Journal of Pharmaceutical and Biological Research
ISSN: 2347-8330 | https://doi.org/10.30904/j.jpbr.2026.4986

Study of Effect of Various Polymers in the Formulation Development of Mucoadhesive Buccal Tablets of Propranolol HCL

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Received: 28-02- 2026 | Revised: 19-03- 2026 | Accepted: 30-04- 2026 | Published: 14-05-2026

ABSTRACT
The release rate of Propranolol HCl from buccal tablets was found to be influenced primarily by the type and concentration of polymer used in tablet formulation. The controlled drug release following first-order kinetics demonstrated that hydrophilic matrix tablets prepared with Carbopol 934 and HPMC K100 are effective as buccoadhesive controlled-release delivery systems. Both pre-compression and post-compression evaluation parameters for all formulations were within acceptable limits. The matrix tablets formulated with HPMC K100 (Formulation F5) exhibited slow, controlled, and nearly complete drug release over 11 hours, achieving 93.45% drug release. These findings suggest that the selected polymers successfully regulate the release profile of Propranolol HCl in buccal delivery systems, ensuring sustained therapeutic effects.
Keywords: Propranolol HCl, buccal tablets, controlled release, hydrophilic matrix, Carbopol 934, HPMC K100

Introduction

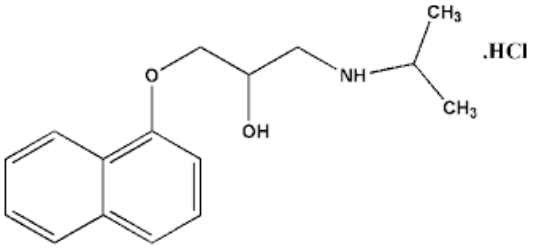

Fig.1: Propranolol Hydrochloride

Molecular Formula: $C_{16}H_{22}ClNO_2$
Molecular Weight: 295.81 g/mol
IUPAC Name: 1-(Isopropylamino)-3-(naphthalen-1-yloxy) propan-2-ol hydrochloride
Chem Spider ID: 4791
Density: Not readily available (solid compound)
Boiling Point: Decomposes before boiling
Melting Point: ~163–164 °C (racemate); ~196–198 °C (R-enantiomer)
Vapour Pressure: Negligible (solid)
Flash Point: Not applicable (non-volatile solid)
Refractive Index: Not applicable
Polar Surface Area: ~41.5 Å²
LogP (Octanol/Water): ~3.48 (for propranolol base)
Generic Name : Propranolol Hydrochloride
Brand Names: Inderal, Inderal LA, Hemangeol, Inno Pran XL
Drug Category: Non-selective β-adrenergic blocker (beta-blocker)
Indications: Hypertension, angina, arrhythmias, migraine prophylaxis, anxiety, tremors
Pharmacology: Blocks β_1 and β_2 receptors; reduces heart rate, cardiac output, and BP
Potency: High affinity for β_1 and β_2 receptors (Ki≈0.8–1.8 nM)
Tolerability: Generally well-tolerated; dose-dependent side effects
Contraindications: bradycardia, heart block, cardiogenic shock
Adverse Effects: Fatigue, dizziness, bradycardia, depression
Availability: Widely available in oral and IV formulations

Methodology

Table 1: List of Materials Used

S.NO.	Materials	Source
1	Propranolol HCL	Sura labs
2	Microcrystalline cellulose	Signet Chemical Corporation, Mumbai
3	Magnesium stearate	Merck Specialities Pvt Ltd, Mumbai
4	Talc	Merck Specialities Pvt Ltd, Mumbai
5	Ethyl cellulose	Merck Specialities Pvt Ltd, Mumbai
6	Carbopol	Merck Specialities Pvt Ltd, Mumbai
7	HPMC K15M	Merck Specialities Pvt Ltd, Mumbai
8	HPMC K100M	Merck Specialities Pvt Ltd, Mumbai

Table 2: List of Equipment's used

S.NO	EQUIPMENT	MODEL/ SOURCE
1	Weighing Balance	Sartourious
2	Tablet Compression Machine (Multistation)	Cemach Limited, India.
3	Hardness tester	Sisco, Mumbai, India.
4	Vernier callipers	Mitutoyo, Japan.
5	Roche Friabilator	Labindia, Mumbai, India
6	Dissolution Apparatus	Labindia, Mumbai, India
7	UV-Visible Spectrophotometer	Labindia, Mumbai, India
8	pH meter	Labindia, Mumbai, India
9	FT-IR Spectrophotometer	Per kin Elmer, United States of America

Preformulation studies: The goals of the preformulation study are: To establish the necessary physicochemical characteristics of a new drug substance. To determine its kinetic release rate

profile. To establish its compatibility with different excipients. Hence, preformulation studies on the obtained sample of drug include colour, taste, solubility analysis, melting point determination and compatibility studies and flow properties.

Estimation of Propranolol HCL:

A) Determination of λmax of Propranolol HCL in phosphate buffer pH 6.8 solution: Weighed amount of Enalapril is dissolved in phosphate buffer pH 6.8 to obtain a 1000 mcg/ml solution. This solution was subjected to scanning between 200-400 nm and absorption maximum was determined. The effect of dilution on absorption maxima was studied by diluting the above solution to10 mcg/ml and scanned from 200-400 nm. From the spectra of drug max of Propranolol HCL216 nm was selected for the analysis. The calibration curve was prepared in the concentration range of 2-12 µg/ml at 216 nm. By using the calibration curve, the concentration of the sample solution can be determined.

Table 2: Angle of Repose values (as per USP)

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

B) Standard calibration curve of Propranolol HCL in phosphate buffer pH 6.8 solution:

Standard Stock Solution: A stock solution containing 1mg/ml of pure drug was prepared by dissolving 100mg of Enalapril in sufficient phosphate buffer pH 6.8 to produce 100 ml solution in a volumetric flask.

Stock solution:

From the standard stock solution, 5 ml of the stock solution was further diluted to 50 ml with phosphate buffer pH 6.8 into a 50 ml volumetric flask and diluted up to the mark with phosphate buffer pH 6.8. Aliquots of 0.2, 0.4, 0.6, 0.8, 1 and 1.2 ml of stock solution were pipette out into 10ml volumetric flasks. The volume was made up to the mark with phosphate buffer pH 6.8. These dilutions give 2, 4, 6, 8, 10 and 12 mcg/ml concentration of Propranolol HCL respectively. The absorbance was measured in the UV-Visible spectrophotometer at 216 nm using distilled water as blank and graph of concentration versus absorbance was plotted. The absorbance data for standard calibration curves are given.

Drug – Excipient compatibility studies

Fourier Transform Infrared (FTIR) spectroscopy:

The physical properties of the physical mixture were compared with those of plain drug. Samples was mixed thoroughly with 100mg potassium bromide IR powder and compacted under vacuum at a pressure of about 12 psi for 3 minutes. The resultant disc was mounted in a suitable holder in Perkin Elmer IR spectrophotometer and the IR spectrum was recorded from 3500 cm to 500 cm. The resultant spectrum was compared for any spectrum changes.

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose:

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$\tan \theta = h / r$

$\tan \theta$ = Angle of repose

h = Height of the cone,

r = Radius of the cone base

Bulk density:

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. 10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read.

The bulk density was calculated using the formula:

$\text{Bulk Density} = M / V_o$

Where, M = weight of sample

V_o = apparent volume of powder

Tapped density:

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:

$\text{Tap} = M / V$

Where, Tap= Tapped Density

M = Weight of sample

V= Tapped volume of powder

Measures of powder compressibility:

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions. In a free-flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value. For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:

Carr's Index = [(tap - b) / tap] × 100
Where, b = Bulk Density
Tap = Tapped Density

Table 4: Carr's index value (as per USP)

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very Very Poor

Results and Discussion

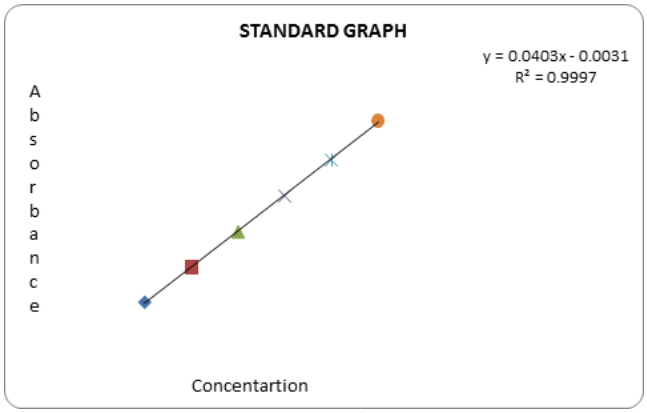

Fig.2: Calibration curve of Propranolol HCL

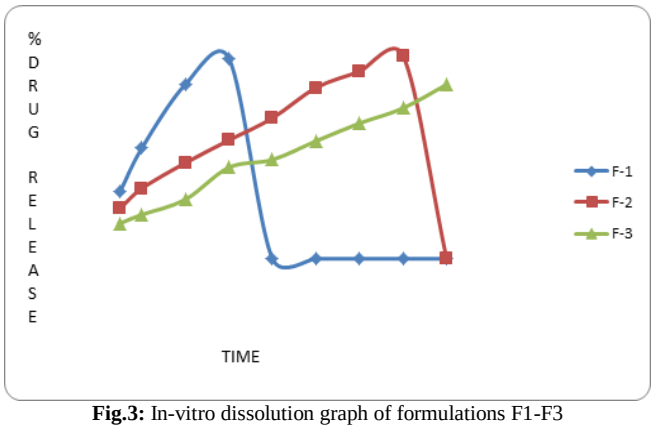

Fig.3: In-vitro dissolution graph of formulations F1-F3

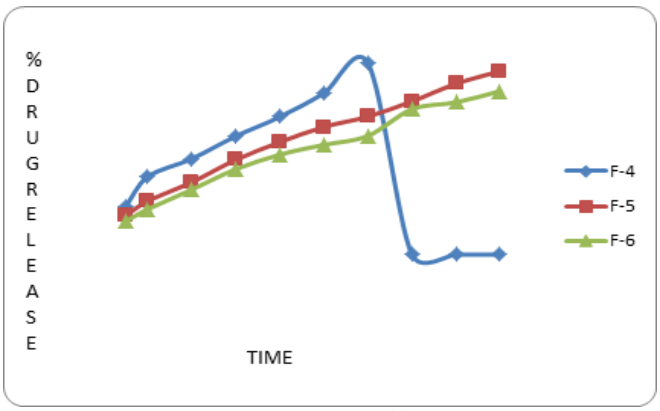

Fig.4: In-vitro dissolution graph of formulations F4-F6

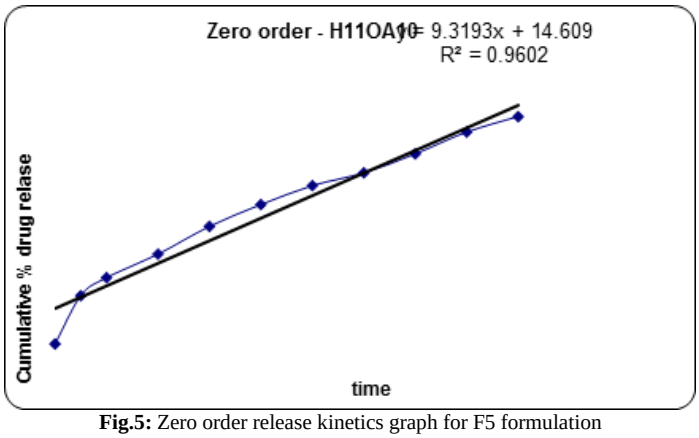

Fig.5: Zero order release kinetics graph for F5 formulation

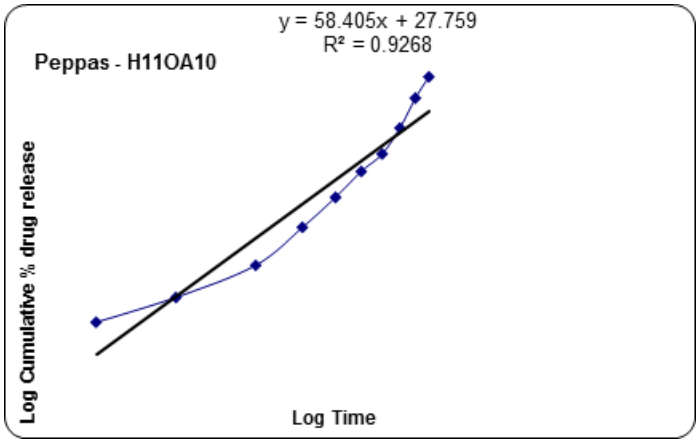

Fig.6: Korsmayer peppas release kinetics graph for F5 formulation

Table 3: Micromeritic properties of powder blend

Formulation Code	Bulk density	Tapped density	Compressibility Index	Hausner's ratio
F1	0.49±0.07	0.57±0.01	16.21±0.06	0.86±0.06
F2	0.56±0.06	0.62±0.05	16.87±0.05	0.98±0.05
F3	0.52±0.03	0.68±0.07	17.11±0.01	0.64±0.03
F4	0.54±0.04	0.64±0.08	17.67±0.08	1.12±0.04
F5	0.53±0.06	0.67±0.03	16.92±0.04	1.2±0.08
F6	0.56±0.05	0.66±0.06	17.65±0.09	1.06±0.09
F7	0.58±0.06	0.69±0.04	16.43±0.05	0.76±0.03
F8	0.48±0.05	0.57±0.02	17.97±0.02	1.15±0.09
F9	0.54±0.08	0.62±0.03	17.54±0.09	1.17±0.02

Table 4: Evaluation Data of Propranolol HCL Buccoadhesive tablets

Formulation code	Hardness (kg/cm)	Thickness (mm)	Weight variation (mg)	Friability (%)	Drug content (%)
F1	4.8±0.02	2.80±0.00	279.6±0.99	0.79±0.01	100.09±0.56
F2	4.3∓0.05	2.83±0.06	278.8±0.99	0.67±0.01	102.73±0.46

F3	4.3±0.05	2.87±0.06	279.8±0.38	0.57±0.01	98.75±0.88
F4	5.7±0.06	2.86±0.06	280.7±0.99	0.55±0.00	99.70±0.34
F5	5.4±0.03	2.87±0.06	279.8±0.38	0.51±0.01	97.95±0.38
F6	5.0±0.02	2.90±0.00	280.1±0.99	0.87±0.03	98.75±0.88
F7	5.6±0.07	2.97±0.06	279.6±0.17	0.46±0.01	103.36±0.83
F8	5.3±0.05	3.01±0.01	281.0±0.40	0.72±0.01	101.09±4.00
F9	5.1±0.02	2.95±0.00	280.0±0.20	0.56±0.02	99.75±0.38

Discussion

- The assayed drug content in various formulations varied between 98.64% and 100.26% (mean 99.68%). The average weight of the tablet was found to be between 281.4 mg and 283.2 mg (mean 280.2 mg), % friability range between 0.46 and 0.76(mean 0.43 %) and thickness of the tablets for all the formulations was found to be between 2.80 mm and 3.00 mm with average of 2.90 mm.
- Buccoadhesive tablets containing Carbopol showed hardness in the range of 5.00 to 5.60 kg/cm 2 and it increased when used in combination with HPMC k100. The hardness of the tablets containing HPMC K15 was much lower, ranging from 4.30 to 4.8 kg/cm2 and increased with increasing amounts of HPMC or Carbopol. The difference in the tablet strengths are reported not to affect the release of the drug from hydrophilic matrices. Drug is released by diffusion through the gel layer and/or erosion of this layer and is therefore independent of the dry state of the tablet.

Conclusion

- From the foregoing investigation it may be conclude that the release rate of drug from the buccal tablets can be governed by the polymer and concentration of the polymer employed in the preparation of tablets.
- Regulated drug release in first order manner attained in the current study indicates that the hydrophilic matrix tablets of Propranolol HCL was prepared using Carbopol 934 and HPMC K100 can successfully be employed as a buccoadhesive controlled released during delivery system.
- The precompression blend foe all formulations were subjected to various evaluation parameters and the results were found to be within limits.
- The post compression parameters for all the formulations also found to be within limits.
- Slow, controlled and complete release of Propranolol HCL over a period of 11 hours was obtained from matrix tablets formulated employing HPMC K 100 (F5 Formualtion) with 93.45 % drug release.

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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