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FORMULATION AND EVALUATION OF FAST DISSOLVING ORAL FILMS OF METOPROLOL TARTRATE FOR HYPERTENSION

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ABSTRACT

Fast-dissolving technology is rapidly evolving so as to facilitate quick onset of action, improve patient compliance, and therapeutic performance of wide variety of drugs. Designed to dissolve within seconds upon contact with saliva, oral fast dissolving films (OFDFs) enable enhanced bioavailability as the drug bypasses hepatic metabolism. These thin films are formulated by employing hydrophilic film-forming polymers viz., hydroxypropyl methylcellulose, polyvinyl alcohol, pullulan etc. Low-dose potent molecules such as antiemetics (ondansetron), analgesics (ketoprofen, diclofenac), antihistamines (loratadine), cardiovascular agents (metoprolol, amlodipine have been developed as OFDFs. The technology is particularly advantageous for geriatric, dysphagic, and psychiatric populations who face challenges when treated with conventional oral dosage forms. Recent advancements in solvent casting, hot-melt extrusion, and nanotechnology-based approaches have further enhanced drug loading capacity, stability, and taste masking. Films are characterised for weight variation, disintegration time, in-vitro dissolution studies, uniformity of drug content, surface pH, folding endurance. Hence this technology is positioned significantly in modern pharmaceutical formulation science. The aim of the study is to formulate and evaluate fast dissolving films of Metoprolol tartrate by solvent casting technique using Pectin, Sodium CMC and Chitosan as polymers. M1-M9 preliminary formulations are prepared by solvent casting method and evaluated for physico-chemical parameters. In-vitro drug release studies are conducted using dissolution type II USP apparatus using pH 6.8 phosphate buffer as dissolution medium. Rapid disintegration time was observed in M7 shows 55 sec and 98.76 % of drug was released within 8min.

KEYWORDS: Fast dissolving oral films, metoprolol tartrate, manufacturing and evaluation parameters, advantages and disadvantages.

1. INTRODUCTION

Fast dissolving formulations offer a new approach to facilitate quick onset of action for critical situations like gastrointestinal disturbances, hypertension, cardiac events, seizures, allergies and many others. In such cases, oral formulations like tablets and capsules are not patient compliant and do not provide rapid relief. Fast dissolving oral films provide an alternate pathway for local and systemic effects bypassing hepatic metabolism. Hence, they reduce dosage and side effects too. Fast dissolving oral films can be formulated for broad categories of drugs.[1]

Metoprolol[1-(isopropylamino)-3-[4-2-methoxyethyl)phenoxy]propan-2-ol] is primarily used as an antihypertensive drug. It is an effective β-adrenoceptor inhibitor recommended for use in essential hypertension and angina pectoris that only works on cardiac cells and has no effect on the beta-2 receptors, this inhibition reduces cardiac output through negative chronotropic and inotropic effects.[2] When taken orally, bioavailability is approximately 50% for the tartrate salt and 40% for the succinate.[1,2] Around 50% of the administered dose is metabolized by the liver (CYP2D63, CYP3A4) during first pass. The present research work intends to develop an oral film for metoprolol tartrate.[3] with an objective to bypass hepatic degradation thereby requiring reduced dosage and side effects.

2. MATERIALS AND METHODS

Metoprolol tartrate was selected as the model drug and was obtained as a gift sample from Dr. Reddy's Laboratories Pvt. Ltd., Hyderabad. Polymers sodium carboxy methyl cellulose, pectin, and chitosan were obtained from Loba Chemie Pvt. Ltd. Hyderabad,

Glycerol from Cargill India Pvt. Ltd., Hyderabad, citric acid, sodium saccharin and sodium starch glycolate obtained from S D Fine-Chem Ltd., Hyderabad, Acetic acid obtained from Oxford Laboratory Chemicals, Maharashtra.

2.1. PREFORMULATION STUDIES[4,5]

Analysis of metoprolol

Absorbance maxima of the drug was determined by scanning a 10µg/ml solution in phosphate buffer pH 6.8 in a wavelength range of 200-400nm using double beam UV spectrophotometer. Standard graph was prepared to obtain the linear equation y=mx+c.

Characterization of the drug

FTIR Studies

IR spectra for Metoprolol Tartrate was obtained, Sample was prepared using pellet method employing a shimadzu FTIR-8400S spectrophotometer.

Melting point

Melting point of metoprolol tartrate is determined by the capillary tube method.

2.2. Preparation of drug loaded fast dissolving films[6]

Nine films were formulated by solvent casting method The composition of each 2x2 film is shown in table no.1. Each film contained 10mg of the drug. All the ingredients were weighed accurately. The water-soluble polymers (Pectin, Sodium CMC, Chitosan) were first dissolved in little amount of solvent while stirring. Metoprolol tartrate and other excipients (glycerol, SLS, Citric Acid, Sodium Saccharin, Sodium starch glycolate and Acetic acid) were dissolved in water and mixed and added to polymer solution. The final mixture was kept aside for for 1 hour and then casted onto a petri dish and allowed to dry at room temperature 27ºC±5° for 24 hrs. The dried film was carefully packed and stored in a cool dry place.

3. EVALUATION OF FILMS[7.8.9.10]

All the prepared films were evaluated for the following parameters.

Weight variation: Individual films were weighed, Weight variation was calculated.

Film thickness: Thickness of film was measured at selected points using vernier calipers and the average of different readings were noted.

Folding Endurance: Folding endurance of films was measured by folding until it breaks. The number of times the film can fold without breaking is an indicator of its flexibility.

Tackiness: Film tackiness was checked by pressing film against the fingertips and noted as tacky and non-tacky.

Content uniformity: It was determined by dissolving 2×2 cm film in pH 6.8 phosphate buffer and the volume made up to 100ml with continuous stirring to achieve homogenous dispersion. The dispersion was filtered using grade 1 Whatman filter paper. The absorbance of the solution was measured at absorbance maxima and the drug content was calculated using linear equation obtained from the standard graph.

Disintegration time: Petri plate was filled with 25ml of pH 6.8 phosphate buffer. Film was carefully placed in the centre of petri plate. Time for film to disintegrate into fine particles was noted.

***In-vitro* dissolution studies:** Dissolution studies for films was carried out in USP paddle type II apparatus, 500ml of pH 6.8 phosphate buffer was employed as a medium and maintained at 37±0.5ºC. The medium was stirred at 50 rpm. 5ml Aliquots of the dissolution medium was withdrawn at regular intervals of 0,5, 1, 2, 4, 6, 8 and 10mins, each time replacimg with an equal amount of fresh medium. Samples are analysed using UV-spectrophotometer at absorbance maxima of metoprolol.

4. RESULTS AND DISCUSSION

Analysis of the drug was done by UV spectrophotometery. Studies determined absorbance maxima to be 222nm and the standard graph developed using serial dilutions of 5, 10, 15, 20 and 25µg/ml, yielded the linear equation y=mx+c to be $y = 0.0311x + 0.0215$, $R^2 = 0.9991$.

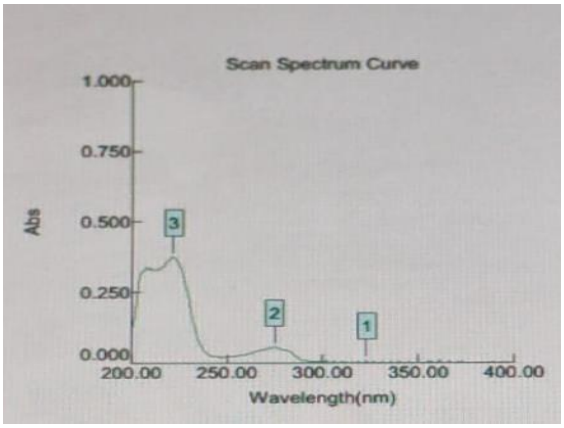


Fig. no. 1: λ max of Metoprolol tartrate in pH 6.8 phosphate buffer.

Melting point

The determination of melting point is done by using capillary tube method to know purity of the drug sample. The MP of the drug sample is observed as 120ºC, which is close to the reported value and it confirming the purity of the drug.

Evaluation data of metoprolol tartrate films

All the formulated Metoprolol tartrate oral films exhibited acceptable weight variation, with values ranging from 0.9± 0.029 mg to 1.66±0.038 mg, indicating uniformity across the batches. The apperance

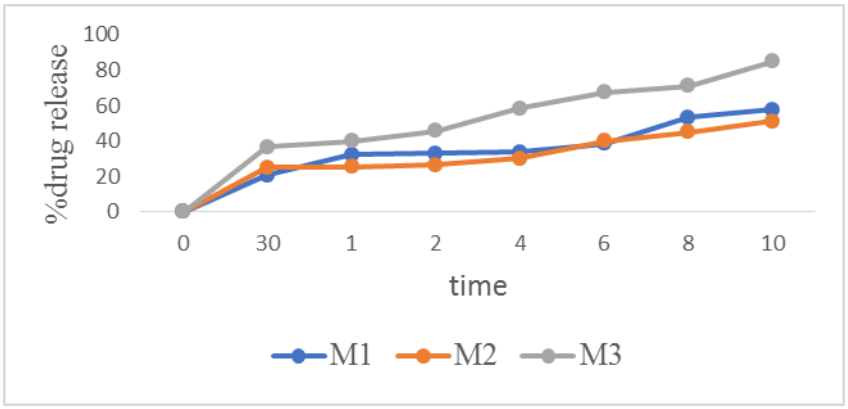
of all formulations was consistently transparent, reflecting good film clarity and uniform polymer distribution. The tack test results showed every formulation was non-tacky, suggesting smooth handling, easy packaging and non-sticky during administration. The pH values of the films ranged between 5.6 and 6.7, which falls within the acceptable range for oral films and is compatible with the oral mucosa, minimizing the risk of irritation. The thickness of the films ranged between 0.4-0.5mm indicating uniform and consistent film formulation and M4-M9 films tolarated 100 folds where as M1,M2 and M3 films were brittle and they can not tolarate on an average of so many number of folds.

Table no. 2: Evaluation Data of Metoprolol Tartrate oral Films.

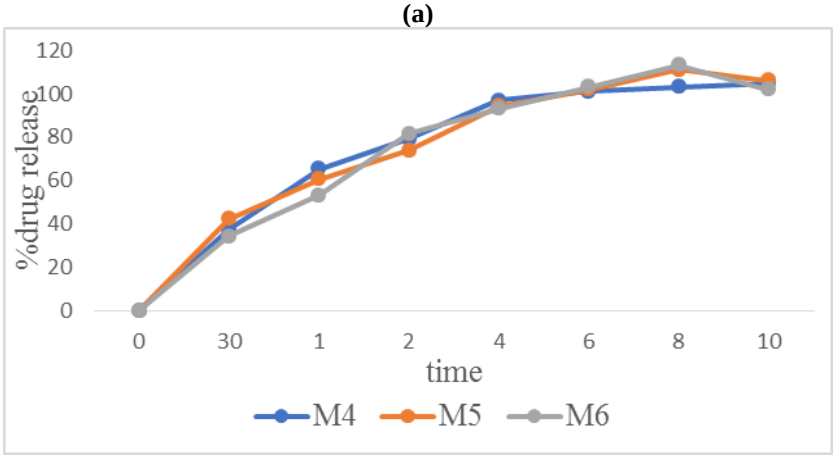
Sr. no	Formulation Code	Folding Endurance	Disintegration time [sec] Mean ± SD	Drug content [%] Mean ± SD
01	M1	14	42±4	85.14±2051
02	M2	20	50±5	87.02±1.89
03	M3	40	60±6	87.56±0.71
04	M4	Flexible	48±5	96.46±1.91
05	M5	Flexible	55±5	96.73±1.22
06	M6	Flexible	62±6	97.89±1.10
07	M7	Flexible	55±5	99.52±5.24
08	M8	Flexible	62±6	95.42±1.48
09	M9	Flexible	70±7	96.76±0.68

% *In-vitro* Cumulative drug release of M1-M9 formulations

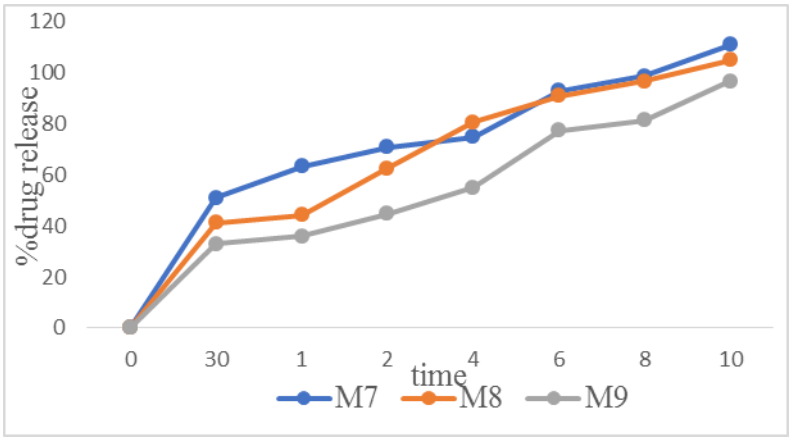
The in-vitro dissolution study of Metoprolol tartrate oral films (M1–M9) showed a rapid and progressive drug release within the first few minutes. All formulations released more than 50% of the drug within 2–3 minutes, indicating fast-dissolving characteristics suitable for oral films. Among the all batches, M4, M5, M6, and M7 exhibited comparatively higher dissolution rates, achieving over 100% release by 10 minutes, while other formulations showed slightly lower but still efficient release profiles. Overall, the results confirm that the developed films provide quick drug release, supporting fast onset of action.



(a)



(b)



(c)

Fig. no. 2: % *In-vitro* Cumulative drug release of formulation M1-M9.

FTIR

The FTIR study was conducted to evaluate the interaction between the drug and excipients. FTIR was performed for both drug as well as the optimized formulation. Table 1 indicates the peaks of the drug and formulation.

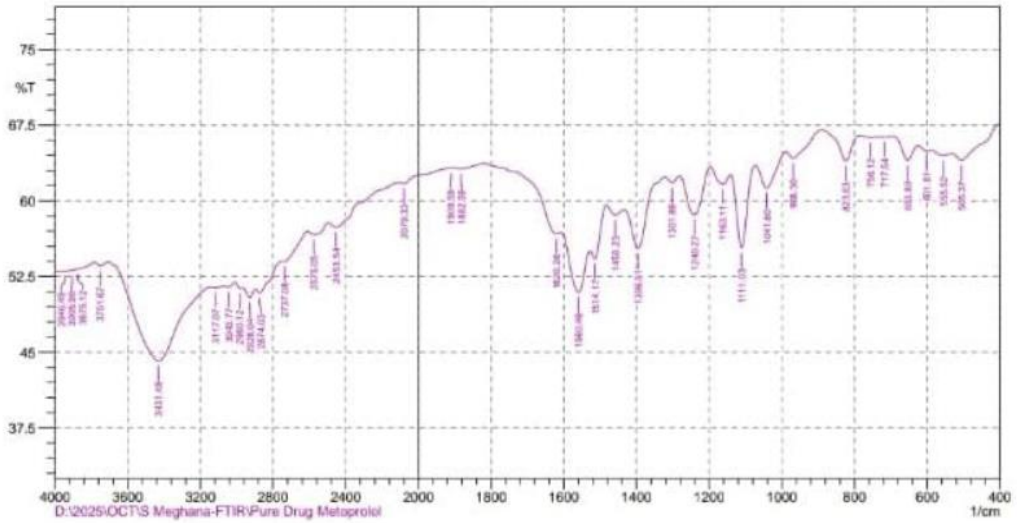


Fig no. 3: IR spectrum of Metoprolol Tartrate.

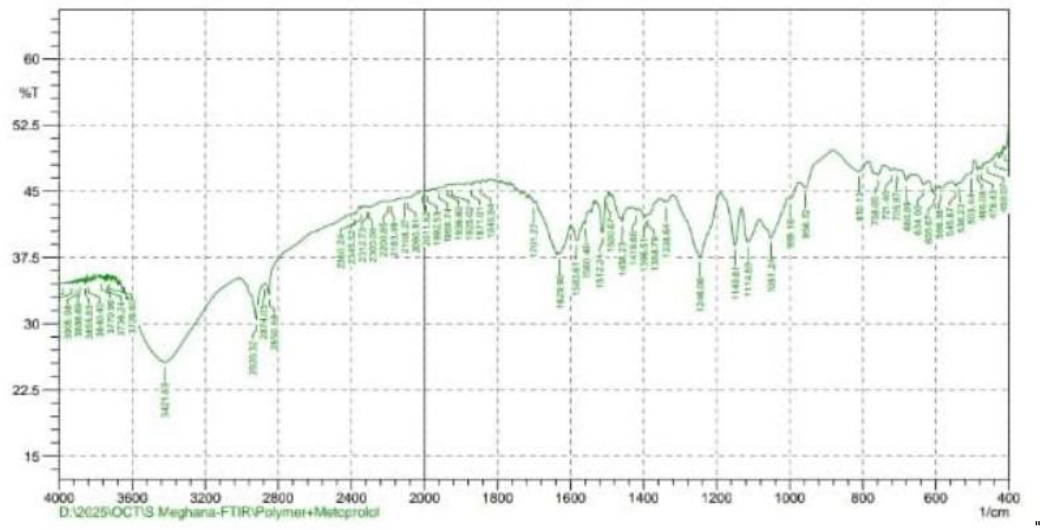


Fig. 4: IR spectrum of Metoprolol Tartrate of M7 film [formulated using chitosan].

Table no. 1: FTIR studies of optimized formulation M7.

Sr. no	Functional group	Observed functional group peak in drug	Observed functional group peak in film
01	O-H	3365	3402
02	C-H	2925	2924
03	C=C	1608	1606
04	N-H	1515	1540
05	C-0-C	1110	1112

CONCLUSION

Metoprolol tartrate films were formulated using different polymers such as Pectin, Sodium CMC, Chitosan in various concentrations. Formulated oral films was evaluated to various evaluation tests, weight variation, thickness, tackiness, folding endurance, pH, drug content and in-vitro dissolution studies. FTIR studies indicated drug and excipients are compatible with each other. From the evaluation parameters. Metoprolol tartrate films of formulation M7 shows 55 sec (disintegration time) and 98.76 % of drug was released within 8min. Results demonstrated that existing studies demonstrated the dissolution studies of tablets for 15min is 99% were as for films the dissolution studies showed 100% of drug release within 6 min, so comparision between tablet and films, films can be considered as better formulations. Further studies are required to demonstrate the usefulness and applicability of the formulation in practice. The studies needs to demonstrate better bioavailability, film stability along with exploring advanced polymers and novel technologies, also opportunity for reducing the dosage this will minimize the toxicity and improves patient compliances. Clinical studies and scale-up research can help establish these films as an effective alternative to conventional tablets for hypertension management.

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