyzed by using UV at 210 nm.

Results and Discussion

The results for evaluation of oral film in presented in table 2. Percentage of drug content of F5 was found to be 98.8% and was considered as best formulation compared to the other formulation. The formulations showed percentage drug content 78.4- 98.8% the different drug content variations are depends on polymer and plasticizers. The In Vitro Drug Release of each formulation (F1 to F6) was tested and results provided in Table No.13. The maximum and minimum drug content was found to be 98.53 % and 7.35 % respectively. The prepared films were found to be flexible, uniform and 98.53% of drug was released from F5 film within 6 minutes which was desirable for rapid absorption.

Table 2: Evaluation Parameters of oral film

Formulation Code	Physical Appearance	Thickness (mm)	Weight (mg)	Surface PH	D.T. (Sec.)	Folding Endurance	Drug Content (%)
F1	Transparent	0.09	48.3	6.6	92	235	78.43
F2	Greasy look	0.10	53.2	6.4	70	248	83.33
F3	Semi- Transparent	0.11	58.4	6.7	70	296	93.13
F4	Semi- Transparent	0.12	49.3	6.5	76	255	83.33
F5	Semi- Transparent	0.14	56.2	6.6	69	252	98.8
F6	Semi- Transparent	0.15	61.1	6.8	90	260	88.24

Table 3: In-vitro drug release of oral film

Time (Mts)	F1	F2	F3	F4	F5	F6
1	7.35	10.29	14.71	8.82	11.76	8.8
2	13.23	17.65	23.53	23.52	25.0	32.35
3	26.47	30.88	29.41	32.35	33.8	52.94
4	35.29	48.53	42.65	42.64	55.8	72.05
5	54.41	67.65	57.35	51.47	66.17	80.8
6	60.29	79.41	63.24	60.29	98.53	89.70
7	77.94	86.76	76.47	72.05	98.53	94.11
8	89.70	91.18	85.29	82.35	98.53	97.05
9	98.53	94.18	92.65	91.17	98.53	97.05
10	98.53	97.06	97.06	94.12	98.53	97.05

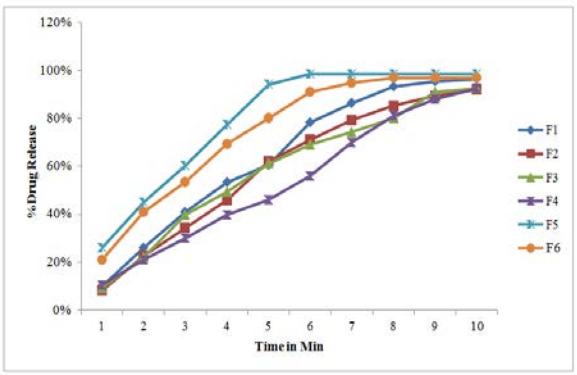

Fig. 1: Invitro drug release

Conclusion

From present investigation it can be concluded that oral fast dissolving films are superior in drug release the films prepared by HPMC E5 and PEG 400 had shown good mechanical strength, drug release, disintegration time and stability. Carbamazepine administered in the form of fast dissolving films will be potential novel drug dosage form for pediatric, geriatric and also for general population by providing faster release and better patient compliance. Angina is a serious medical condition has become a major public health issue and its prevalence is rapidly increasing among the population. Since it requires immediate pharmacological action, Oral Films becoming an alternative to conventional dosage forms. The prepared films of all the formulations were evaluated for physical characters like, weight variation, in-vitro drug release. Carbamazepine release from the mouth dissolving film was studied in phosphate buffer pH 6.8. The release profiles of formulation F5 are released 98.5 % of the drug in 6 min. Finally it can be concluded that Oral Film containing Carbamazepine (F5 formulation) complete drug release spread over 3 - 8 min. Among the Six formulations, F5 showing the highest percentage of drug release and shows minimum disintegration time Hence, F5 is considered as the optimized formulation among six Films.

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Cite this article as:
Hardiya H. and Mann M. (2021). Formulation and Evaluation of mouth dissolving film of Carbamazepine, *Int. J. of Pharm. & Life Sci.*, 12(9):1-4.

Source of Support: Nil
Conflict of Interest: Not declared
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