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Research Article

Design And Characterization of Buccoadhesive Drug Delivery System

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ABSTRACT

The study demonstrated the feasibility of using a buccal patch system for sustained Metoprolol Succinate release, with F5 being the most optimized patch. The polymer ratio plays a crucial role in determining release characteristics and mechanical performance. The optimal combination of HPMC K4M and ethyl cellulose offers improved patient compliance and sustained therapeutic effect. The release of Metoprolol Succinate from patches over 10 hours is influenced by polymer composition, with formulations with higher ethyl cellulose content showing slower drug release, while higher HPMC K4M content shows faster release.

INTRODUCTION

Bio adhesive drug delivery formulations were introduced in1947 when gum tragacanth was mixed with dental adhesive powder to apply penicillin to the oral mucosa. In recent years delivery of therapeutic agents via Mucoadhesive drug delivery system has become highly interesting. Certain drugs have lack of efficacy due to decreased bioavailability, GI intolerance, unpredictable and erratic absorption or pre-systemic elimination of other potential route for administration. The recent development in the drug delivery has intensified the investigation of mucosal drug delivery. Such route includes oral, buccal, ocular, nasal and pulmonary routes etc. Mucoadhesive drug delivery systems are delivery systems, which utilized the property of bioadhesion of certain polymers, which become adhesive on hydration and hence can be used for targeting a drug to particular region of the body for extended period of time. The ability to maintain a delivery system at a particular location for an extended period of time has great appeal for both local as well as systemic drug bioavailability. Pharmaceutical aspects of mucoadhesion have been the subject of great interest during recent years because it provides the possibility of avoiding either destruction by gastrointestinal contents or hepatic first-pass inactivation of drug.

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Traditional oral and parenteral methods face challenges like low bioavailability and gastrointestinal degradation, leading to higher doses and side effects. Buccal drug delivery bypasses these issues by directly absorption into the systemic circulation through the buccal mucosa. The buccal mucosa is easily accessible, making dose forms simple to administer. This is one of the benefits of the buccal drug delivery system. Administered and even taken out of the application location.

Buccal drug delivery system ideal characteristics

Mucoadhesiveness: To guarantee that the drug stays in contact with the absorption site for an extended amount of time, the system should stick to the buccal mucosa properly. This aids in keeping the drug's release steady and under control.

Controlled Drug Release: It should be able to regulate the drug's release rate, guaranteeing a consistent and reliable delivery profile. This aids in preserving the ideal medication concentrations in the bloodstream.

Enhancement of Permeability: To guarantee effective absorption, the system should increase the drug's permeability through the buccal mucosa. Permeation enhancers, which momentarily alter the mucosal barrier, can be used to accomplish this.

➢ MATERIALS AND METHODS:

Preformulation Studies- A preformulation study is a crucial stage in drug development, evaluating a drug's physicochemical properties before formulating it into a dosage form. It provides insights into the drug's intrinsic characteristics, aiding in designing a safe, effective, and stable formulation. Preformulation studies establish a solid foundation for subsequent formulation development, identifying potential challenges and risks, and enabling rational decision-making.

Preparation of standard calibration curve- Metoprolol was dissolved in phosphate buffer 7.4 to create a 1000 µg/ml concentration. It was serially diluted with phosphate buffer 6.8 to 2-14 µg/ml. The absorbance was measured and plotted against concentration to obtain the standard calibration curve.

Drug-excipient compatibility studies-

Drug-excipient compatibility studies are crucial in pharmaceutical industry preformulation and formulation development. They evaluate potential interactions between drugs and excipients, identifying chemical, physical, or mechanical interactions that could affect dosage stability, efficacy, or safety. These studies help formulation scientists make informed decisions about excipient selection, design, and process optimization. I.R. Spectroscopy was used to determine drug compatibility with excipients.

Formulation of Metoprolol Buccal Patch The mucoadhesive buccal patches of metoprolol were prepared using a solvent casting method. Formulations were prepared using varying ratios of hydroxypropyl methylcellulose and ethyl cellulose, with PEG 400 as a plasticizer. The solvent mixture was mixed with chloroform and methanol to dissolve the drug and polymers. The drug was dissolved in methanol, and the plasticizer PEG 400 was added to the mixture. Patches were cast in a petri dish and dried for 24 hours.

Table 01: Composition of Metoprolol Buccal Patch

Sr. No.	Batches	F1	F2	F3	F4	F5	F6
1.	Metoprolol succinate (mg)	177	177	177	177	177	177
2.	HMPCK4M (mg)	400	500	600	700	800	900
3.	Ethyl cellulose (mg)	600	500	400	300	200	100
4.	PEG 400 (mg)	50	50	50	50	50	50
5.	Peppermint oil	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
6.	Chloroform: Methanol (1:1)	20	20	20	20	20	20

Evaluation of Buccal Patches

The evaluation of buccal patches with the help of such parameter i.e. Physical appearance, Thickness, Weight variation, drug content, folding endurance, percentage moisture uptake, percentage moisture loss, mucoadhesion strength, release studies and stability studies.

Stability studies

A stability study evaluates the quality of a drug substance or product over time, considering environmental factors like temperature, humidity, and light. A formulation was chosen based on physiochemical characteristics and in vitro drug release, subjected to accelerated stability studies, and stored for 6 months.

➢ RESULT AND DISCUSSION:

Preformulation Studies

Determination of Melting Point- The capillary method determined the melting point of Metoprolol Succinate, which ranges from 138 to 140°C, confirming the purity of the drug sample.

Solubility

Metoprolol Succinate is soluble in water and methanol, slightly soluble in ethanol, and insoluble in acetone chloroform and ether.

UV-Spectroscopy (Determination of λ max)

A stock solution of Metoprolol Succinate was prepared using phosphate buffer pH 6.8, and the UV Spectrum was scanned using Shimadzu 1601, observing a maximum wave length of 275 nm.

Standard calibration curve

The standard calibration curve of Metoprolol Succinate, prepared from 2 to 14 µg/ml in phosphate buffer solution, was plotted and analyzed at 275 nm. The study examines the infrared spectra of the polymer and pure drug, revealing no chemical interaction or physical bond formation between the two.

Evaluation of buccal patches

Table 2: Evaluation of Metoprolol Succinate Buccal Patches (F1 to F6)

Batch	Thickness (mm) +- SD*	Weight variation (mg) +- SD*	Drug Content %+- SD*	Folding Endurance+- SD*	Surface pH %	% Moisture uptake	% Moisture loss
F1	0.52 +- 0.03	181.14+- 1.20	97+-1.06	97.46+-1.06	6.7	3.16+- 0.61	2.34+- 0.32
F2	0.53+- 0.04	183.19+- 2.14	96.12+- 1.23	96.12+-1.23	6.7	3.86+- 0.65	2.39+- 0.29
F3	0.53+- 0.02	182.21+- 1.23	74.15+- 1.36	74.15+-1.36	6.6	4.45+- 0.80	2.56+- 0.34
F4	0.52+- 0.04	181.23+- 1.61	81.34+- 1.14	81.34+-1.14	6.7	5.12+- 1.13	3.05+- 0.18
F5	0.52+- 0.03	179.42+- 1.38	96.30+- 0.66	96.30+-0.66	6.8	5.74+- 0.62	3.12+- 0.16
F6	0.54+- 0.05	180.15+- 2.17	94.51+- 0.61	94.51+-0.61	6.8	6.21+- 0.66	2.12+- 0.43

The study indicates that increasing HPMC K4M content improves flexibility, moisture absorption, and drug content uniformity, while maintaining acceptable pH and thickness, making F5 and F6 strong candidates for buccal delivery.

Mucoadhesion Strength

The study determined the mucoadhesion strength of Metoprolol Succinate buccal patches using sheep buccal mucosa as a model, finding that higher HPMC concentration increases mucoadhesive strength. Formulation F1 had the lowest strength. Mucoadhesion strength of all batches of buccal patches formulation was found in the range of 4.56±0.53 to 9.20±0.82.

In Vitro Drug Release Study

The study presents the in vitro drug release profiles of metoprolol succinate buccal patches formulated with varying HPMC K4M and ethyl cellulose ratios. The polymer composition significantly influenced drug release rate and extent. Formulation F1 had the slowest release, with only 66.3% released after 10 hours due to ethyl cellulose's hydrophobic nature. Formulation F2 and F3 showed moderate release rates of the drug, with 72.27% and 78.84% released by 10 hours respectively. Formulation F4, which contained 700 mg of HPMC and 300 mg of ethyl cellulose, showed further enhancement, reaching 95.28%. Formulation F5 achieved 98.45% release, while Formulation F6 had an even faster release profile, limiting its utility in extended-release applications. The study found that increasing HPMC K4M concentration in buccal patch formulations improves drug release rate, with F5 showing a desirable release profile for sustained, nearly complete delivery of metoprolol succinate.

Drug Release Kinetics

The Zero Order model, which describes a constant drug release rate, showed the highest R^2 values for most formulations, indicating a nearly constant drug release pattern over time. The First Order model had lower R^2 values, suggesting partial dependence on remaining drug concentration. The Higuchi model, which describes drug release through diffusion through a porous matrix, showed moderate to good fits, indicating a diffusion-controlled process, particularly in F5 and F6, where HPMC concentration is higher.

Overall, the kinetic data unequivocally demonstrate that the drug release moves from diffusion-controlled to relaxation/erosion-controlled mechanisms as the percentage of HPMC K4M rises, more closely following zero-order kinetics. The Korsmeyer–Peppas model is followed by the optimized batch formulation F5, which has an R2 value of 0.985. The value of "n" (0.870), indicating non-fickian transport mechanism, implying that drug release is influenced by polymer relaxation, swelling, and erosion. The Korysmeyer-Peppas model of optimal buccal patch formulation, zero order, first order, and higuchi release mechanism are all represented graphically. F5.

Stability Studied

The optimized formulation F5 was studied for stability, following ICH recommendations. The buccal patches were wrapped in aluminum foil and kept in a stability chamber for three months. The patches showed no color variations or microbial or fungal development. The drug content was measured at 98.78±0.82% after three months, and the in vitro drug release was found to be 98.04±3.34%, indicating no significant difference. The optimized batch F5 remained stable after the stability study, exhibiting minimal performance variation, with a value of 95.54±2.18 after the period.

➢ CONCLUSION

The findings confirm that the polymer ratio plays a pivotal role in determining the release characteristics and mechanical performance of buccal patches. An optimal combination of HPMC K4M and ethyl cellulose provides a promising platform for buccal delivery of Metoprolol Succinate, offering improved patient compliance, avoiding first-pass metabolism, and maintaining steady plasma drug levels for prolonged therapeutic effect. Further studies including in vivo evaluation and long term stability testing would strengthen the application of this buccal patch system for potential clinical use.

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