Original Article

Formulation and Evaluation of Ropinirole Buccal Patches Using Different Mucoadhesive Polymers

N.G. Raghavendra Rao*[1] and Keyur Patel[2]

[1]Dept of Pharmaceutics, Jyothishmathi Institute of Pharmaceutical Science, Karimnagar - 505481, AP, India
[2]Department of Pharmaceutics, Luqman College of Pharmacy, Gulbarga-585 102. Karnataka, India

ABSTRACT

The purpose of this study was to develop and optimize formulations of mucoadhesive patches of Ropinirole. The Ropinirole is a non-ergoline dopamine agonist with high relative specificity and full intrinsic activity at the D_2 and D_3 dopamine receptor subtypes. Ropinirole buccal patches are prepared using different mucoadhesive polymers by solvent casting technique. Buccal patches were characterized for parameters like physical appearance and surface texture, mass uniformity, thickness, folding endurance, swelling index, surface pH, drug content uniformity, *in-vitro* residence time, Bursting strength, *Ex-vivo* mucoadhesive force, *Ex-vivo* permeation study, *in-vitro* drug release study and drug-excipients interaction study. The release of Ropinirole from all the formulations was in the range of 76.64 to 90.73% at the end of 8 hrs. The permeation of the drug through the buccal mucosa was found to be release dependant in the range of 73.91 to 85.52%. Drug compatibility with excipients was checked by FTIR studies and it revealed that, there was no incompatibility of the drug with the excipients used. Release of Ropinirole from all patches followed zero order and mechanism was diffusion rate limited. The best mucoadhesive performance and matrix controlled release was exhibited by the formulation RBP8. From this study, it can be concluded that, these formulations of Ropinirole mucoadhesive buccal patches promising one as the controlled drug delivery, shows moderate swelling, convenient resident time will lead to improve the bioavailability and greater therapeutic efficacy.

Keywords: Ropinirole, HPMC (5cps, 50cps), PVP, Chitosan, NaCMC, Bioadhesive patches.

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Address for correspondence
Dr. N.G. Raghavendra Rao
Professor and Principal
Jyothishmathi Institute of Pharmaceutical Science
Ramakrishna Colony,
Thimmapur,
Karimnagar-505481,
Andhra Pradesh
Mob No: +919966794479,
+919448570193
E-mail:
ngraghu@rediffmail.com

INTRODUCTION

Bioadhesive formulations have a wide scope of applications, for both systemic and local effects of drugs. The mucosa is relatively permeable with a rich blood supply. The oral transmucosal drug delivery bypasses liver and avoids pre-systemic elimination in the GI tract and liver[1]. Moreover, it is easily accessible for self-medication and suitable for dosage forms administration and removal. For this reason, various bio-adhesive buccal formulations, such as tablets, gels and patches, have been developed using mucoadhesive polymers which can establish a strong adhesive contact with the buccal mucosa, allowing to increase residence time of delivery systems and to optimize drug bioavailability.[2] In particular, mucoadhesive buccal patches can ensure an accurate drug dosing with respect to liquid formulations and gels, which can be easily washed away by saliva, and can be more comfortable with respect to conventional solid formulations. In fact, patches are flexible and elastic, so that patient compliance is increased and also adequately strong to withstand breakage, caused from mouth movements.[3] The patch is confined to the buccal area over which it is attached and therefore the absorption profile may have less inter and intra-individual variability. Ropinirole is a non-ergoline dopamine agonist activity at the D_2 and D_3 dopamine receptor subtypes, used for the treatment of Parkinson's disease. The absolute oral bioavailability is about 50 to 55%.[4] The

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half-life of ropinirole is 6 hrs and it undergoes hepatic metabolism. In order to overcome such hepatic metabolism and poor bioavailability the drug is selected as suitable candidate for bioadhesive buccal drug delivery as the pKa of the drug should be greater than 2 for an acid and less than 10 for a base.[5,6] The objective of present work was to develop the mucoadhesive patches of ropinirole using solvent casting technique by using different polymers like hydroxy propyl methyl cellulose 5cps (HPMC 5cps), hydroxy propyl methyl cellulose 50cps (HPMC 50cps), Carboxy methyl cellulose sodium (NaCMC), Carbopol 934P, PVP K30 and evaluated for different parameters.

MATERIALS AND METHODS

Ropinirole drug is procured as a gift sample from Ind-Swift Laboratories Ltd, Punjab, India. HPMC 5cps, HPMC 50cps, NaCMC, Carbopol 934P, PVP K30 purchased from Loba chemical Pvt. Ltd., Mumbai. All other materials used were of pharmaceutical grade.

Buccal patches of ropinirole were prepared[7–9] by solvent casting technique using HPMC C15, NaCMC, PVP K30 and Chitosan as polymers, Propylene glycol as plasticizer and Tween 80 as permeation enhancer. The calculated amount of polymer was dispersed in three fourth volume of water with continuous stirring using magnetic stirrer and the final volume was adjusted with distilled Water. The calculated amount of ropinirole was incorporated in the polymeric solutions after levigation with 30% propylene glycol of polymer weight. The solution was casted onto mercury substrate then kept in hot air oven at 40°C for 24 hrs. The patch was punched into size 10 mm patches containing 0.5 mg of ropinirole.

The prepared Ropinirole buccal patches were evaluated for following properties like weight uniformity, thickness, folding endurance, swelling index, surface pH, drug content, *in-vitro* residence time, bursting strength, *ex-vivo* mucoadhesive force, *ex-vivo* permeation study, *in-vitro* release study and drug polymer interaction.

Weight uniformity[10] was tested in three different, randomly selected, individual 10 mm diameter patches from each batch using an electronic balance and average was taken. Thickness of patches was measured by using standard screw gauge at three different spots of patches and average was calculated.

Folding endurance[11] of the patch was determined by repeatedly folding a small strip 2 cm^2 of patch at the same place till it broke. The number of times, the patch could be folded at the same place, without breaking, gave the value of folding endurance.

The percent Swelling[12] patch was calculated by using following equation. A buccal patch of 10 mm diameter was weighed on a pre-weighed cover slip, the initial weight of the film was recorded (W0) and then it was kept in a petri dish containing 5 ml of phosphate buffer pH 7.4. The cover slip was removed at time interval of 0.5, 1, 2, 3, 4, 5, 6, 7, 8 hrs, excess of water was carefully removed and swollen films were re-weighed (Wt).

$$\%S = \frac{Wt - Wo}{Wo} \times 100$$

For the determination surface pH[13] three patches of each formulation were allow to swell for 2 hrs in a petri dish containing 5 ml of phosphate buffer pH 7.4. The surface pH was measured by bringing a combined glass electrode or pH paper near the surface of patches and allowing equilibrate for 1 min. The average of the three readings was recorded.

The bursting strength[14] of a patch is defined as the resistance of the material to a force tending to tear it apart. Bursting strength of the patch was determined with Digital Bursting Tester Tinius olsen (model HT 400 Pneumatic Grip Controller force). The sensitivity range of the machine is 1 to 10 Newtons. It consisted of two load cell grips. The lower one was fixed and upper one was movable. The test patch of size (1 × 4 cm^2) was fixed between these cell grips and force was gradually applied till the patch broke. The bursting strength of the patch was taken directly from the dial reading in Newtons, which was converted into kilograms or calculated by using eq.

$$\text{Bursting strength} = \frac{\text{Force at failure}}{\text{Cross} - \text{sectional area of the patch}}$$

The *in-vitro* residence time[15] was determined using IP disintegration apparatus. The disintegration medium was 800 ml of pH 7.4 phosphate buffer maintained at 37 ± 0.5°C. The segments of rat intestinal mucosa, each of 3 cm length, were glued to the surface of a glass slab, which was then vertically attached to the apparatus as shown in figure below. Three mucoadhesive patches were hydrated from one surface using pH 7.4 phosphate buffer solutions and then hydrated surface was brought into contact with the mucosal membrane. The glass slab was vertically fixed to the apparatus and allowed to move up and down. The patch was completely immersed in the pH 6.8 phosphate buffer solution at the lowest point and was out at the highest point. The time required for complete erosion or detachment of the patch from the mucosal surface was recorded.

The patches were tested for drug content.[16] Patches of 10 mm diameter were cut from three different places from casted patches. Each patch was placed in separate 100 ml volumetric flask and dissolved in pH 7.4 phosphate buffer and continuous stirred for 24 hrs. The

solutions were filtered through 0.45 µm Whatman filter paper, and diluted and analyzed at 250 nm using UV/visible spectrophotometer (Shimadzu UV-1700). The average of drug content of three patches was taken. The percentage drug content was determined using the standard graph.

Ex-vivo Mucoadhesion studies[17–19] were carried out using the mucoadhesion test apparatus working on the principle of double beam physical balance using goat buccal mucosa. The goat buccal mucosa excised and washed. It was connected to the wooden block with cynoacrylate glue with the mucosal side upwards. This was then kept below left hand setup of the balance. The patch ware cut in portions of 2 cm^2 and stuck with a little moisture, on to the lower surface of left hand side of the balance using cynoacrylate glue. It was brought in contact with the mucosa placed on block by removing 5 gm weight from the right pan of the balance. The balance was kept in this position for 3 min and then slowly weights were added on the right pan, till the patch separated from the mucosal surface. The excess weight on the pan i.e. total weight minus 5 gms is force required to separate the patch from mucosa. This gave the mucoadhesive strength of the patch in 'gm'. The maximum adhesive force is the average of three measurements.

In-vitro release studies were carried out by attaching sigma dialysis membrane to one end of the open cylinder which acted as donor compartment. Prepared buccal patches containing drug was placed inside donor compartment. Receptor compartment consist of 100 ml of pH 7.4 phosphate buffer, which is agitated continuously using magnetic stirrer and then temperature was maintained at 37 ± 1°C. Sample of 2 ml were withdrawn at periodic intervals from receptor compartment and replaced with fresh pH 7.4 phosphate buffer immediately. The samples were filtered through 0.45 µm Whatman filter paper, and assayed UV spectrophotometrically at 250 nm (Shimadzu UV-1700). Release rate was studied for all prepared formulations.

Ex-vivo permeation studies[20,21] were carried out by using buccal mucosa as a barrier membrane. From the local slaughter house the buccal mucosa of sheep was collected and immediately transported to the laboratory in cold normal saline solution. Then buccal epithelium was isolated from the underlying tissue. The buccal epithelium was used within 2 hrs upon removal. The modified Franz diffusion cell was used to permeation studies, it consists of two compartments, one is donor compartment and another is receptor compartment. The receptor compartment was covered with water jacket to maintain temperature 37° ± 1°C. The separated buccal epithelium was mounted between two chambers and in receptor chamber phosphate buffer pH 7.4 was filled and buccal epithelium was allowed to stabilization. After stabilization of buccal epithelium, the patch was kept on buccal epithelium and donor compartment filled with phosphate buffer pH 7.4. Periodically samples were withdrawn and same volume fresh medium was replaced. The aliquots were analyzed spectrophotometrically at 250 nm.

To analyze the mechanism[24–25] of drug release form ropinirole mucoadhesive buccal patches the in vitro dissolution data were fitted to zero order ($K = kt$), korsmeyer and peppas model ($F = kt^n$), higuchi ($F = k\sqrt{t}$) release models. Where F is the fraction of drug release, k is the release constant and t is time.

Characterization of Ropinirole patches

The IR spectra for drug Ropinirole, excipients and formulations RBP1, RBP3, RBP5, RBP7, RBP9 and

Table 1: Composition of Ropinirole Mucoadhesive Buccal Patches

FC	Polymers % w/w					PG	Tween 80	Remarks
	HPMC (5cps)	HPMC (50cps)	Na CMC	Carbopol 934M	PVP			
RBF1	7%	–	–		–	30%	0.5%	++
RBF2	8%	–	–		–	30%	0.5%	+++
RBF3	–	4%	–		–	30%	0.5%	+++
RBF4	–	5%	–		–	30%	0.5%	++
RBF5	–	–	3%		–	30%	0.5%	+++
RBF6	–	–	4%		–	30%	0.5%	+++
RBF7	7%	–	–	0.5%	–	30%	0.5%	++
RBF8	7%	–	–		0.5%	30%	0.5%	++
RBF9	–	4%	–	0.5%	–	30%	0.5%	+++
RBF10	–	4%	–		0.5%	30%	0.5%	+++
RBF11	–	–	3%	0.5%		30%	0.5%	+++
RBP12	–	–	3%		0.5%	30%	0.5%	+++

FC = Formulation Code
RBP = Ropinirole Buccal patch
* = % Of The Polymer Weight
Each 10 mm patch contains 0.5 mg of ropinirole

RBP11 were recorded in a Fourier transform infrared (FTIR) spectrophotometer (FTIR 410, Jasco) with KBr pellets.

RESULTS AND DISCUSTION

Buccal patches of ropinirole were prepared by solvent casting technique with the use of mucoadhesive polymers like HPMC C15, HPMC 50cps, NaCMC, PVP K30 and Carbopol 934 P. The prepared patches were evaluated for weight uniformity, thickness, folding endurance, swelling index, surface pH, drug content, *in-vitro* residence time, bursting strength, *ex-vivo* mucoadhesive force, *ex-vivo* permeation study, *in-vitro* release study.

The physical characteristics of various patches are given in Table 2. The weight of 1 cm^2 patch was in the range of 11.33–26.33 mg and patch thickness in the range of 0.085–0.221 mm. The patches show folding endurance values in between 300 and 326. The folding endurance of the patches is more than 300 which shows the patches are having high mechanical strength and good elasticity.[24] The folding endurance was measured manually by folding repeatedly till it broke, and it was considered as the end point. RBP4 showed minimum folding endurance. However, all the patches showed satisfactory flexibility. The swelling behavior of the mucoadhesive polymers are observed as given in Table 2. The percent swelling index for the patches is in between 32.433 to 44.560%. The comparative swelling of polymer in patch was shown in Figure 1. The swelling index was found in order of RBP7<RBP1<RBP8. This shows that the percentage swelling of all the formulations was increased by the addition of PVP due to free solubility in water. The percentage swelling index was decreased by the addition of Carbopol. The patches prepared by polymer with more hydroxyl groups shows high percent swelling index. The void volume is expected to be occupied by the external solvent diffusing into the patch and thereby accelerating the dissolution of the gels.[25] In all the cases the calculated standard deviation values are very low which suggest that the prepared patches shows uniform swelling index.

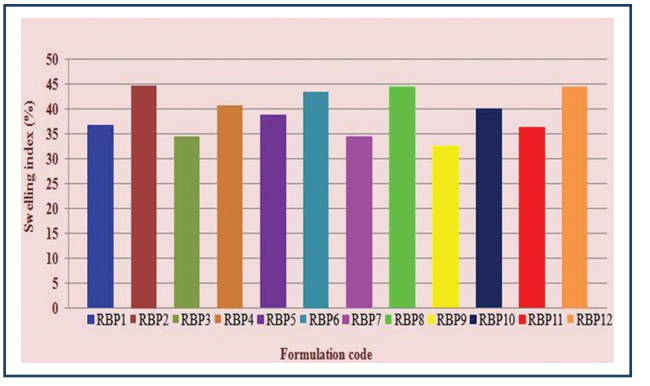

Figure 1: Comperative swelling of Ropinirole mucoadhesive patches.

The *in-vitro* residence time of the mucoadhesive polymers are observed as given in Table 3. The *in-vitro* residence time for the patches is in between 4.11 to 4.99 hrs. As the particle swells, the matrix experiences intra matrix swelling force which promotes disintegration and leaching of drug leaving behind a highly porous matrix.[26] The *in-vitro* residence time increases with increase in polymer concentration. Addition of carbopol to the patches increases the *in-vitro* residence time whereas, PVP had a negative effect on *in-vitro* residence time; that is, as the concentration of PVP increased in-vitro residence time decreased.[27] The surface pH was determined in order to investigate the possibility of any side effects, in the oral cavity. Acidic or alkaline pH is bound to cause irritation to the buccal mucosa. Attempt was made to keep the surface pH close to the neutral pH. Surface pH of patch was in the range of 6.22 to 6.82 which is near to the neutral pH. Hence it is assumed that these formulations cause no irritation in the oral cavity.

Table 2: Physical Evaluation of Mucoadhesive Buccal Patches of Ropinirole

FC	Avg. Weight (mg) ± SD, n = 3	Avg. Thickness (mm) ± SD, n = 3	Avg. Folding Endurance ± SD, n = 3	Avg. Swelling Index (%) ± SD, n = 3
RBP1	20.33 ± 1.527	0.181 ± 0.004	326.00 ± 2.645	36.610 ± 0.658
RBP2	26.33 ± 1.154	0.221 ± 0.003	310.66 ± 3.055	44.560 ± 0.336
RBP3	12.66 ± 0.577	0.093 ± 0.003	309.33 ± 3.055	34.496 ± 0.733
RBP4	18.33 ± 1.527	0.125 ± 0.005	300.33 ± 1.154	40.613 ± 1.08
RBP5	11.33 ± 0.577	0.085 ± 0.005	302.33 ± 3.214	38.656 ± 0.753
RBP6	13.33 ± 0.577	0.113 ± 0.002	301.00 ± 2.645	43.436 ± 1.284
RBP7	24.33 ± 1.527	0.206 ± 0.004	314.33 ± 2.081	34.466 ± 0.661
RBP8	21.66 ± 2.081	0.184 ± 0.003	325.66 ± 3.055	44.316 ± 0.845
RBP9	16.00 ± 1.732	0.115 ± 0.004	305.66 ± 1.527	32.433 ± 0.240
RBP10	13.66 ± 0.573	0.096 ± 0.016	313.66 ± 2.309	39.916 ± 0.455
RBP11	12.33 ± 1.527	0.106 ± 0.010	302.33 ± 3.055	36.336 ± 0.981
RBP12	12.00 ± 1.732	0.111 ± 0.007	307.33 ± 2.081	44.420 ± 0.482

Note: Values in parenthesis are standard deviation (± SD).
FC= Formulation Code

Table 3: Physical, Mechanical Evaluation of Mucoadhesive Buccal Patches of Ropinirole

FC	Avg. Surface pH ± SD, n = 3	Avg. Bursting Strength (Kg/cm²) ± SD, n = 3	Avg. In vitro Residence (hrs) ± SD, n = 3	Avg. Drug content Uniformity (%) ± SD, n = 3
RBP1	6.48 ± 0.025	5.353 ± 0.065	4.47 ± 0.210	96.910 ± 2.446
RBP2	6.23 ± 0.109	5.876 ± 0.406	4.84 ± 0.270	96.008 ± 0.512
RBP3	6.24 ± 0.056	5.263 ± 0.610	4.32 ± 0.332	98.487 ± 0.941
RBP4	6.23 ± 0.120	5.713 ± 0.585	4.84 ± 0.141	97.861 ± 0.467
RBP5	6.70 ± 0.05	4.823 ± 0.155	4.35 ± 0.235	96.483 ± 0.645
RBP6	6.80 ± 0.100	5.136 ± 0.055	4.90 ± 0.255	98.149 ± 0.659
RBP7	6.22 ± 0.105	4.916 ± 0.110	4.94 ± 0.231	98.347 ± 0.676
RBP8	6.35 ± 0.096	5.056 ± 0.080	4.11 ± 0.062	96.162 ± 0.389
RBP9	6.82 ± 0.036	5.090 ± 0.085	4.70 ± 0.190	98.344 ± 0.347
RBP10	6.65 ± 0.105	5.013 ± 0.105	4.24 ± 0.240	96.817 ± 0.380
RBP11	6.78 ± 0.075	4.348 ± 0.065	4.99 ± 0.155	97.249 ± 0.951
RBP12	6.39 ± 0.090	4.468 ± 0.110	4.22 ± 0.160	95.165 ± 0.351

Note: Values in parenthesis are standard deviation (± SD)
FC = Formulation Code

The drug content results were shown in Table 3 in all the formulations drug was uniformly distributed throughout the patches in the range of 95.16–98.48%. The bursting strengths of drug-loaded patches were in the range of 4.34 to 5.87 Kg/cm^2. The results are given in Table 3. Among all the patches studied patch RBP2 showed highest bursting strength and patch RBP11 showed lowest bursting strength. Bursting strength of patch increased as the concentration of the polymer is increased. The patches containing PVP or carbopol shows decreasing bursting strength than the patches prepared without them.

The *Ex-vivo* mucoadhesion force studies were done using modified weighing balance with goat buccal mucosa. The weight required to separate the patch from the goat buccal mucosa was recorded as *Ex-vivo* mucoadhesion force in 'gm'. *Ex-vivo* mucoadhesion force values of all the prepared patches lies in between 11.597 and 24.313 gm as shown in Table 3. PVP had a negative effect on *Ex-vivo* mucoadhesion force, whereas carbopol increases the *Ex-vivo* mucoadhesion force. The order of *Ex-vivo* mucoadhesion force was seen like RBP7>RBP1>RBP8, RBP9>RBP3>RBP10 and RBP11>RBP5>RBP12. As the polymer concentration increases the mucoadhesion force also increases like RBP1<RBP2, RBP3<RBP4, RBP5<RBP6.

The data obtained from *in-vitro* drug release study performed up to 8 hrs gives a clear indication that prepared patches shows necessary control release profile desire for bucco adhesive drug delivery. The *in-vitro* release studies of various formulations were performed in pH 7.4 phosphate buffer solutions at 250 nm. The drug release profiles of Ropinirole patches were given in Table 4. Amongst them, Formulation RBP8 shows highest drug release at 8th hr. The differences of release profile may be due to differences in characteristics and presence of different functional groups of introduced polymers. Again it has been found that increase solid content of polymer has a negative effect on drug release. Addition of PVP retards the drug release where as the carbopol content increases the drug release.

Ex-vivo drug permeation studies was carried out for a period of 8 hrs and data of all the prepared

Table 4: *Ex-vivo* Mucoadhesion, Dug Release and Drug Permeation of Mucoadhesive Buccal Patches of Ropinirole

FC	*Ex-vivo* mucoadhesive force (g) ± SD, (n = 3)	Drug Released in 4 hrs ± SD, (n = 3)	Drug released in 8 hrs ± SD, (n = 3)	Drug permeated in 4 hrs ± SD, (n = 3)	Drug permeated in 8 hrs ± SD, (n = 3)
RBP1	11.597 ± 0.646	49.00 ± 0.832	88.88 ± 1.036	40.67 ± 0.736	82.84 ± 0.465
RBP2	12.477 ± 0.380	42.39 ± 0.324	84.97 ± 0.385	39.70 ± 0.539	78.12 ± 0.589
RBP3	15.347 ± 0.425	51.00 ± 0.922	87.50 ± 0.456	45.70 ± 0.396	80.64 ± 0.453
RBP4	18.477 ± 0.409	41.61 ± 0.682	82.97 ± 0.678	37.15 ± 0.265	75.91 ± 0.556
RBP5	22.207 ± 0.658	55.55 ± 0.472	89.45 ± 0.787	49.24 ± 0.426	83.67 ± 0.923
RBP6	24.253 ± 0.775	44.91 ± 0.878	83.00 ± 0.387	52.94 ± 0.189	85.52 ± 0.945
RBP7	12.453 ± 0.645	42.55 ± 0.519	85.36 ± 0.573	38.55 ± 0.643	78.30 ± 0.733
RBP8	11.980 ± 0.661	50.39 ± 0.738	91.09 ± 0.765	47.42 ± 0.722	82.21 ± 0.678
RBP9	16.673 ± 0.566	36.36 ± 0.821	81.55 ± 0.432	34.85 ± 0.187	73.91 ± 0.284
RBP10	15.277 ± 0.405	47.52 ± 0.529	87.85 ± 0.282	47.18 ± 0.912	82.27± 0.249
RBP11	24.313 ± 0.388	46.67 ± 0.389	83.88 ± 1.118	36.76 ± 0.487	78.85 ± 0.437
RBP12	22.570 ± 0.409	55.12 ± 0.492	90.73 ± 0.873	47.12 ± 0.955	81.94 ± 0.292

Note: Values in parenthesis are standard deviation (± SD)
FC = Formulation Code

formulations were given in Table 4 at the end of 4 hrs and 8 hrs. The detail *Ex-vivo* permeation studies data were plotted between percent drug permeated from the formulation and time as shown in Figures 2–4. The permeation of Ropinirole through buccal mucosa from all the patches was in the range of 34.85 to 52.94 and 73.91 to 85.52% at the end of 4 hrs and 8 hrs respectively. Addition of the permeation enhancer Tween 80 helps the drug to permeate the buccal mucosa faster due to permeation promoting activity of non-ionic surfactant like Tween 80 which is due to the reduction in surface tension, improvement in the wetting of skin and enhanced distribution of the drug. As the polymer concentration in the patches increased, the viscosity and strength of the gel layer also increases, which results in the reduction of drug permeation.

Kinetics drug release result shown in Table 5 reveals that all formulations follow zero-order kinetics as

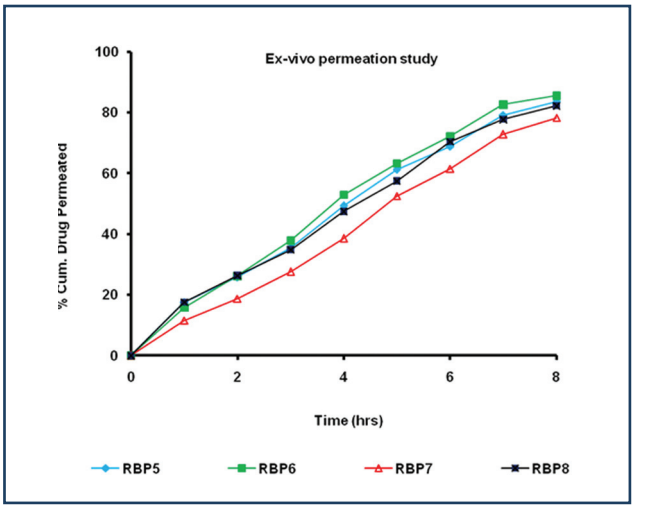

Figure 3: *Ex-vivo* permeation plots of Ropinirole Buccal patches RBP5 to RBP8.

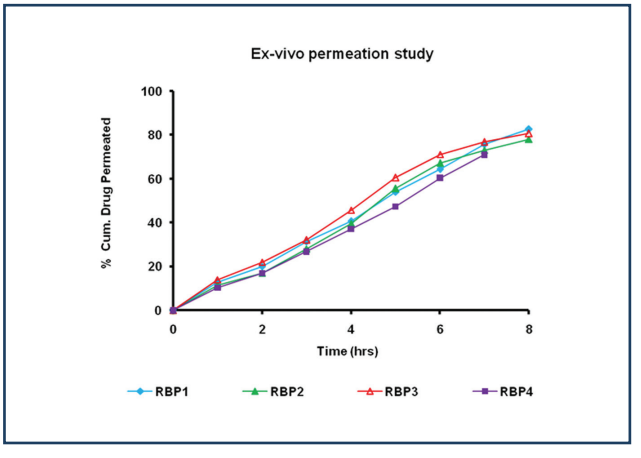

Figure 2: *Ex-vivo* permeation plots of Ropinirole Buccal patches RBP1 to RBP4.

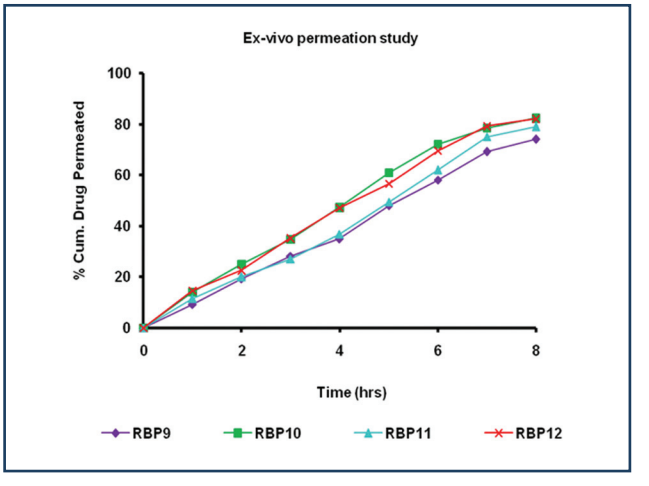

Figure 4: *Ex-vivo* permeation plots of Ropinirole Buccal patches RBP9 to RBP12.

Table 5: Kinetic Parameters of Mucoadhesive Buccal Patches of Ropinirole

FC	Zero-order (r^2)	First- order (r^2)	Higuchi plot (r^2)	Peppas plot	
				(r^2)	n-value
RBP1	0.9886	0.9599	0.9623	0.9947	0.8122
RBP2	0.9921	0.9476	0.9264	0.9921	0.8728
RBP3	0.9815	0.9718	0.9649	0.9908	0.8990
RBP4	0.9967	0.9462	0.9021	0.9968	1.0333
RBP5	0.9815	0.9586	0.9693	0.9956	0.7289
RBP6	0.9939	0.9612	0.9407	0.9948	0.8192
RBP7	0.9962	0.9288	0.9083	0.9894	0.9224
RBP8	0.9890	0.9435	0.9508	0.9939	0.7816
RBP9	0.9920	0.9295	0.8951	0.9879	0.9400
RBP10	0.9901	0.9509	0.9352	0.9945	0.8635
RBP11	0.9928	0.9640	0.9174	0.9935	0.9952
RBP12	0.9854	0.9622	0.9544	0.9958	0.8193

Note: FC = Formulation Code

correlation coefficient (r^2) values are higher than that of first-order release kinetics. Mechanism of drug release pattern i.e. diffusion and swelling was confirmed by Higuchi plots. The Higuchi plots represent of cumulative percentage drug release versus square root of time. The Higuchi plots were found to be linear with correlation coefficient values shown in Table 5. It was concluded that the release of drug from the patches followed the diffusion controlled mechanism in all the formulations. The plots of log cumulative percentage drug release versus log time were found to be linear to the all formulations. On the basis of plots it is concluded that the release of Ropinirole from patches have obeyed Super Case-II transport.

IR spectra of pure drug Ropinirole and formulations RBP1, RBP5, RBP7, RBP8, RBP11 and RBP12 are shown in Figure 5. The IR Spectra of pure drug Ropinirole and formulations all the characteristics absorption peak are observed and found that no chemical reaction taken place. Hence drug present in free state not in the form of reaction product. These peaks can be considered as characteristic peaks of Ropinirole and were not affected and prominently observed in IR spectra of Ropinirole along with polymers, indicated no interaction between drug and polymers.

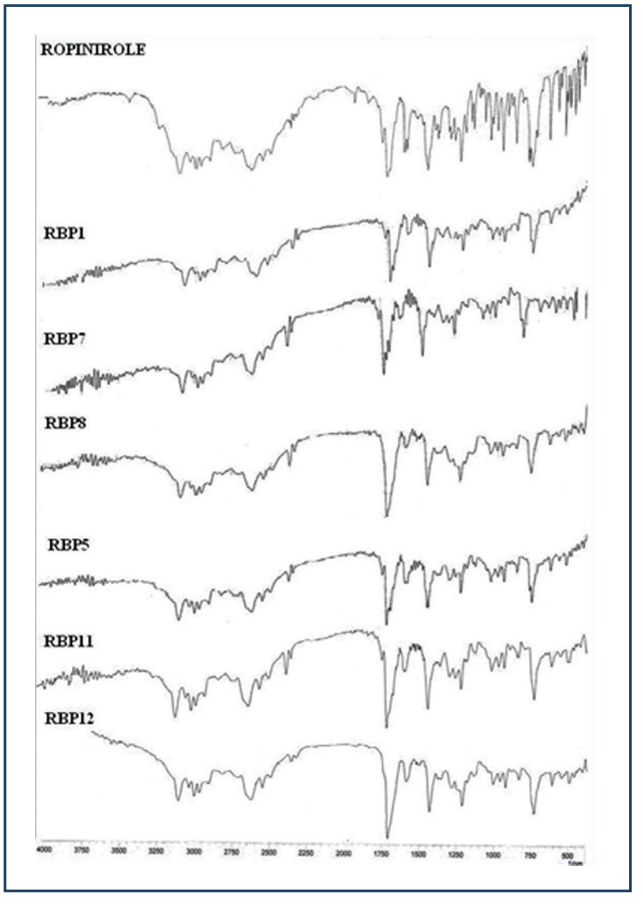

Figure 5: FTIR spectra of pure drug and Mucoadhesive Buccal patches of Ropinirole.

CONCLUSION

Release of Ropinirole from all patches followed zero order and mechanism was diffusion rate limited. Hence these formulations of Ropinirole mucoadhesive buccal patches promising one as the controlled drug delivery, shows moderate swelling, convenient resident time will lead to may improve the bioavailability and greater therapeutic efficacy. Incorporation of hydrophilic polymer PVP K-30 enhanced the drug release, swelling index but significantly decreased the mucoadhesive strength. Addition of carbopol 934p decreased the drug release, swelling index but increased the mucoadhesive time and mucoadhesive strength.

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