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Formulation and Evaluation of Ivabradine Oral Thin Films

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ABSTRACT
In present study oral thin films of Ivabradine were developed to have a faster on set of action. The oral thin films were developed by using polymers HPMC E5, HPMC E 15 and PVP K90.Oral thin films were prepared by employing solvent casting method. Propylene glycol was selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F6, and all the formulations were evaluated for various physical parameters Physical appearance, Weight variation, Thickness, Folding endurance, Tensile strength, Drug content, Moisture uptake, Moisture content and all the results were found to be were found to be with in the pharmacopeial limits, in-vitro drug release studies by using dialysis membrane. Among all the 6 formulations F1 formulation which contain HPMC E15 300mg and shown 97.2.% cumulative drug release within 30 min. And compared to HPMC E15, HPMC E5 and PVP K90, HPMC E 15 showed better drug release profile.

INTRODUCTION

Oral films are considered as a most promising and important drug delivery system today because of their rapid disintegration, improved dissolution properties especially with paediatric and geriatric patients. Even though most of the formulation today are developed as ODTs, oral film has gain more popularity because of their easy portability, improved patience compliance and ease of administration. They can be applied by both oral and buccal routes. Apart from being used as medicated films (local anaesthetics, vitamins supplements, and cold allergy remedies) they can also be used for refreshing the breath. This technology is growing in fast pace challenging most of the pharmaceuticals companies to develop oral films for a wide range of active pharmaceuticals ingredients [.

Fig.1: oral thin film

Oral medicated strips/films[1,2]

A strip or film can be defined as a dosage form that employs a water-dissolving polymer (generally a hydrocolloid, which may be a bio adhesive polymer), which allows the dosage form to quickly hydrate, adhere, and dissolve when placed on the tongue or in the oral cavity (i.e., buccal, palatal, gingival, lingual, or sublingual, etc.) to provide rapid local or systemic drug delivery [1-5].

Future challenges for Oral thin films

Fast dissolving intraoral products face many challenges as given below, these challenges are related to new technologies and products as they mature.

- Most of the drugs need taste masking.
- A novel manufacturing process is a challenge, due to new equipment, technology and process.
- Limited drug loading due to technology limitation, taste masking and tablet size.
- Need more clinical trials to study more clinical/medical benefits.
- Older patient benefits by change in taste, flavour and dissolve too fast.
- Cost of the product is a major challenge

A drug can be administered via a many different routes to produce a systemic pharmacological effect. The most common method of drug administration is via per oral route in which the drug is swallowed and enters the systemic circulation primarily through the membrane of the small intestine. The oral route of drug administration is the most important method of administering drugs for systemic effect. The parenteral route is not routinely used for self–administration of medication. It is probable that at least 90 % of all drugs used to produce systemic effects are administered by the oral route [6-8].

Fig.2: Various parts of Carica papaya plant i) Carica papaya plant, ii) Carica papaya seeds, iii) Fresh Carica papaya seeds, iv) Dried Carica papaya seeds.

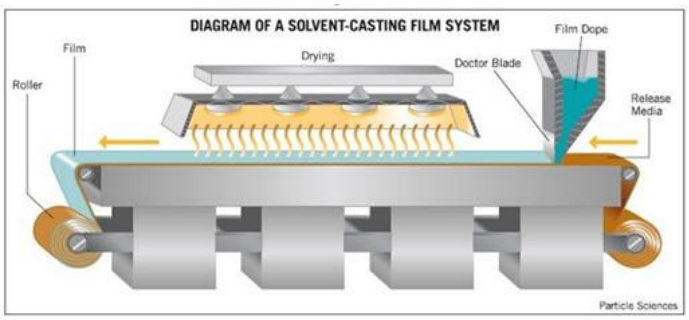

Fig.2: Solvent casting film method

MATERIALS AND METHODS

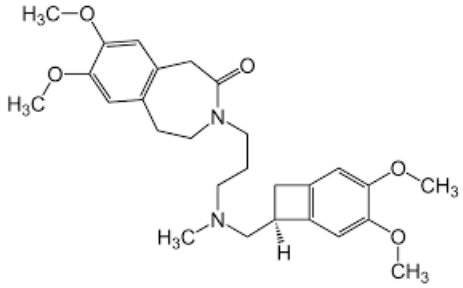

Fig.3: Ivabradine

Drug name : Ivabradine
Category : Bradycardia-Causing Agents
Synonyms : Ivabradina, Ivabradine, Ivabradinum

Ivabradine is a novel heart rate lowering medicine for the symptomatic management of stable angina pectoralis and symptomatic chronic heart failure. Ivabradine, brand name Corlanor, was approved by the FDA in April 2015 for the treatment of chronic heart failure in patients with an ejection fraction of ≤35%, in sinus rhythm with resting heart rate ≥70 beats per minute, who are not on beta-blockers due to contraindications or already receiving maximum beta-blocker dose. Ivabradine acts by selectively inhibiting the "funny" channel pacemaker current (If) in the sinoatrial node in a dose-dependent fashion, resulting in a lower heart rate and thus more blood to flow to the myocardium. Although non-dihydropyridine calcium channel blockers and beta blockers also effectively lower heart rate, they exhibit adverse events due to their negative ionotropic effects. Therefore, as ivabradine is designed as a "pure" heart rate-lowering drug by selectively acting on the If channels, it may offer a more favorable side effect profile due to its lower likelihood of causing serious adverse effects [5-9].

Table.1: List of materials

S.NO	Material Name
01	Ivabradine
02	HPMC E15
03	HPMC E5
04	PVP K90
05	Propylene Glycol
06	Citric Acid
07	Aspartame

Table 2: List of equipment's

S.No.	Instruments	Manufacturer
1.	Digital weighing balance	Wensar
2.	Digital pH meter	Lab India
3.	Franz diffusion cell	Borosil
4.	Glassware	Borosil, Mumbai, India.
5.	UV-Spectrophotometer	Lab India

Analytical Method Development for Ivabradine

Before preparation of OD films, standard curve of Ivabradine in 6.8 pH saline phosphate buffer, was obtained to quantify the samples. All solutions were freshly prepared before use.

Preparation of saline phosphate buffer pH 6.8

About 1 gm of potassium dihydrogen ortho phosphate, 2 gm of dipotassium hydrogen ortho phosphate and 8.5 gm sodium chloride were added to water in 1 L volumetric flask. The contents are thoroughly mixed to get a clear solution. The volume was made up to 900 ml with water. The pH was adjusted to 6.8 with 0.2M phosphoric acid or sodium hydroxide solution.

Preparation of standard solution of Ivabradine

Accurately weighed 100 mg of Ivabradine was placed in a 100 ml volumetric flask and to this 50 ml of ethanol was added to dissolve the drug. The volume was made up to 100 ml using ethanol to give 1000 mcg/ml solution (stock solution – I). A 10 ml aliquot was taken and placed in a 100 ml volumetric flask and diluted with water to 100 ml to get 100 mcg/ml (stock solution -II). From stock solution -II, a 10 ml of aliquot was diluted to 100 ml to obtain 10 mcg/ml (stock solution-III). Similar dilutions were performed from stock solution -I in different media like 6.8 pH saline phosphate buffer [10-14].

Determination of absorption maxima (λmax) for Ivabradine

A 10mcg/ml standard solution of Ivabradine was scanned on a double beam spectrophotometer against respective media blanks. An absorption maximum (λmax) of 260nm was obtained for all solutions and was selected to prepare standard curve.

Preparation of standard curve for Ivabradine

Standard curves for FXH were obtained in water, 6.8 pH saline phosphate buffer. Aliquots of 0.5,1,1.5,2,2.5 and 3 ml of Ivabradine standard solution of 100 mcg/ml (stock solution-II) was taken and diluted to obtain concentrations from 2 to 12 mcg/ml with appropriate media. The absorbance of solutions were determined at 260 nm against respective media as blank. The experiment was repeated six times for each buffer and a calibration curve was determined from the mean value[15].

Selection of drug and other ingredients:

Ivabradine was selected as model drug based on its physico-chemical and biological properties and also based on its suitability.

- HPMC E 5 (mg), HPMC E 15 (mg) and PVP K90 were selected as polymers.
- Propylene glycol was selected as permeation enhancer and plasticizer.

Dose Calculation

OD films are generally of stamp size but the range acceptable is around 5-20 sqcm. Each patch with 4 cm2 was chosen as optimum size based up on dose, ease of handling and administration. Calculation of total amount of drug required per petri plate is given below.

Dose of Ivabradine per each film : 4mg

Area of the film designed : 4 cm2
Area of the petri plate : 31.4 cm2
Amount of polymer solution per plate : 15 ml The amount of drug required for total plate is around: 31.4 mg.
Hence per each plate approximately 8 films of 4 cm2 were obtained

Formulation:

Development of Oral thin films: Oral thin films were prepared by solvent casting method.

Solvent casting method: HPMC E5 and HPMC E15 were weighed in required ratios and they were then dissolved in water (Cold water) as solvent. Ivabradine(31.4mg), Propylene glycol was added to the above dispersion under continuous stirring. The uniform dispersion was poured in the petri plate. The rate of evaporation of solvent was controlled by inverting cut funnel over the thin films. After 24h, the dried thin film were taken out and stored in desiccator[16].

RESULTS AND DISCUSSION

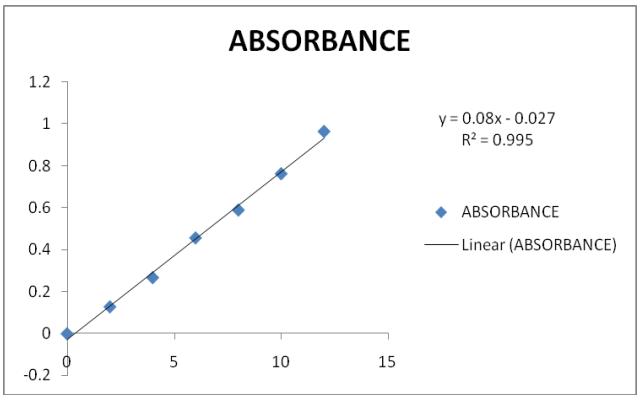

Fig.4: Standard graph of Ivabradine in pH 6.8 Phosphate buffer

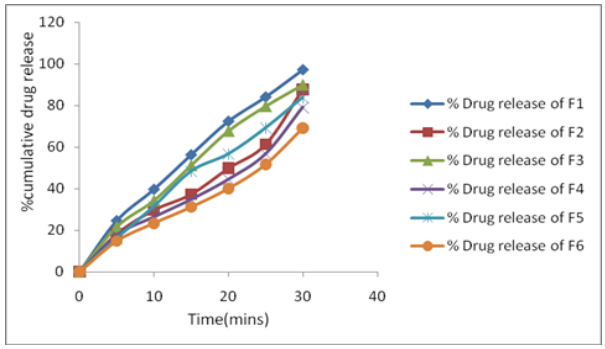

Fig.5: Dissolution graph of all formulations (F1-F6)

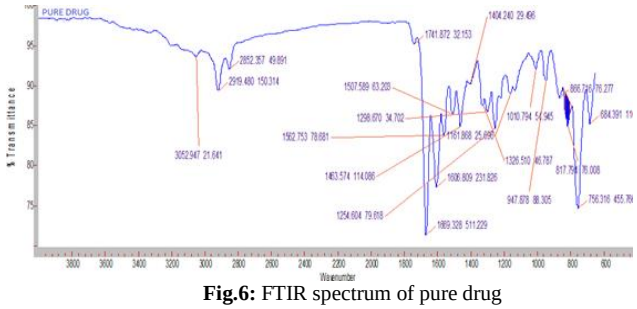

Fig.6: FTIR spectrum of pure drug

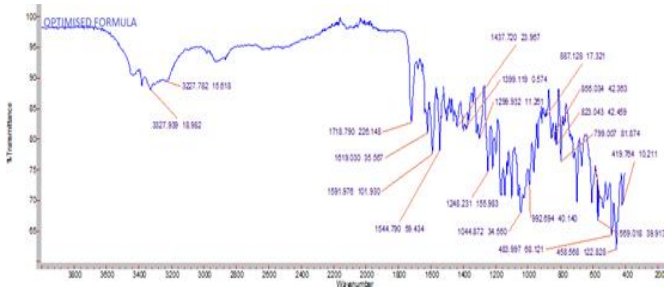

Fig.7: FTIR spectrum of optimized formulation

Table 3: Evaluation of Oral thin films by physical methods

Formulation	Thickness (mm)	Folding endurance	Drug content (%)	Moisture uptake (%)	Moisture content (%)	Weight variation
F1	0.3569	20	45	7.98	3.77	27.46
F2	0.3520	25	65	25.05	9.2	32.57
F3	0.3470	27	57.5	13.09	5.16	29.21
F4	0.3496	24	60	15.63	5.66	33.65
F5	0.3460	30	67.5	11.73	4.87	28.39
F1	0.3517	32	92.5	19.65	12.67	35.53

Table 4: In-Vitro Drug Release

Time (Min)	F1	F2	F3	F4	F5	F6
5	24.6	18.2	21.7	17.7	16.2	14.8
10	39.7	29.7	34.3	26.4	31.6	23.4
15	56.3	37.3	51.2	34.8	48.4	31.2
20	72.4	49.8	67.7	44.5	56.7	40.1
25	84.1	61.3	79.6	56.7	69.2	51.7
30	97.2	87.8	89.9	79.2	83.9	69.2

CONCLUSION

In present study oral thin films of Ivabradine were developed to have a faster on set of action. The oral thin films were developed by using polymers HPMC E5, HPMC E 15 and PVP K90. Oral thin films were prepared by employing solvent casting method. Propylene glycol was selected as permeation enhancer and plasticizer. Drug excipient compatibility studies were carried out by using FTIR, and it was observed that there were no interactions. Formulations were prepared with the varying concentrations polymers ranging from F1-F6, and all the formulations were evaluated for various physical parameters Physical appearance, Weight variation, Thickness, Folding endurance, Tensile strength, Drug content, Moisture uptake, Moisture content and all the results were found to be were found to be with in the pharmacopeial limits, invitro drug release studies by using dialysis membrane. Among all the 6

formulations F1 formulation which contain HPMC E15 300mg and shown 97.2.% cumulative drug release within 30 min. And compared to HPMC E15, HPMC E5 and PVP K90, HPMC E 15 showed better drug release profile.

CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL: Not applicable

FUNDING: This study received no specific funding from public, commercial, or not for profit funding agencies.

AI TOOL DECLARATION

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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