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Formulation and Evaluation of Fast Dissolving Films of Telmisartan

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Abstract: *The development and assessment of Telmisartan's orodispersible film was the aim of this study. The purpose of this formulation was to improve patient compliance by delivering the rapid start of action of the medication Telmisartan in the treatment of hypertension. lengthen the dosage form's release period at the absorption site, which will improve absorption and bioavailability. For patients who have trouble swallowing pills, capsules, or other medications, the idea of an oral dissolving drug delivery system provides an answer. This study looked at the feasibility of creating Telmisartan rapid dissolving films, which improve patient compliance and enable quick, repeatable drug dispersion in the oral cavity. The hypertension medication telmisartan is a member of the Angiotensin Receptor II Antagonist family. It's a inadequately answerable medicine belongs to BCS class- II. The orodispersible film of Telmisartan was prepared by solvent casting system which is simple and cost effective. Total four Formulation were developed using varying attention of film forming agents. HPMC is used as a film forming agent. glycol were used as a plasticizer. were subordinated to evaluation study like, consistence, weight variation, folding evidence, disintegration time, drug content. The consistence and weight variation for all batch formulation were satisfactory. Folding endurance test for all film formulation was set up satisfactory.*

Keywords: Telmisartan, Solid dispersions, Fast is dissolving film, Solvent-casting method, Mouth dissolving tablets

I. INTRODUCTION

Oral dissolving medicine delivery systems have started gaining fashionability and acceptance as new medicine delivery systems which aim to enhance safety and efficacity of a medicine patch by formulating into a accessible oral form for administration and to achieve better case compliance. They suffer rapid-fire decomposition in the salivary fluids of the oral depression, where they release the medicine(1). Oral medicine delivery is having the maximum case compliance with its safest point of medicine delivery. Mouth dissolving tablets which can also called as fast Dissolving film are generally salutary for older, pediatric and bedridden cases and for those active cases with busy schedule and traveling and when there's lack of water. Mouth dissolving Film are disintegrating or dissolve faster in the sollow without biting or the need for water(2). The fast dissolving oral film forms are appertained by different names by experimenters like quick disintegrating, orally disintegrating, fastly disintegrating, mouth dissolve or melt in mouth (3).

Hypertension is a major health problem throughout the world because of its high frequence and its association with increased threat of cardiovascular complaint. formulate oral dissolving film of Telmisartan, using film forming polymer, plasticizer and padding which increases the dissolution rate of Telmisartan helpful to increases the bioavailability. Telmisartan Anti- hypertensive agent. It inhibits the angiotensin receptors and controls the hypertension(4). Telmisartan doesn't inhibit the angiotensin converting enzyme, other hormone receptors, or ion channels(5).

Usually Applicable Fields of MDFs (Mouth Dissolving Film) includes

1. Elderly cases having difficulties in taking other oral forms like tablets, and capsules etc. This can be due to numerous reasons including hand temblors and dysphagia.

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2. Now day's individualities generally have problem in swallowing because of their underdeveloped muscular and nervous systems.
3. Other cases who may face problems in other oral forms including the mentally ill, physically impaired, uncooperative cases, and those having drop liquid- input plans.
4. Other uses which extent the cause of product are –(i) lack of water,(ii) difficulty in swallowing other solid lozenge forms, (iii)nausea, (iv) stir sickness, (v) unforeseen antipathetic attack or coughing(6).

The manufacturing process of MDFs involves ways like solvent casting, hot- melt extrusion, or electrospinning, each chosen grounded on the parcels of the medicine and the asked film characteristics. Solvent casting is the most common system, where the polymer result containing the API is cast onto a flat face and dried to form a thin film. Quality control measures, including assessments of film consistence, surface PH, Disintegration time(7).

Ideal properties of mouth dissolving film

- It can dissolve or disintegrate in mouth in few second.
- It does not require water to swallow.
- It is compatible with excipients.
- It is portable and its transportion is easy.
- It allows high drug loading.
- It shows less sensitivity to environment condition.

Advantages of fast dissolving film include

- Case of increases Hypertension not able to swallow large amounts of water.
- In case of high blood pressure quick onset of action needed because unbridled high blood pressure produce Strokes, Heart attack, order Problem.
- Hypertension markedly reduces functional capability and extremely restlessness in similar cases rapid-fire onset of action needed.
- Especially intended to senior cases who have problem of swallowing(8).

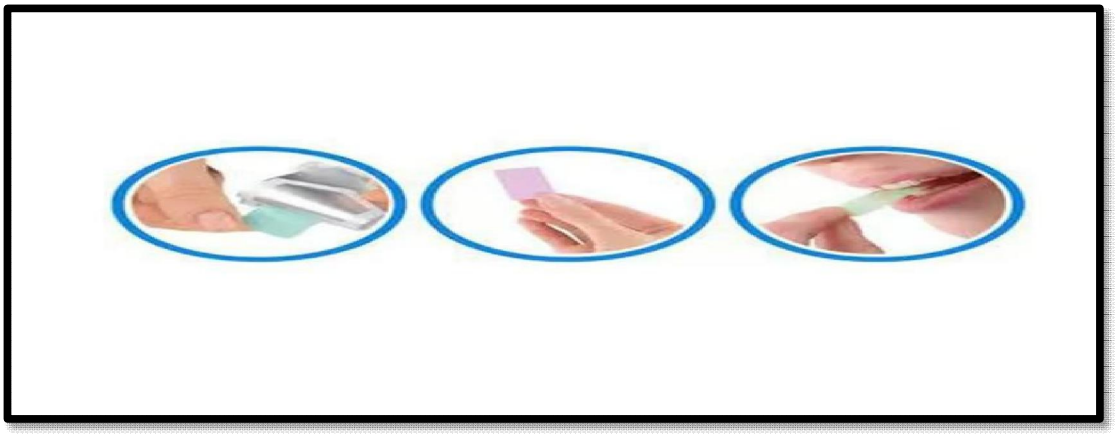

Fig.No.1. Oral Dissolving Film

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DRUG PROFILE

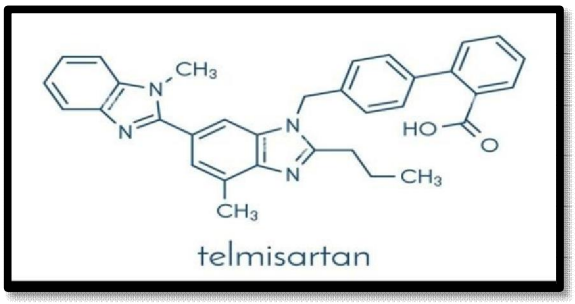

Fig. No. 2 Structure of Telmisartan

Molecular Formula : C33H30N4O2 Molecular Weight : 514.617g/mol.
Solubility Profile : BCS II
History : Telmisartan was Patended in 1991 and came into medical use in 1999. Uses : Treat high blood pressure. They are also used to decrease the chance of heart attack, Stroke.

II. MATERIALS AND METHODS

Telmisartan were kindly supplied by Nivi Exim(Navi Mumbai, India), All the products and materials used in this study comply with the pharmaceutical and analytical standards, respectively. All the research work was carried out at Nootan College of pharmacy, Kavathemahankal, Sangli, Maharashtra

Formulation of Telmisartan Orodispersible Films:

Orodispersible films of Telmisartan were prepared by solvent casting method using HPMC and as film forming material or polymer. In this formulation, Sodium lauryl sulphate was used as super disintegrating agent, Sucrose was used as sweetening agent, citric acid is used as saliva stimulating agent, while glycerol is used as plasticizer.

Procedure:

The required amount of drug where weighed and dissolved in water (Solution A).
The other excipients such as polymer, plasticier, saliva stimulating agent, sweetening agent, colouring agent, flavouring agent was mixed (Solution B)
And both Solution was then mixed by using stirrer for 30 minutes.
The resulting solution was casted slowly and with continuous flow on a glass petri plates.
The plates were kept in Room temperature for 24 Hours.
The film was removed and cut into the required size of 2 x 2 (4 cm2).
The formulation details of Orodispersible film were given in table 1. [9 – 11]

Table 1: Composition of Orodispersible Film of Telmisartan

INGREDIENTS	F1	F2	F3	F4
Telmisartan	40mg	40mg	40mg	40mg
HPMC	100mg	150mg	200mg	250mg
Glycerol	1ml	1 ml	1ml	1ml
Citric acid	10mg	10mg	10mg	10mg
Sodium lauryl sulphate	15mg	15mg	15mg	15mg
Sucrose	2mg	2mg	2mg	2mg
Peppermint oil	q.s	q.s	q.s	q.s
Water	10ml	10ml	10ml	10ml

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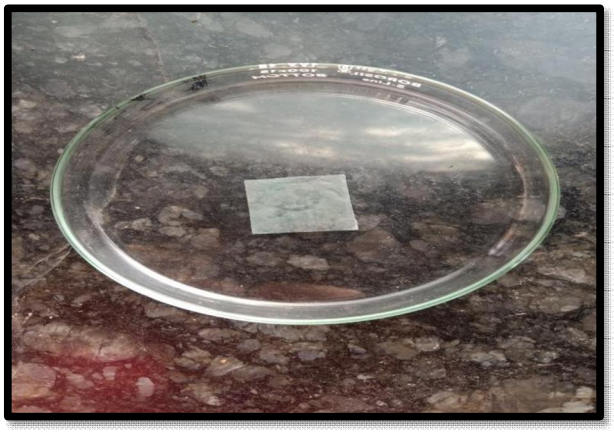

Fig.No.3 Oral dispersed film of telmisartan

Evaluation of Oral dispersible Films Thickness of Film:
The thickness of the film should be measured , using vernier callipers and the mean thickness is calculated. Samples with air bubbles, nicks or tears and having mean thickness variation of greater than 5% are excluded from analysis[12].

Physical Appearance and surface texture of film:
Films of each formulation were randomly selected and visually inspected for texture by feel or touch[13] .

Weight uniformity of films:
Three films of the size 2×2 cm2 were weighed individually using digital balance and the average weights were calculated[14].

Folding Endurance:
Folding endurance was determined by folding the film repeatedly from the same place until it breaks or visible cracks was not observed. The number of times film folded without breaking is the value of folding endurance[15].

Disintegration time
Disintegration time of Orodispersible film was determined by petri dish method. This technique was carried out on a petri plate. The oral thin film was placed in the centre of a petri dish filled with 10 mL of distilled water. The time taken for the thin layer to disintegrate is measured, and the procedure is done thrice[16,17].

Drug content uniformity study:
The films were tested for drug content uniformity by U.V-Spectrophotometric method. Films of 2×2 cm2 were each film was placed in 10 ml volumetric flask and diluted with phosphate buffer pH 6.8 up to 10 ml. The absorbance of the solution was measured at296nm using U.V visible spectrophotometer after suitable dilution. The percentage drug content was determined [18,19]

In vitro Dissolution test
The in vitro dissolution test was performed using the USP basket apparatus. The dissolution studies carried out at 37±0.5 0C; with stirring speed 50 rpm in 500 ml phosphate buffer pH 6.8. The film size required for dose delivery (2 × 2 cm2) was used. Five milliliters aliquots of dissolution media collected at specific time interval of 2,4,6,8,10 up to 12 minutes. The collected sample is filtered and the concentration of Telmisartan in film was determined at a wavelength of 296nm using U.V. spectrophotometer[20].

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Surface pH of films

Surface pH was determined to reduce the irritation of oral mucosa due to alkaline or acidic pH. It was kept in the range of salivary pH. The pH of the film was determined by pH paper[21].

III. RESULTS AND DISCUSSION

IR Spectrum:

For characterization of pure Telmisartan IR studies were carried out. The observed and reported indicating the presence of the drug in its original chemical form and IR spectrum is shown in (Fig.4).

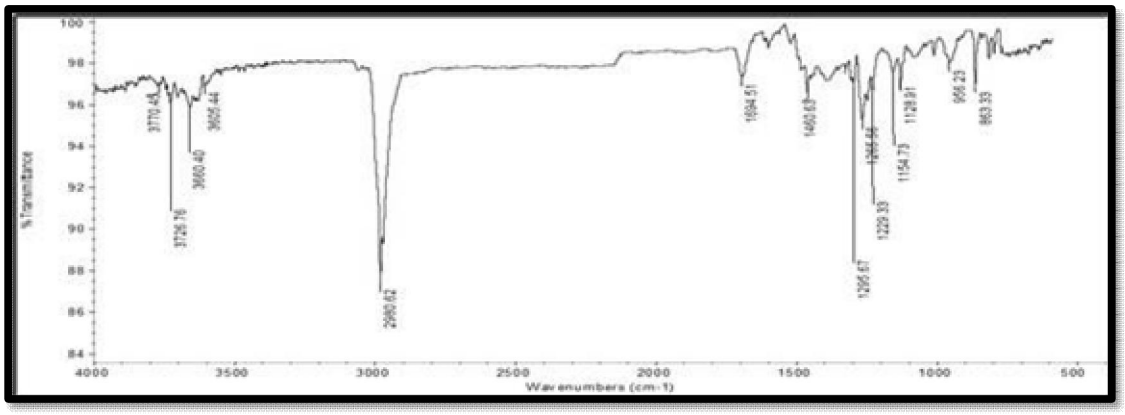

Fig.No. IR spectra of drug Telmisartan

EVALUATION OF ORODISPERSIBLE FILMS

Thickness of films

Thickness of the film was found in increasing order. As polymer conc. increases the thickness of the film also increases. Film thickness of formulation F1- F4 was found in the range 0.29±0.01 to 0.32±0.03 mm. The thickness of the films was measured using Vernier calliper. Results of thickness are shown in table 2.

Physical appearance:

This parameter was checked simply with visual inspection of films and evaluation of texture by feel or touch. The observation suggests that the films were having smooth surface and Translucent.

Weight uniformity of films

Three films of the size 2×2 cm2 were weighed individually using digital balance and the average weights were calculated. Weight of the film was found in the increasing order. As the weight of polymer increases the weight of the film also increases. Weight of the films of F1- F4 was found in the range 22.5mg to 24.05 mg. Weight of film was found uniform in all batches, ensuring uniform drug distribution among the prepared films. Result was shown in table 2

Folding endurance of films

The folding endurance of the films was determined by repeatedly folding a small strip of the films at the same place till it broke and the average folding endurance of all films was given in table2. The folding endurance of the film was found between 94 to101. Among all batches, F3 batch shows higher folding endurance, while batch F1 showed lower folding endurance.

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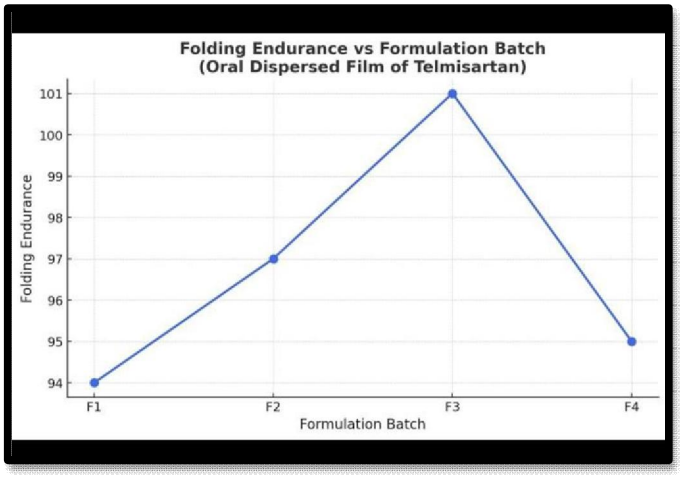

Fig No.5. Graph of Folding Endurance of orodispersed film of telmisartan

In vitro disintegration time of films

Disintegration time for all batch of Orodispersible film formulation (F1 to F4) was found in the range of 68 seconds to 115 seconds. Formulation showed lowest disintegration time of 68 seconds, while batch F4 showed higher disintegration time of 115sec

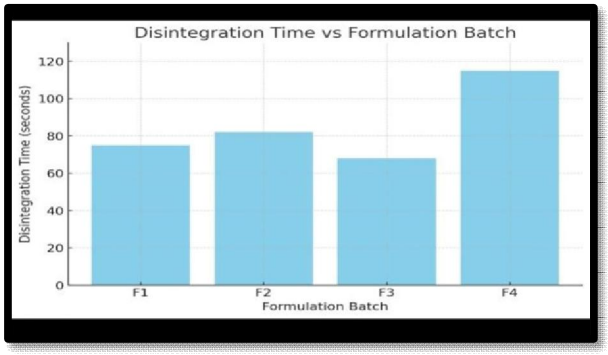

Fig No.2 Graph of Disintegration time of Orodispersible film of telmisartan (F1 to F4)

Drug content uniformity study of films

Drug content uniformity for all formulation were shown in table 2. The prepared film formulations were analyzed for drug content and it was observed that all the formulation found to contain almost uniform quantity of drug as per content uniformity studies indicating reproducible technique. Drug content for all formulation was found to be in the range of 96.17 % to 98.07% which shows uniformity of drug content in all formulation. Batch F3 formulation showed highest 98.07 percent of drug content.

Table 2. Evaluation Orodispersible film of Telmisartan.

Batch no.	Thickness (mm)*	Folding Endurance*	Weight Variation (mg)*	DT (Sec)*	Drug content (%)*	Surface pH	Appearance
F1	0.29± 0.01	94± 0.56	22.5±004	75±0.64	96.17±0.82	6.8	Translucent
F2	0.31±0.02	97± 1.23	23±0.05	82±0.95	97.25±0.02	6.7	Translucent
F3	0.32±0.03	101± 1.80	24.05±0.08	68±0.59	98.07±1.08	6.6	Translucent
F4	0.31±0.02	95± 0.67	23.5±0.06	115±1.26	96.84±0.05	6.8	Translucent

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IV. CONCLUSION

From the present study following conclusion were observed. The orodispersible films of telmisartan can be prepared by solvent casting method by using film forming agent HPMC. All the prepared formulations were showed satisfactory results required for the orodispersible type of products. Formulation F3 was consider as the ideal formulation which exhibited lowest disintegration time (68 sec) and shows 98.07% drug release in 15 min. Future detailed investigation is required to established in vivo efficiency of orodispersible films of Telmisartan.

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