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Formulation And Evaluation of Propranolol Hydrochloride Buccal Emulgel Using Permeation Enhancer and Naturally Occurring Polymer

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ABSTRACT

Introduction: Propranolol Hydrochloride is a beta-blocker used to treat various cardiovascular conditions. The goal is to enhance the drug's bioavailability and provide a controlled release system suitable for buccal administration. **Objectives:** The main objectives are to develop a stable buccal emulgel formulation using PHCL and gellan gum, and to evaluate this formulation

Methods: PHCL was formulated into various buccal emulgel using gellan gum and different concentrations of oleic acid. The formulations were assessed for organoleptic properties, drug content, pH, viscosity, spreadability, and extrudability. The in vitro drug release was tested, and the optimized formulation was subjected to ex vivo drug release and stability studies**.**

Results: The study investigates the formulation and evaluation of Propranolol HCL emulgel, focusing on drug release and permeability properties. Various formulations (F1-F6) were prepared and tested for in vitro drug release, ex vivo permeability, and stability. The F5 formulation demonstrated superior drug release and permeability, achieving 91.16% drug permeability at 4 hours, compared to 75.48% for the F1 formulation. In vitro release data were analyzed using different kinetic models, with the F5 formulation showing the highest correlation with the Zero-order model, indicating a consistent drug release rate. Stability tests conducted at 40°C and 75% relative humidity confirmed the physical stability of the emulgel.

Conclusion: A buccal emulgel was formulated of PHCL using gellan gum. The optimized F5 formulation showed promising results in terms of drug release and stability, making it a potential candidate for further development and scale-up for buccal delivery of PHCL

Key-words: Propranolol Hydrochloride, buccal emulgel, Gellan gum, drug release, stability, in vitro, ex vivo

INTRODUCTION

Oral drug administration is a common and convenient method for taking medications. However, it presents significant drawbacks, particularly for drugs that undergo extensive hepatic first-pass metabolism or degradation by digestive enzymes. This is especially problematic for drugs like peptides and proteins, which are susceptible to breakdown before reaching systemic circulation.[1]To overcome these limitations, scientists have been investigating alternative drug delivery routes that utilize various mucosal membranes, such as those in the nose, mouth, eyes, rectum, and vagina.[2]Transmucosal drug delivery systems offer several advantages over traditional oral administration. These systems can bypass the liver's first-pass metabolism and avoid gastrointestinal degradation, enhancing drug bioavailability and providing a more

favourable environment for drug absorption.[3] Among the different transmucosal routes, the buccal mucosa—the inner lining of the cheeks—stands out due to its accessibility, large smooth muscle area, and relative immobility.[4]This makes it an attractive site for drug delivery systems that require prolonged contact. Buccal drug delivery systems can deliver a wide range of drugs, including large and unstable proteins, hydrophilic substances like oligonucleotides and polysaccharides, as well as small drug molecules.[5] The oral cavity has been effectively used for both systemic and local drug delivery, and buccal adhesive drug delivery systems, which adhere to the inside of the cheek, represent a promising area for continued research.[6] The purpose of this study is to develop and evaluate a novel buccal drug delivery system using emulgel formulations to enhance the delivery and efficacy of propranolol hydrochloride, a drug commonly used for cardiovascular conditions. The hypothesis is that the emulgel formulation will improve the bioavailability and therapeutic effectiveness of propranolol hydrochloride when administered via the buccal route.

MATERIAL AND METHODS

Materials

Propranolol hcl was obtained from Sai Supreme chemicals, Mumbai. All other compounds were analytical grade and were utilized without further chemical modification.

Methods

Selection of Drug

Propranolol hydrochloride (PHCL) is chosen for this study. It is a nonselective β-adrenergic receptor blocker used to treat hypertension, angina pectoralis, cardiac arrhythmia, and myocardial infarction. However, its effectiveness is limited by substantial hepatic first-pass metabolism, resulting in low oral bioavailability (10-30%). To improve its systemic delivery, alternative dosage forms are required. The buccal route is promising due to the high vascularity and permeability of the buccal mucosa. Additionally, the buccal route is beneficial for drugs that undergo extensive first-pass metabolism or gastrointestinal enzyme degradation.[7]

Characterization of Propranolol Hydrochloride:

Preformulation testing involves examining the physical, chemical, and mechanical properties of the drug alone and with excipients. This step is essential to develop a stable, effective dosage form. The key areas of preformulation study include:
Physical Description: Colour, odour, Appearance, and melting point.
Bulk Characteristics: Flow property, hygroscopicity, crystallinity, and polymorphism.
Solubility Analysis: Evaluating how well the drug dissolves in various solvents.
Stability Analysis: Determining the stability of the drug under different conditions.

Organoleptic Properties

The color of propranolol hydrochloride was observed by taking a small quantity of the drug on butter paper and viewing it in a well-illuminated place.

Compatibility Study

Compatibility studies were conducted to ensure no interaction between the drug and excipients. The study involved mixing propranolol hydrochloride with various excipients under controlled conditions (40°C ± 2°C & 75±5 % RH) and at room temperature. The mixtures were examined for any signs of incompatibility.[8]

Characterization of Polymers

Gellan gum, the chosen polymer, was characterized for its organoleptic properties and melting point. Compatibility studies were conducted to confirm that there was no interaction between the drug and the polymer. The results of these studies were reported in the thesis.[9]

Interaction Study using FTIR

FTIR (Fourier Transform Infrared Spectroscopy) was used to analyse the chemical interaction between the drug and the polymer. The drug and potassium bromide (KBr) were mixed in a 1:1 ratio, triturated, and compressed into pellets. These pellets were scanned in the frequency range of 4000-400 cm^{-1} to identify any interactions based on the absorbance of functional groups.[10]

Preparation of propranolol hydrochloride Emulgel:

Gellan gum was dissolved in water, Oil phase was prepared with tween 80, propranolol hcl drug was dissolved separately in water and introduced in oil phase. Tween 80 was dissolved in water to make the aqueous phase. Methyl paraben and propyl paraben were dissolved separately in peg 200, and added to the aqueous phase. Aqueous and oil phase were heated to 70-80^0 C separately. Oily phase was poured in aqueous phase with constant stirring to form emulsion. Emulgel was prepared adding emulsion and gel in equal ratios and stirring. Oleic were incorporated in Emulgel at polymer dispersion step. And triethanolamine were added to neutralize the formulation six formulations.[11]

Table 1. Formulations of propranolol hydrochloride emulgel with penetration enhancer

Ingredients	Quantity mg/10ml					
	F1	F2	F3	F4	F5	F6
Propranolol hcl	100	100	100	100	100	100
Gellan gum	100	100	100	100	100	100
Tween 80	1.0	1.0	1.0	1.0	1.0	1.0
Peg 200	1.5	1.5	1.5	1.5	1.5	1.5
Saccharin	60	60	60	60	60	60
Triethanolamine	q.s	q.s	q.s	q. s	q. s	q. s
Oleic acid	0.5	0.6	0.7	0.8	0.9	1
Methyl paraben	0.18	0.18	0.18	0.18	0.18	0.18
Propyl paraben	0.02	0.02	0.02	0.02	0.02	0.02
Purified water q.s.	10	10	10	10	10	10

Evaluation of propranolol hcl Emulgel with penetration enhancer

Physical appearance

The prepared propranolol Hydrochloride emulgel with essential oils were inspected for their colour, odour, homogeneity, Consistency, phase separation, texture and grittiness visually.

pH

The pH of 1% aqueous solutions of the produced emulgel was measured using pH metre

Spreading coefficient

The spreading coefficient was calculated using the emulgel' s 'Slip' and 'Drag' features. A ground glass slide was kept on the wooden block, about 2 g emulgel was placed on this slide, second glass slide with hook was placed on it. Air was evacuated and time taken (in seconds) by top slide to travel a 5 cm distance was recorded. The higher the coefficient of spreading, the shorter the interval. A formula is used to determine spreadability- Spreadability = $\frac{Weight \times Distance}{Time}$.[12]

Rheological Studies

Viscosity of Propranolol HCL emulgel formulations at 25°C. was measured by Brookfield Viscometer with Spindle no. 18.

Drug content

The drug content of Propranolol HCL in emulgel was determined dissolving a known amount of the emulgel formulation (1.0 g) in 100 ml water, diluting appropriately, using UV spectrophotometer at 291 nm.[13]

Extrudability

Extrudability measures force required to extrude material from a tube. The weight in gram required to extrude at least a 0.5 cm ribbon of emulgel in 10 seconds was used to estimate extrudability in this investigation. Extrudability improves as the amount of material extruded increases.>90% extrudability- excellent, >80% extrudability – Good, >70% extrudability- Fair.[14]

In vitro diffusion study

A modified Franz diffusion (FD) cell was used for the in vitro drug release studies. Membrane was soaked in dissolving media for 24 hrs before study. The formulation was put between the donor and receptor compartments of the FD cell on a dialysis membrane. The dissolving media was phosphate buffer pH 7.4. A circulating water jacket kept the cell temperature at 37˚c. The solution was continuously stirred using a magnetic bead while the entire assembly was kept on a magnetic stirrer. As a control, a similar blank set was run at the same time. At appropriate intervals, the sample (2 ml) was taken and replaced with equal volumes of the fresh dissolving medium. The cumulative percent drug release was estimated using spectrophotometric analysis at 291 nm on the samples. In each case, the difference between the drug release and control readings was taken as the actual reading.

Ex vivo permeability study

Ear Of Pig Ex vivo permeation study was performed using ear of pig on six station digital Franz diffusion cell apparatus (Dolphin, Mumbai). The ear of pig was collected from local slaughter house. The ear of pig was cleaned and its hairs were removed. The shaved ear was placed between donor and receptor compartment of Franz diffusion cell. Then 1g emulgel of optimized formulation, f 5 was applied on donor side of Franz Diffusion Cell. The temperature of the cell was maintained constant 37±2°C by circulating water jacket. The whole assembly was kept on magnetic stirring and diffusion fluid (Phosphate Buffer pH 7.4) solution was continuously stirred using magnetic beads at 200rpm. 2ml of sample was

withdrawn and same volume was replaced with fresh diffusion fluid (Phosphate buffer pH 7.4) to maintain sink condition. Samples were withdrawn at 30, 60, 90,120,150, 180-, 210-, and 240-min. Samples were analysed at 291 nm and amount of drug permeated was determined.[15]

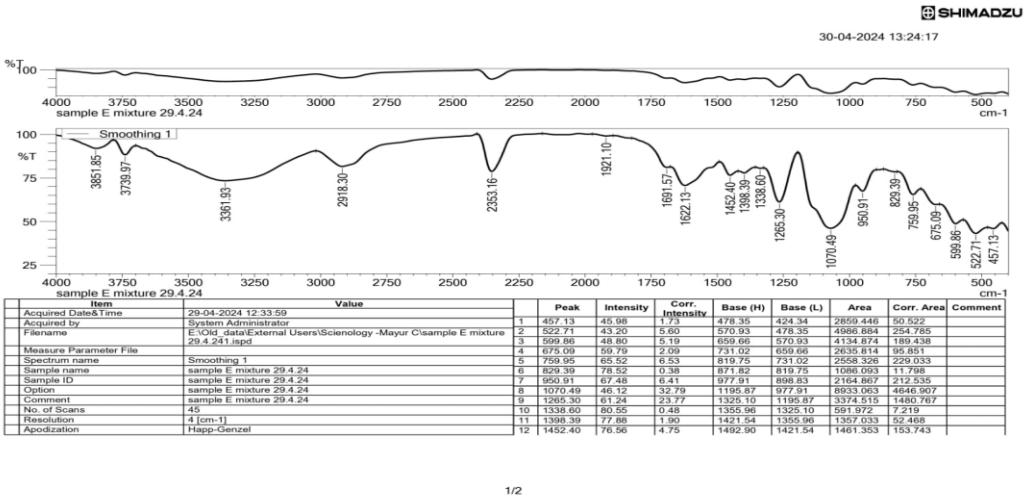
Stability Studies

The formulation batch F5 was wrapped in aluminium foil and subjected to 40 ±0.50C temperature in stability chamber for the period of one month. Organoleptic properties of the formulation were investigated. Physical appearance, pH, rheological characteristics, drug content, and drug release were all assessed.[16]

RESULTS AND DISCUSSION

Drug-Excipients Compatibility Studies Infrared Spectroscopy

Drug-excipients interaction study shown no interaction between Propranolol HCL and selected excipients as there was no significant shift of peaks in IR spectrum. Thus, the Propranolol HCL was found to be compatible with the selected excipients.



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Comment	sample E mixture 29.4.24
No. of Scans	45
Resolution	4 [cm-1]
Apodization	Happ-Genzel

	Peak	Intensity	Corr. Intensity	Base (H)	Base (L)	Area	Corr. Area	Comment
1	457.13	45.98	1.73	478.35	424.34	2859.446	50.522	
2	522.71	43.20	5.60	570.93	478.35	4986.884	254.785	
3	599.86	48.80	5.19	659.66	570.93	4134.874	189.438	
4	675.09	59.79	2.09	731.02	659.66	2635.814	95.851	
5	759.95	65.52	6.53	819.75	731.02	2558.326	229.033	
6	829.39	78.52	0.38	871.82	819.75	1086.093	11.798	
7	950.91	67.48	6.41	977.91	898.83	2164.867	212.535	
8	1070.49	46.12	32.79	1195.87	977.91	8933.063	4646.907	
9	1265.30	61.24	23.77	1325.10	1195.87	3374.515	1480.767	
10	1338.60	80.55	0.48	1355.96	1325.10	591.972	7.219	
11	1398.39	77.88	1.90	1421.54	1355.96	1357.033	52.468	
12	1452.40	76.56	4.75	1492.90	1421.54	1461.353	153.743	

1/2

Fig 1: FT- IR Spectrum of Propranolol HCL+ all excipients

Table 2: FTIR data of Propranolol HCL + all excipients

Standard Wavelength	Observed Wavelength (nm)	Functional group
Hydroxy –OH	3361.93	3200-3600
Aromatic C=C	1452.40	1450-1600
C-N	1265.30	1180-1360
C-O	1070.29	1050-1300
Aromatic C-H	759.95	675-900

Evaluation of propranolol hcl Emulgel with penetration enhancer

Physical appearance

Table 3 shows the physical appearance of all batches, including colour, homogeneity, consistency, phase separation. All emulgel trials were found to be white, with a characteristic odour and acceptable homogeneity, consistency, and texture. There was no grit and no phase separation in any of the formulations.

Table 3: Physical appearance of different emulgel formulations

Formulation	Colour	Homogeneity	Consistency	Phase Separation
F1	White	Excellent	Excellent	None
F2	White	Excellent	Excellent	None
F3	White	Excellent	Excellent	None
F4	White	Excellent	Excellent	None
F5	White	Excellent	Excellent	None
F6	White	Excellent	Excellent	None

pH

The pH of the emulgel batches was found to be in the range of 5-7, which is equivalent to the pH of the buccal mucosa (table 4)

Table 4: pH of emulgel formulation

F1	F2	F3	F4	F5	F6
6.69	6.76	6.79	6.81	6.76	6.63

Spreading coefficient

Table 5 represents the spreading coefficients of emulgel formulations. It was determined that all of the created formulations had adequate spreadability, with F5 and F2 formulations having more spread ability than the others i.e. 29.2±3.82 and 28.3±3.41 respectively. (Table 5)

Table 5: Spreading coefficient of the formulation F1– F7 (mean ± SD).

F1	F2	F3	F4	F5	F6
23.9±1.15	28.3±2.93	27.1±4.43	26.3±3.41	29.2±5.30	25.6±5.29

Rheological study

Table no.6 represents viscosity of formulations. Formulations F2 and F5 had the highest viscosity. It could be due to a low concentration of essential oils. For all formulations, the viscosity range was 12,500-14000 Cps.

Table 6: Rheological study of emulgel formulation

F1	F2	F3	F4	F5	F6
13400 Cps	13700 Cps	13100 Cps	12700 Cps	13800 Cps	12900 Cps

Drug content

Drug content of all the formulations were carried out as per procedure stated in the methodology section. Drug content of all the formulations was found to be in the range 74.24%-88.90%.

Table 7: Drug content of emulgel Formulation

F1	F2	F3	F4	F5	F6
74.24	74.78	73.78	83.19	88.90	88.36

Extrudability

Table 8 represents emulgel' s ability to extrude from the tube, which is crucial during application and patient acceptance. All of the formulations had outstanding and satisfactory extrudability results.

Table 8: Extrudability of Emulgel batches

F1	F2	F3	F4	F5	F6
96.89%	96.84%	94.7%	95.87%	95.78%	95.83%

In vitro diffusion study

The in-vitro release profiles showed that formulation F5 had the highest cumulative drug release (CDR) over time compared to other formulations (Table 9 and Figure 2). F5 exhibited a zero-order release kinetics and conformed to the Hixson-Crowell model, indicating the significant effect of surface area changes during diffusion

Table 9.The In-vitro study of Propranolol HCL Emulgel by its percent release

TIME	%CDR					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	**0**	**0**
30	7.030	8.444	8.708	11.992	**10.877**	**8.307**
60	13.228	14.919	15.470	20.088	**18.592**	**14.761**
90	20.614	22.666	23.160	28.959	**27.657**	**25.290**
120	28.399	31.504	31.998	38.7	**37.776**	**37.038**
150	37.407	41.132	41.647	48.661	**49.541**	**49.241**
180	48.961	52.808	53.395	59.684	**62.530**	**62.165**
210	61.739	66.117	67.909	71.4	**76.662**	**76.001**
240	76.070	81.231	83.842	87.130	**92.818**	**90.159**

Fig 2. % Drug Release of Propranolol Hcl emulgel

Kinetic assessment of *In vitro* release of drug from prepared Propranolol Hcl

The analyzed release data was fitted into a number of mathematical models, including the Zero order,First order, Hixon-Crowell, Higuchi model and Korsmeyer-Peppas models. The findings were shownin Table no 10.

Table 10.Regression coefficient value of *In vitro* diffusion Studies of Propranolol HCL

Batches	Coefficient of regression R				
	ZeroOrder	FirstOrder	liguchimodel	Hixon- Crowell model	Korsmeyer Peppas
F1	0.9895	0.9598	0.8634	0.972	0.6296
F2	0.9877	0.9441	0.85	0.9441	0.6091
F3	0.9938	0.9535	0.8848	0.9716	0.6604
F4	0.9921	0.9615	0.8742	0.9745	0.6449
F5	0.998	0.9758	0.9152	0.9758	0.9874
F6	0.9928	0.9625	08784	0.9755	0.6508

Ex-Vivo Permeability

The ex-vivo study showed that formulation F5 had a higher drug permeability (91.16% at 240 minutes) compared to F1 (75.48% at 240 minutes), indicating enhanced skin permeation (Table 10 and Figure 3)

Table 11.Ex- vivo permeability study of Propranolol HCL

Time	%CDR	
(Min)	F1	F5
0	0	0
30	6.908108	9.539189
60	12.64054	17.20135
90	20.02703	27.29595
120	27.81081	38.31892
150	36.81892	50.03514
180	48.37297	62.10405
210	61.15135	75.44189
240	75.48243	91.16757

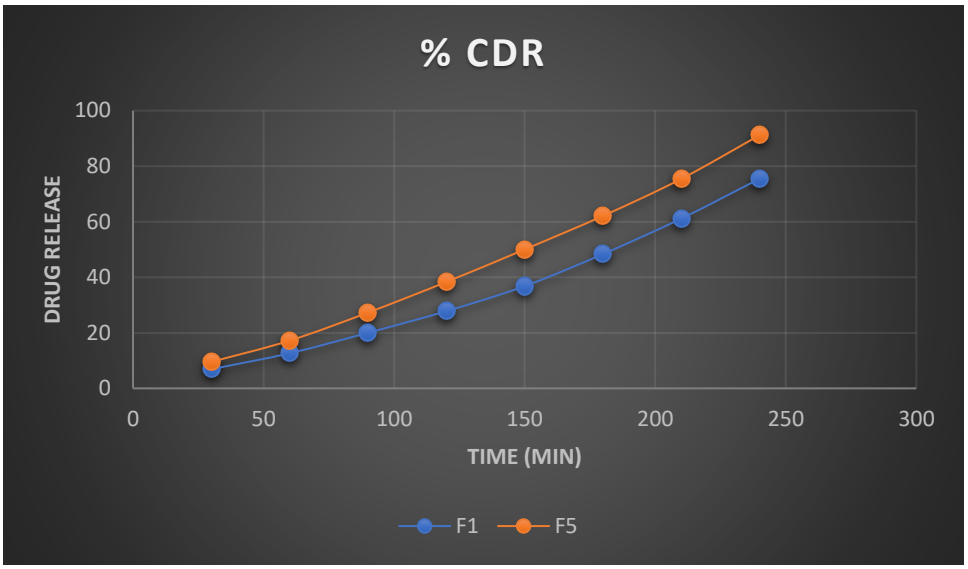

Fig 3.% Drug Release of Ex-Vivo Propranolol Hcl emulgel

Stability Study

The stability test results indicated no significant changes in the physical properties, drug content, pH, and viscosity of formulation F5 after one month of accelerated storage, confirming its stability.

Table 12.Parameters studied on optimized batch formulation before and after stability study

Sr. No.	Parameters	Before stability study	After stability study
1	Colour	white	White
2	Drug content	88.90 %	89.85%
3	pH	6.76	6.78
4	Viscosity	13800	12864

CONCLUSION

The study successfully developed a buccal emulgel formulation of Propranolol Hydrochloride using gellan gum. Among the various formulations tested, batch F5 exhibited the best physicochemical properties and the highest drug release in both in vitro and ex vivo studies. The optimized F5 formulation demonstrated zero-order kinetics and followed the Hixon-Crowell model, indicating a significant influence of surface area changes on drug release. Stability tests revealed that the F5 formulation remained stable under accelerated conditions with minimal changes in physical characteristics, drug content, pH, and viscosity. These findings suggest that the F5 formulation is a promising candidate for further development and scale-up for buccal delivery of Propranolol Hydrochloride.

ABBREVIATIONS

PHCL: Propranolol Hydrochloride **;FTIR:**Fourier Transform Infrared Spectroscopy**; KBr:** Potassium Bromide**; FD:** Franz Diffusion**; PEG :**Polyethylene Glycol**; RH :** Relative Humidity**;UV :**Ultraviolet**; HCL :**Hydrochloride.

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AUTHORS' CONTRIBUTIONS

Whole research work was conducted by Shivani nage.All research work has carried out under the guidance of Dr.A.P.Bhosale and Dr.R. R. Karmarkar. Other co-authors contributed in formulation optimization, manuscript preparation and editing.

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