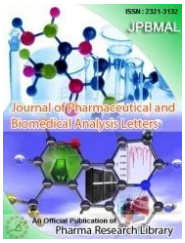

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Preparation and Evaluation of Floating Beads of Propranolol Hydrochloride

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A B S T R A C T

This study focused on developing and characterizing floating microspheres of Propranolol HCl, aiming to enhance gastric retention and sustained drug release. A UV-Visible spectrophotometric method was validated for drug quantification in 0.1N HCl at 256 nm, exhibiting strong linearity over the concentration range of 2 to 10 µg/ml. Compatibility studies using FTIR spectroscopy confirmed no chemical interactions between the drug and polymers, ensuring formulation stability. The prepared microspheres showed high percentage yields between 81.58% and 95.50%, with drug entrapment efficiency improving as polymer concentration increased due to higher solution viscosity reducing drug diffusion during formation. Further evaluations revealed that the microspheres exhibited satisfactory swelling behavior and mucoadhesive properties essential for prolonged gastric residence. In vitro release experiments demonstrated efficient and controlled drug liberation over 12 hours, with release kinetics fitting diffusion-controlled models such as zero-order, first-order, Higuchi, and Korsmeyer-Peppas. Optimized formulations showed promising potential for sustained release and enhanced gastroretention, which could improve therapeutic effectiveness and patient adherence.

Keywords: Propranolol HCl, floating microspheres, UV-Visible spectrophotometry, sustained release, mucoadhesion, drug release kinetics, FTIR compatibility.

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

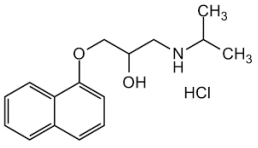

Fig.1: Propranolol Hydrochloride

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,InnoPran 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,β_2 receptors (Ki≈0.8–1.8 nM)
Tolerability: Generally well-tolerated; dose-dependent side effects
Contraindications: Asthma, bradycardia, heart block, cardiogenic shock
Adverse Effects: Fatigue, dizziness, cold extremities, bradycardia, depression
Availability: Widely available in oral and IV formulations

2. Materials and Methods

Table 1: List of Materials and Suppliers

S.NO	Ingredients	Suppliers
1	Propranolol HCL	Supplied by Pharma Train, Hyderabad
2	Ethyl cellulose	SD Fine Chemicals, Mumbai
3	Poly ethylene oxide	SD Fine Chemicals, Mumbai
4	HPMC K15M	SD Fine Chemicals, Mumbai
5	Eudragit RS 100	SD Fine Chemicals, Mumbai

Table 2: List of Equipment's and Companies

S.NO	Name of the equipment	Model
1	Electronic weighing balance	Scale-tec
2	Friabilator	Roche Friabilator Electrolab, Mumbai
3	Laboratory oven	Dtc-00r
4	Compression machine	Cmd (Cadmach)
5	Tablet hardness tester	Pfizer Hardness Tester, Mumbai
6	UV	Labindia Uv 3000+
7	Dissolution apparatus	Electrolab TDT-08L
8	Vernier calipers	Cd-6"Cs

Analytical Method Development in 0.1N Hcl:
Preparation of 0.1N Hcl:
To prepare o.1N Hcl, Pipette out 8.5ml of concentrated Hydrochloric acid in 1000ml volumetric flask and make up to the mark with distilled water.
Determination of λ_{max} of Propranolol HCL in 0.1N Hcl:
Working standard: 100mg of Propranolol HCL was weighed and dissolved in 10ml Methanol and then make up to a volume of 100ml with 0.1N Hcl it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 0.1N Hcl it will give 100µg/ml concentrated solution.
Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 0.1N Hcl it will give 10µg/ml concentrated solution. This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as $\lambda_{max.}$
Standard Calibration curve of Propranolol HCL in phosphate buffer pH 7.4 solution:
Working standard: 100mg of Propranolol HCL was weighed and dissolved in 10ml Methanol and then make up to a volume of 100ml with 0.1N Hcl it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard solution 10ml was diluted to 100ml with 0.1N Hcl it will give 100µg/ml concentrated solution. From the dilution 1, Aliquots of 0.1, 0.2, 0.3, 0.4 and 0.5ml of solution were pipette out in to 10ml volumetric flask. The volume was made up to the mark with phosphate buffer pH7.4. These dilutions gives 2, 4,6,8 and 10µg/ml concentrations of Propranolol HCL respectively. The absorbance was measured in the UV-visible spectrophotometer at 256nm using distilled water as blank and graph of concentration versus absorbance was plotted. The absorbance data for standard calibration curves are given in the results table.
Compatibility Studies
A proper design and formulation of a dosage form requires considerations of the physical, chemical and biological characteristics of both drug and excipients used in fabrication of the product. Compatibility must be established between the active ingredient and other excipients to produce a stable, efficacious, attractive and safe product. If the excipient(s) are new and if no previous literature regarding the use of that particular excipient with an active ingredient is available, then compatibility studies are of paramount importance. Hence, before producing the actual formulation, compatibility of Propranolol HCL with different polymers and other excipients was tested using the Fourier Transform Infrared Spectroscopy (FT-IR) technique.
Fourier Transform Infrared Spectroscopy (FT-IR):
In order to check the integrity (Compatibility) of drug in the formulation, FT-IR spectra of the formulations along with the drug and other excipients were obtained and compared using Shimadzu FT-IR 8400 spectrophotometer. In the present study, Potassium bromide (KBr) pellet method was employed. The samples were thoroughly blended with dry powdered potassium bromide crystals. The mixture was compressed to form a disc. The disc was placed in the spectrophotometer and the spectrum was recorded. The FT-IR spectra of the formulations were compared with the FT-IR spectra of the pure drug and the polymers.
Method of Preparation
Solvent evaporation method:

1. The floating floating microspheres are prepared by solvent evaporation technique.
2. **Organic solvent:** In one beaker the drug and polymer were mixed with DCM and Ethanol in 1:1 ratio.
3. **Aqueous solvent:** In another beaker 500ml of water was taken and add PVA & Tween 80 (used

as surfactant) in the ratio of 1:1 at 1000rpm at 60^0C for 3hours.

4. Take the organic solvent in to the syringe and add drop wise in to aqueous solvent.
5. Then the solvent was completely evaporated and the floating microspheres were filtered and collected.

Fig.2: Photograph of prepared floating microspheres

Characterization of floating microspheres:

Percentage Yield: The percentage of production yield was calculated from the weight of dried microspheres recovered from each batch and the sum of the initial weight of starting materials. The percentage yield was calculated using the following formula:

$$\% \text{ Yield} = \frac{\text{Practical mass (Floating microspheres)}}{\text{Theoretical mass (Polymer + Drug)}} \times 100$$

Drug entrapment efficiency:

Floating microspheres equivalent to 2 mg of the drug Propranolol HCL were taken for evaluation. The amount of drug entrapped was estimated by crushing the floating microspheres. The powder was transferred to a 100 ml volumetric flask and dissolved in 10ml of methanol and the volume was made up using 0.1N Hcl. After 24 hours the solution was filtered through Whatmann filter paper and the absorbance was measured after suitable dilution spectrophotometrically at 256nm. The amount of drug entrapped in the floating microspheres was calculated by the following formula,

$$\% \text{ Drug Entrapment Efficiency} = \frac{\text{Experimental Drug Content}}{\text{Theoretical Drug Content}} \times 100$$

Swelling study:

Swelling ratio of different dried floating microspheres were determined gravimetrically in simulated gastric fluid pH 1.2. The floating microspheres were removed periodically from the solution, blotted to remove excess surface liquid and weighed on balance. Swelling ratio (% w/v) was determined from the following relationship:

$$\text{Swelling ratio} = \frac{(Wt - W0)}{(W0)} \times 100$$

Where W0&Wt are initial weight and Final weight of floating microspheres respectively.

Evaluation of mucoadhesive property:

The mucoadhesive property of floating microspheres was evaluated by an in vitro adhesion testing method known as wash-off method. Freshly excised pieces of goat stomach mucous were mounted on to glass slides with cotton thread. About 20 floating microspheres were spread on to each prepared glass slide and immediately thereafter the slides were hung to USP II tablet disintegration test. At an interval of 1 hour up to 8 hours the machine is stopped and number of floating microspheres still adhering to mucosal surface was counted.

$$\% \text{ Mucoadhesion} = \frac{\text{Number of floating microspheres adhered}}{\text{Number of floating microspheres applied}} \times 100$$

In vitro drug release study:

The dissolution studies were performed in a fully calibrated eight station dissolution test apparatus (37 ± 0.5^0C, 50 rpm) using the USP type – I rotating basket method in 0.1N Hcl (900ml). A quantity of accurately weighed microspheres equivalent to 40mg Propranolol HCL each formulation was employed in all dissolution studies. Aliquots of sample were withdrawn at predetermined intervals of time and analyzed for drug release by measuring the absorbance at 256nm. At the same time the volume withdrawn at each time intervals were replenished immediately with the same volume of fresh pre-warmed 0.1N Hcl maintaining sink conditions throughout the experiment.

In-Vitro Drug Release Kinetics:

The release data obtained was fitted into various mathematical models. The parameters 'n' and time component 'k',the release rate constant and 'R',the regression coefficient were determined by Korsmeyer-Peppas equation to understand the release mechanism. To examine the release mechanism of Propranolol HCL from the floating microspheres, the release data was fitted into Peppa's equation,

$$\mathbf{Mt / M\infty = Kt^n}$$

Where, Mt/M∞ is the fractional release of drug, 't' denotes the release time, 'K' represents a constant incorporating structural and geometrical characteristics of the device, 'n' is the diffusional exponent and characterize the type of release mechanism during the release process.

Table 3

Release exponent (n)	Drug transport mechanism	Rate as a function of time
0.5	Fickian diffusion	$t^{-0.5}$
0.5<n<1.0	Anomalous transport or non-Fickian	t^{n-1}
1.0	Case-II transport	Zero-order release
Higher than 1.0	Super Case-II transport	t^{n-1}

If n<0.5, the polymer relaxation does not affect the molecular transport, hence diffusion is Fickian. If n>0.5, the solid transport will be nonfickian and will be relaxation controlled.

3. Results and Discussion

Construction of Standard calibration curve of Propranolol HCL in 0.1N Hcl: The absorbance of the solution was measured at 256nm, using UV spectrometer with 0.1N Hcl as blank. The values are shown in table no 11. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 10 to 50 µg/ml

Table 4: Standard Calibration graph values of Propranolol HCL in 0.1N Hcl

Concentration(µg/ml)	Absorbance
0	0
2	0.131
4	0.267
6	0.388
8	0.521
10	0.658

Standard plot propranololHCL plotted by taking absorbance on Y–axis, concentration (µg/ml) on X–axis, the plot is shown below figure.

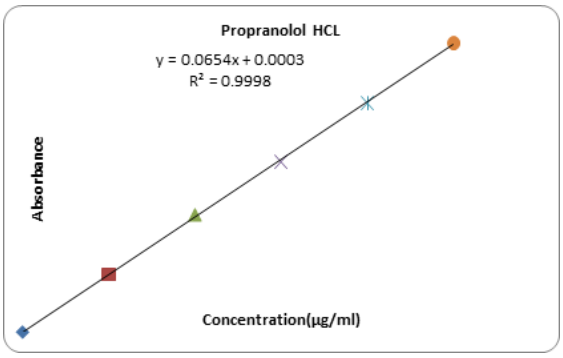

Fig.3: Standard calibration curve of Propranolol HCL in 0.1N Hcl

Inference: The standard calibration curve of Propranolol HCL in 0.1N Hcl showed good correlation with regression value of 0.999

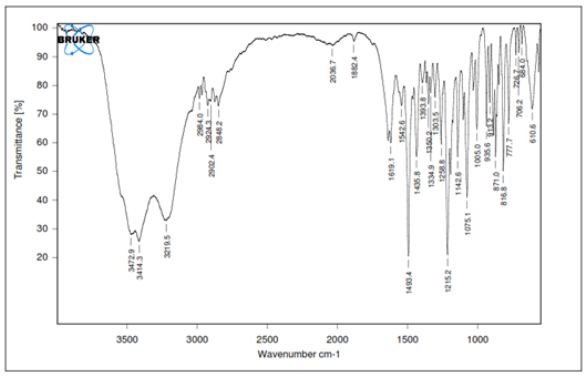

Fig.4: FT-IR spectra of Propranolol HCL

Compatibility Studies

Drug polymer compatibility studies were carried out using Fourier Transform Infrared spectroscopy to establish any possible interaction of Propranolol HCL with the polymers used in the formulation. The FT-IR spectra of the formulations were compared with the FTIR spectra of the pure drug. The results indicated that the characteristic absorption peaks due to pure Propranolol HCL have appeared in the formulated floating microspheres, without any significant change in their position after successful encapsulation, indicating no chemical interaction between Propranolol HCL and Polymers.

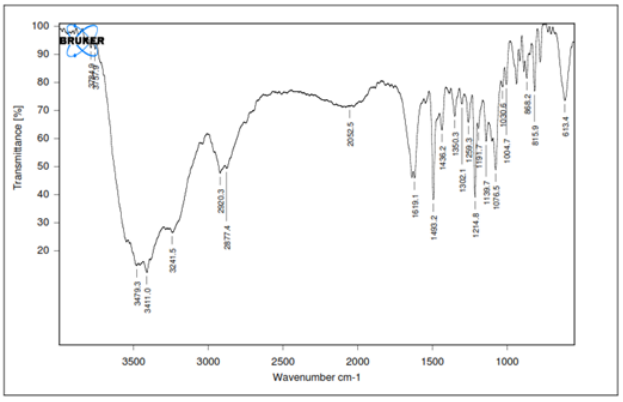

Fig.5: FT-IR spectra of Propranolol HCL best formulation

Evaluation and Characterization of Floating Microspheres Percentage Yield: It was observed that as the polymer ratio in the formulation increases, the product yield also increases. The low percentage yield in some formulations may be due to blocking of needle and wastage of the drug polymer solution, adhesion of polymer solution to the magnetic bead and floating microspheres lost during the washing process. The percentage yield was found to be in the range of 81.58 to 95.50% for floating microspheres is recorded.

Drug Entrapment Efficiency

The drug entrapment efficiency of the prepared floating microspheres increased progressively with an increase in proportion of the respective polymers. Increase in the polymer concentration increases the viscosity of the dispersed phase. The particle size increases exponentially with viscosity. The higher viscosity of the polymer solution at the highest polymer concentration would be expected to decrease the diffusion of the drug into the external phase which would result in higher entrapment efficiency.

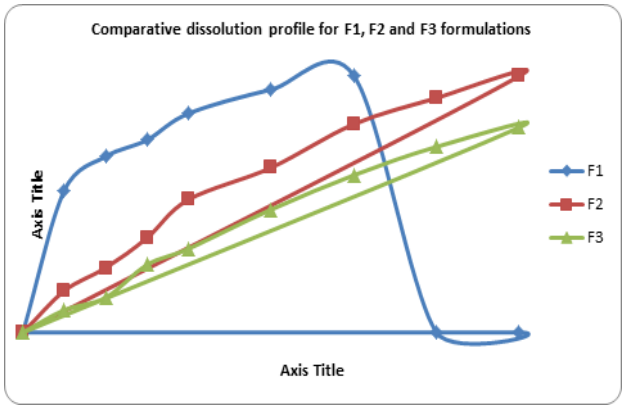

Fig.6: Comparative dissolution profile for F1, F2 and F3 formulations

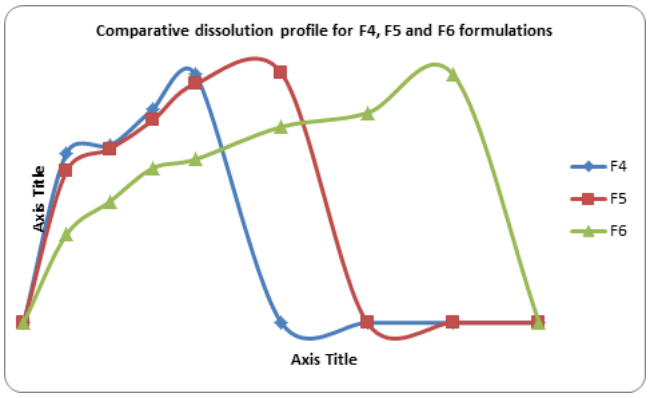

Fig.7: Comparative dissolution profile for F4, F5 and F6 formulations

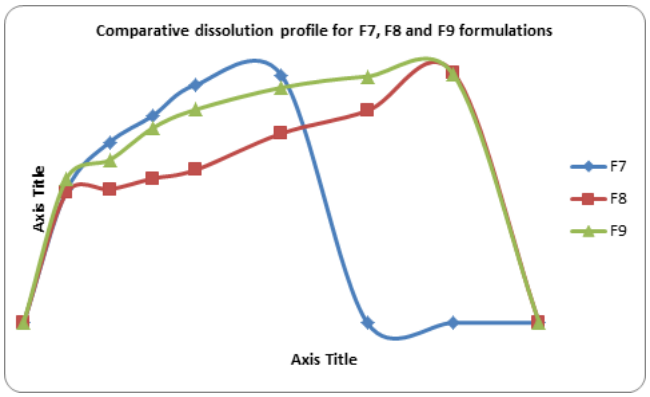

Fig.8: Comparative dissolution profile for F7, F8 and F9 formulations

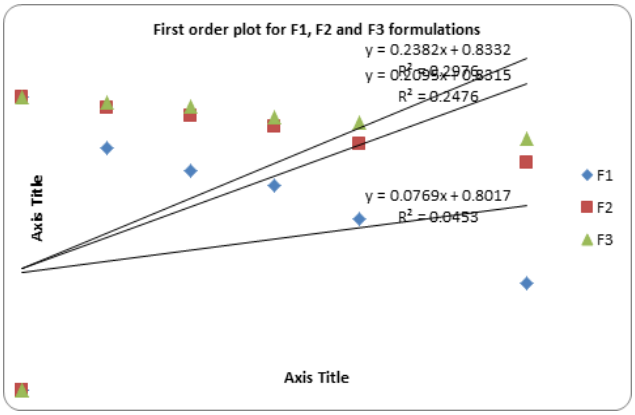

Fig.9: First order plot for F1, F2 and F3 formulations

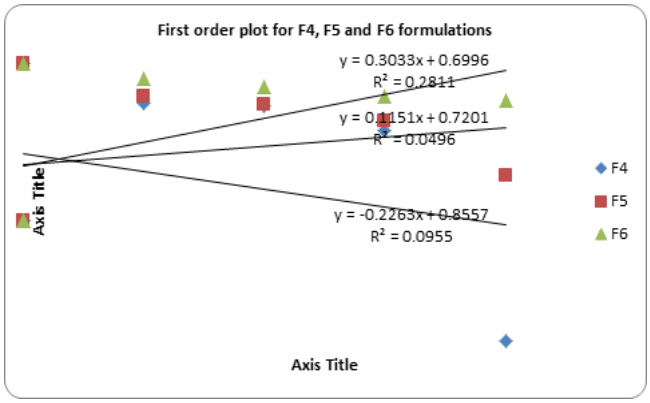

Fig.10: First order plot for F4, F5 and F6 formulations

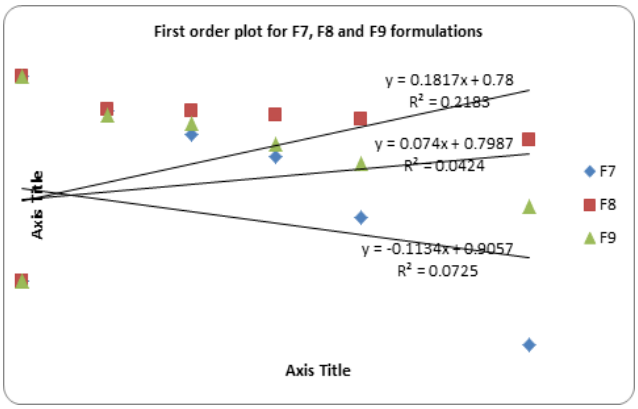

Fig.11: First order plot for F7, F8 and F9 formulations

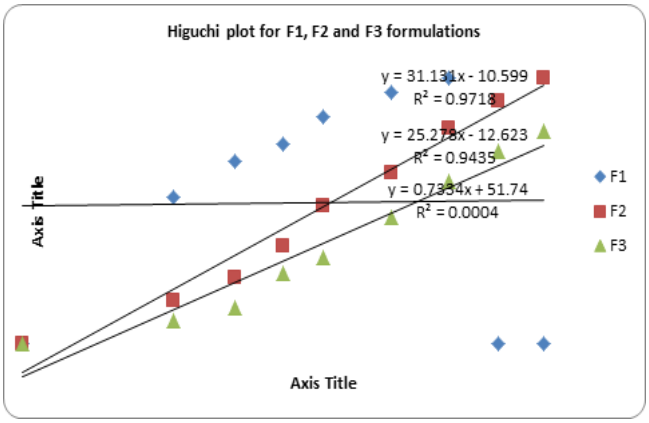

Fig.12: Higuchi plot for F1, F2 and F3 formulations

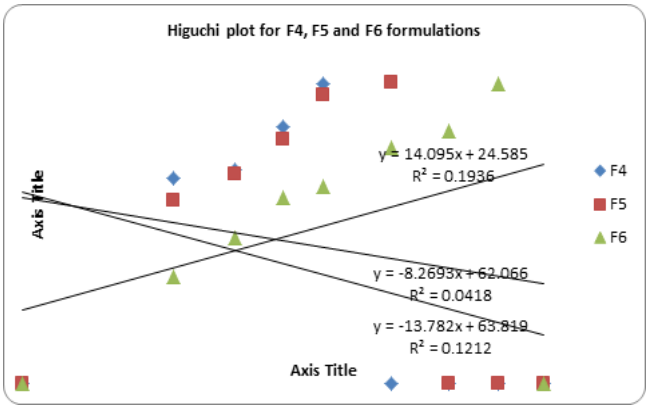

Fig.13: Higuchi plot for F4, F5 and F6 formulations

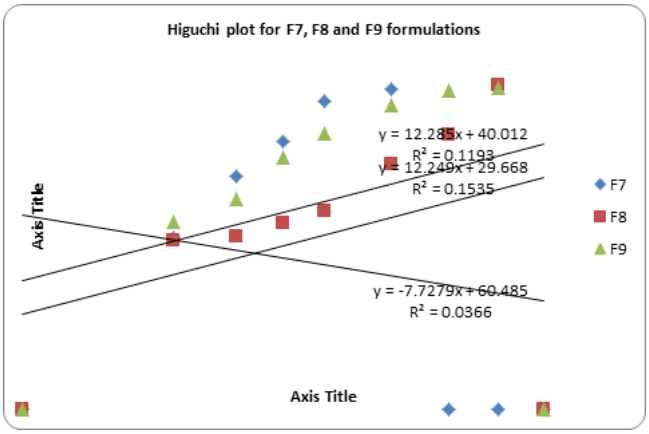

Fig.14: Higuchi plot for F7, F8 and F9 formulations

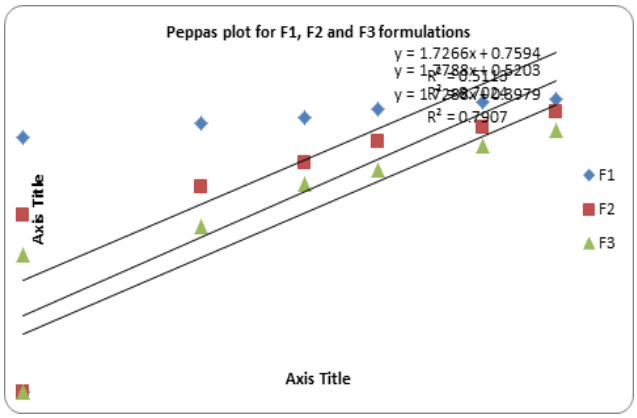

Fig.15: Peppas plot for F1, F2 and F3 formulations

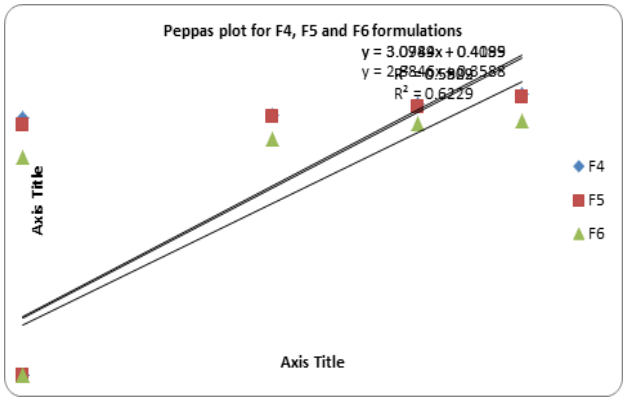

Fig.16: Peppas plot for F4, F5 and F6 formulations

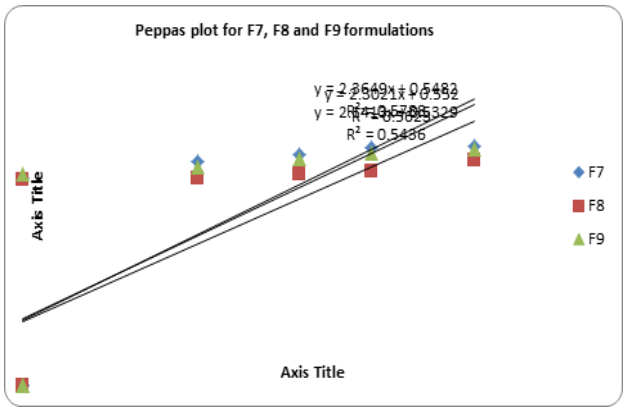

Fig.17: Peppas plot for F7, F8 and F9 formulations

Table 5: Percentage yield and percentage drug entrapment efficiency of the prepared floating microspheres

S.No.	Formulation code	% yield	% Drug entrapment efficiency
1	F1	85.76	70.33± 0.052
2	F2	95.50	91.20± 0.08
3	F3	83.80	67.86± 0.15
4	F4	87.29	77.13± 0.45
5	F5	89.59	82.93± 0.75
6	F6	91.05	86.67± 0.45
7	F7	81.58	74.26± 0.085
8	F8	88.75	85.80± 0.42
			83.33± 0.75

4. Conclusion

A UV-Visible spectrophotometric method was developed and validated for the quantification of Propranolol HCl using 0.1N HCl as the solvent, with absorbance measured at 256 nm. The calibration curve demonstrated excellent linearity within a concentration range of 2 to 10 µg/ml, showing a strong correlation coefficient of 0.999. Compatibility studies using FTIR spectroscopy confirmed no significant chemical interactions between Propranolol HCl and the polymers used in the preparation of floating microspheres, preserving the drug's integrity. The percentage yield of the microspheres ranged from 81.58% to 95.50%, with higher polymer concentrations contributing to increased product yield and drug entrapment efficiency due to increased viscosity that limits drug diffusion. Further evaluations showed the floating microspheres possessed considerable swelling capacity and mucoadhesion, crucial for gastric retention and sustained drug delivery. In vitro drug release studies revealed that formulations exhibited efficient and sustained drug release over a 12-hour period, with certain formulations achieving near-complete release. Kinetic analyses indicated that drug release followed diffusion-controlled mechanisms, supported by fitting to zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. Overall, this work successfully developed Propranolol HCl floating microspheres with optimized formulation parameters, providing promising sustained release and gastric retention attributes, potentially enhancing therapeutic efficacy and patient compliance.

Table 6: Percentage swelling of the prepared floating microspheres

S. No.	Formulation Code	Percentage Swelling
1	F1	85
2	F2	90
3	F3	68
4	F4	73
5	F5	82
6	F6	94
7	F7	69
8	F8	64
9	F9	71

Table 7: Percentage mucoadhesion of the prepared floating microspheres

S. No.	Formulation Code	No. of Floating microspheres		Percentage Mucoadhesion
		Initial	Final	
1	F1	20	16	80
2	F2	20	18	90
3	F3	20	14	70
4	F4	20	15	75
5	F5	20	17	85
6	F6	20	18	90
7	F7	20	17	85
8	F8	20	16	80
9	F9	20	14	70

Table 8: In-Vitro drug release data of Propranolol HCL floating microspheres

Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	**0**	0	0	0	0	0	0	0
1	55.34	**16.23**	8.73	68.43	61.17	35.59	53.37	52.37	58.12
2	68.56	**25.17**	13.58	71.26	69.86	48.73	72.71	53.7	65.52
3	74.98	**36.85**	26.35	85.94	81.49	62.24	83.29	58.1	78.38
4	85.29	**51.73**	32.62	99.97	96.23	65.83	95.74	61.53	85.81
6	94.61	**64.21**	47.89	-	100.58	78.91	99.76	76.26	94.69
8	100.12	**81.15**	61.29	-	-	84.45	-	85.34	99.22
10	-	**91.32**	72.34	-	-	99.93	-	100.81	100.13
12	-	**99.89**	79.88	-	-	-	-	-	-

Table 9: R^2 and N result table

Formulation code	R^2 values				N value
	Zero order	First order	Higuchi matrix	Koresmeyer-peppas	
F1	0.847	0.990	0.970	0.993	0.29
F2	0.984	0.995	0.986	0.991	0.795
F3	0.993	0.993	0.993	0.984	0.976
F4	0.892	0.837	0.977	0.836	0.267
F5	0.865	0.957	0.976	0.939	0.315
F6	0.924	0.979	0.994	0.986	0.463
F7	0.875	0.973	0.982	0.97	0.362
F8	0.894	0.918	0.970	0.794	0.194
F9	0.811	0.991	0.949	0.975	0.285

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