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Research Article

Formulation and In-Vitro Evaluation of Ropinirole Sustained Release Tablets

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Abstract
Ropinirole is a medication used to treat Parkinson's disease (PD) and restless legs syndrome. In PD the dose needs to be adjusted to the effect and treatment should not be suddenly stopped. It is taken by mouth. The aim of the present study was to develop sustained release formulation of Ropinirole Hydrochloride to maintain constant therapeutic levels of the drug for over 12hrs. Various natural polymers such as Guar gum, karaya gum and locustbean gum were employed as polymers. Ropinirole Hydrochloride dose was fixed as 5 mg. Total weight of the tablet was considered as 60 mg. Polymers were used in the concentration of 10mg, 15mg and 20mg concentration. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F6) showed better and desired drug release pattern i.e.,97.35 % in 12 hours. It followed zero order release kinetics mechanism.

Keywords: Ropinirole Hydrochloride, Guargum, gum karaya and locust bean gum, sustained release tablets

Article Info

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CONTENTS

1. Introduction

Oral drug delivery is the most widely utilized routes for administration of drugs, which has been explored for systemic delivery via various pharmaceutical products as different dosage form. In long-term therapy for the treatment of chronic disorders, conventional formulations are required to be administered frequently in multiple dosage regimens, and therefore have several undesirable effects. Hence, in order to reduce the drawback associated with multiple dosing, sustained release solid unit dosage forms as tablets were developed. The Ropinirole Hydrochloride is a non-ergoline dopamine agonist with high relative specificity and full intrinsic activity at the D2 and D3 dopamine receptor subtypes. This action in humans correlates with treatment for Parkinson's disease due to stimulation of postsynaptic dopamine D2-type receptors.

2. Methodology

Materials: Ropinirole Hydrochloride, Guargum, Karaya gum, Locust bean gum, Micro crystalline cellulose, Magnesium stearate and Talcall the chemicals were laboratory grade.

Formulation development of Tablets:

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 1.The tablets were prepared as per the procedure given below and aim is to prolong the release of Ropinirole Hydrochloride. Total weight of the tablet was considered as 60mg.

Procedure: Ropinirole Hydrochloride and all other ingredients were individually passed through sieve no ≠ 60.All the ingredients were mixed thoroughly by triturating up to 15 min. The powder mixture was lubricated with talc. The tablets were prepared by using direct compression method.

Evaluation of post compression parameters for prepared Tablets:

The designed formulation tablets were studied for their physicochemical properties like weight variation, hardness, thickness, friability and drug content.

3. Results and Discussion

Analytical Method: Graphs of Ropinirole Hydrochloride was taken in Simulated Gastric fluid (pH 1.2) and in p H 6.8 phosphate buffer at 258 nm and 256 nm respectively.

Table 1: Observations for graph of Ropinirole Hydrochloride in 0.1N HCl (258nm)

Conc [µg/l]	Abs
0	0
1	0.157
2	0.293
3	0.415
4	0.542
5	0.712

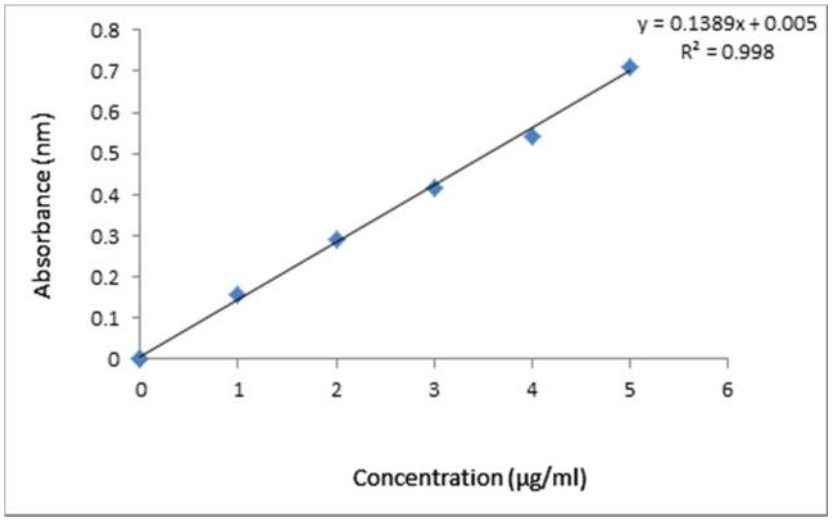

Fig 1: Standard graph of Ropinirole Hydrochloride in 0.1N HCl

Table 2: Observations for graph of Ropinirole Hydrochloride in p H 6.8 phosphate buffer (256nm)

Conc [µg/l]	Abs
0	0
1	0.167
2	0.298
3	0.423
4	0.565
5	0.748

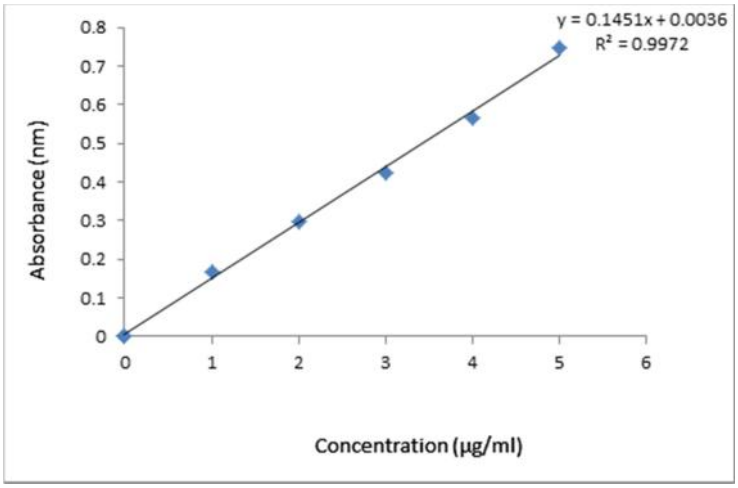

Fig 2: Standard graph of Ropinirole Hydrochloride in pH 6.8 phosphate buffer (256nm)

Pre formulation parameters of powder blend

Table 3: Pre-formulation parameters of powder blend

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	22.05	0.51	0.52	15.02	0.97
F2	23.38	0.57	0.55	15.46	0.99
F3	21.42	0.53	0.56	16.91	0.98
F4	20.19	0.52	0.54	14.43	1.05
F5	23.52	0.55	0.57	15.74	1.13
F6	25.64	0.54	0.55	16.28	1.05
F7	24.98	0.55	0.56	16.47	1.08
F8	23.41	0.53	0.54	15.61	1.05
F9	24.52	0.52	0.52	14.08	0.98

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.51 to 0.57 (gm/cm3) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.52 to 0.57 showing the powder has good flow properties. The compressibility index of all the formulations was found to be ranging between 14 to 17 which shows that the powder has good flow properties. All the formulations has shown the hausner ratio ranging between 0.97 to 1.13 indicating the powder has good flow properties.

Quality Control Parameters For tablets: Tablet quality control tests such as weight variation, hardness, and friability, thickness, and drug release studies in different media were performed on the compressed tablets.

Table 4 In-vitro quality control parameters for tablets

Formulation codes	Weight variation(mg)	Hardness(kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	61	4.3	0.52	1.7	97.02
F2	59	4.5	0.52	1.5	99.13
F3	60	4.3	0.51	1.6	98.53
F4	62	4.6	0.53	1.8	97.44
F5	59	4.4	0.52	1.7	98.76
F6	61	4.5	0.52	1.8	97.91
F7	62	4.6	0.56	1.6	98.05
F8	62	4.5	0.55	1.7	99.13
F9	64	4.6	0.57	1.6	97.11

All the parameters such as weight variation, friability, hardness, thickness and drug content were found to be within limits.

Table 5: Dissolution Data of Ropinirole Hydrochloride (F1, F2, F3 formulations)

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED		
	F1	**F2**	**F3**
0.5	5.05	6.12	6.12
1	9.63	11.13	11.46
2	14.11	16.44	16.81
3	21.61	24.76	25.44
4	31.52	33.91	33.61
5	38.17	40.52	46.73
6	47.61	48.06	52.91
7	55.81	57.61	61.15
8	63.64	66.15	68.77
9	70.14	73.63	75.61
10	75.66	80.79	81.63
11	81.74	86.92	85.71
12	88.44	91.05	89.08

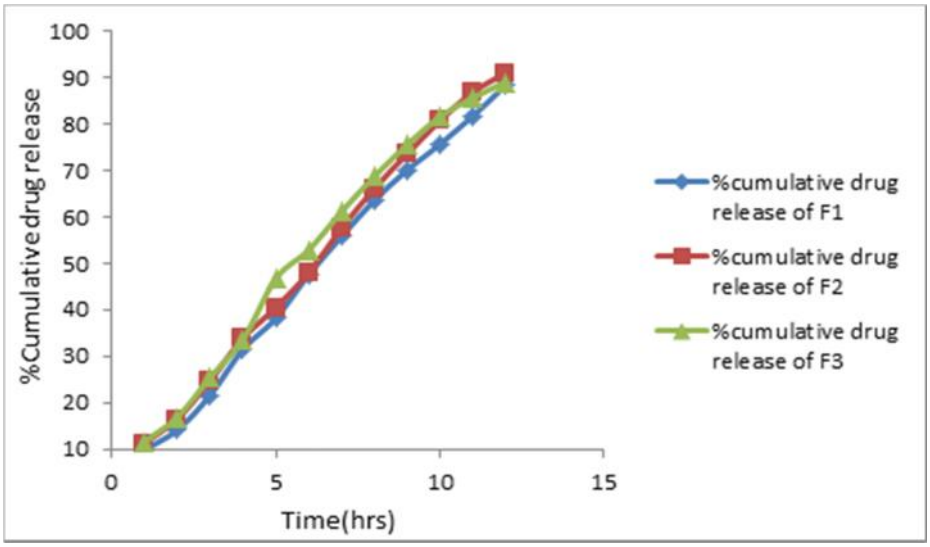

Fig 3: Dissolution profile of Ropinirole Hydrochloride (F1, F2, F3 formulations)

Table 6: Dissolution Data of Ropinirole Hydrochloride (F4, F5, F6 formulations)

TIME (hr)	**Cumulative percent drug Released**		
	F4	**F5**	**F6**
0.5	5.42	7.03	5.12
1	10.36	13.11	9.76
2	17.14	19.35	16.11
3	25.05	27.81	25.63
4	32.63	35.62	33.75
5	41.11	43.78	42.11
6	47.81	51.64	51.46
7	54.23	58.81	60.08
8	60.14	67.14	69.46
9	66.61	75.86	78.83
10	71.14	79.14	87.46
11	77.23	83.66	95.14
12	83.19	87.09	97.35

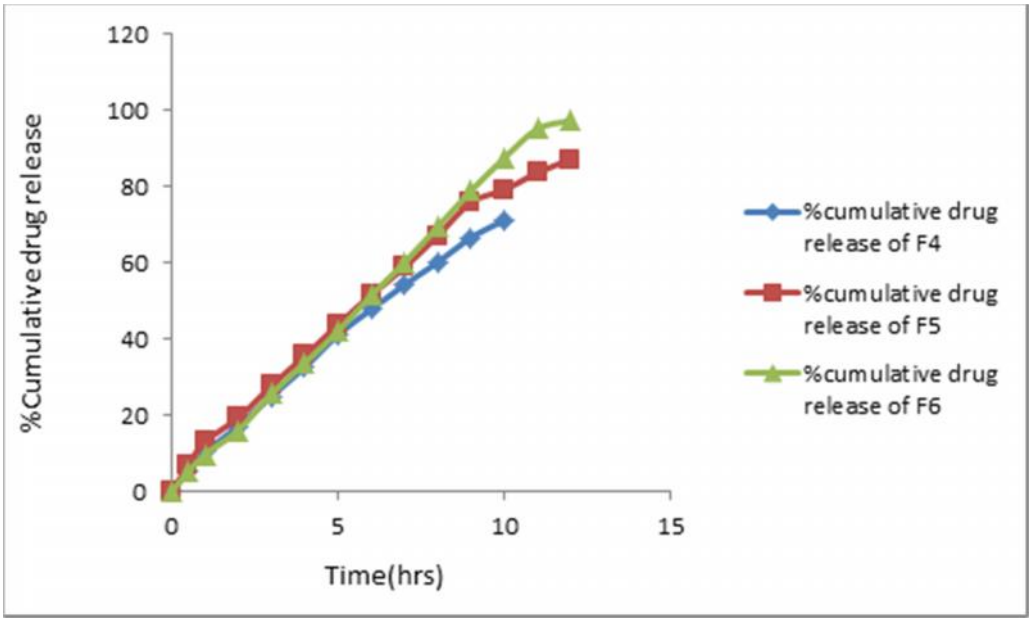

Fig 4: Dissolution profile of Ropinirole Hydrochloride (F4, F5, F6 formulations)

Table 7: Dissolution Data of Ropinirole Hydrochloride (F7, F8, F9 formulations)

TIME (hr)	CUMULATIVE PERCENT DRUG RELEASED		
	F7	**F8**	**F9**
0.5	6.12	6.46	8.13
1	12.91	12.42	14.46
2	20.44	19.63	18.52
3	28.75	27.16	26.15
4	33.62	35.71	35.47
5	42.91	44.06	42.93
6	51.77	53.72	50.18
7	58.63	59.76	58.06
8	65.18	63.92	67.42
9	73.66	69.14	76.63
10	81.73	76.75	81.93
11	86.15	81.52	85.15
12	94.04	89.53	89.06

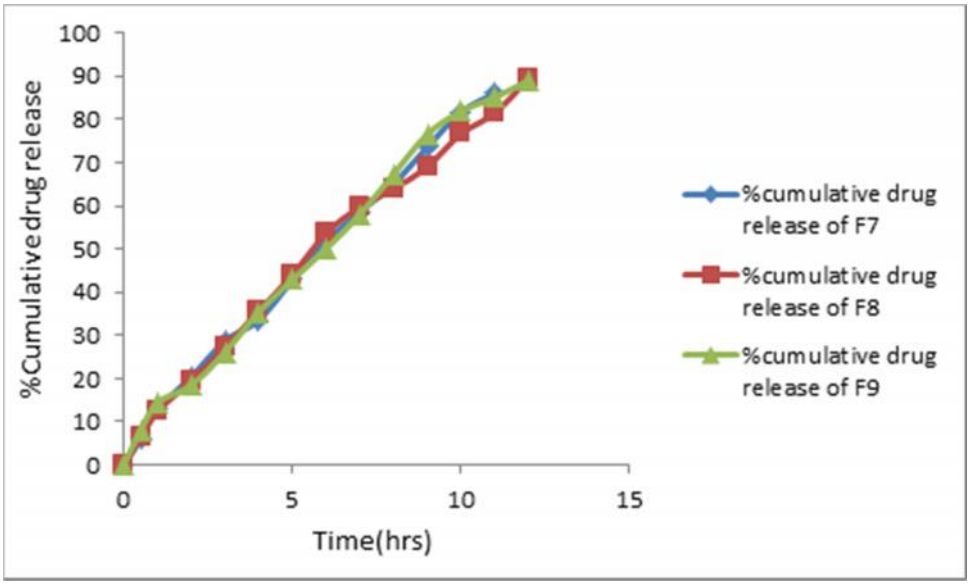

Fig 5: Dissolution profile of Ropinirole Hydrochloride (F7, F8, F9 formulations)

From the dissolution data it was evident that the formulations prepared with guar gum as polymer were unable to retard the drug release up to desired time period i.e., 12 hours. Whereas the formulation prepared with karaya gumretarded the drug release in the concentration of 10 mg showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 97.35% in 12 hours with good retardation. The formulations prepared with locust bean gum showed more retardation even after 12 hours they were not shown total drug release. Hence they were not considered.

Application of Release Rate Kinetics to Dissolution Data:

Various models were tested for explaining the kinetics of drug release. To analyze the mechanism of the drug release rate kinetics of the dosage form, the obtained data were fitted into zero-order, first order, Higuchi, and Korsmeyer-Peppas release model.

Table 8: Release kinetics data for optimized formulation

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM % RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3 -Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
5.12	0.5	0.707	0.709	0.301	1.977	10.240	0.1953	1.291	94.88	4.642	4.561	0.081
9.76	1	1.000	0.989	0.000	1.955	9.760	0.1025	1.011	90.24	4.642	4.485	0.156
16.11	2	1.414	1.207	0.301	1.924	8.055	0.0621	0.793	83.89	4.642	4.378	0.264
25.63	3	1.732	1.409	0.477	1.871	8.543	0.0390	0.591	74.37	4.642	4.205	0.436
33.75	4	2.000	1.528	0.602	1.821	8.438	0.0296	0.472	66.25	4.642	4.046	0.595
42.11	5	2.236	1.624	0.699	1.763	8.422	0.0237	0.376	57.89	4.642	3.868	0.773
51.46	6	2.449	1.711	0.778	1.686	8.577	0.0194	0.289	48.54	4.642	3.648	0.994
60.08	7	2.646	1.779	0.845	1.601	8.583	0.0166	0.221	39.92	4.642	3.418	1.224
69.46	8	2.828	1.842	0.903	1.485	8.683	0.0144	0.158	30.54	4.642	3.126	1.516
78.83	9	3.000	1.897	0.954	1.326	8.759	0.0127	0.103	21.17	4.642	2.766	1.875
87.46	10	3.162	1.942	1.000	1.098	8.746	0.0114	0.058	12.54	4.642	2.323	2.318
95.14	11	3.317	1.978	1.041	0.687	8.649	0.0105	0.022	4.86	4.642	1.694	2.948
97.35	12	3.464	1.988	1.079	0.423	8.113	0.0103	0.012	2.65	4.642	1.384	3.258

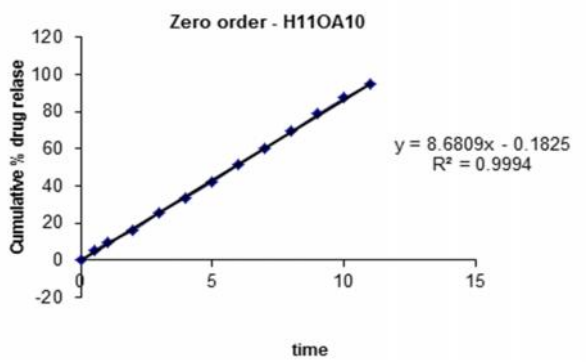

Fig 6 : Zero order release kinetics graph

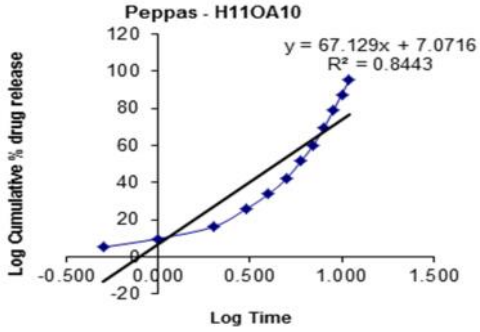

Fig 8: Kars mayer peppas graph

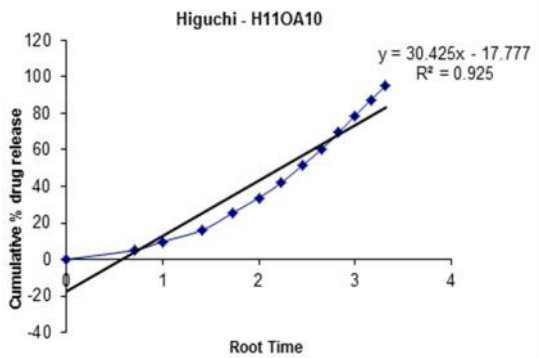

Fig 7 : Higuchi release kinetics graph

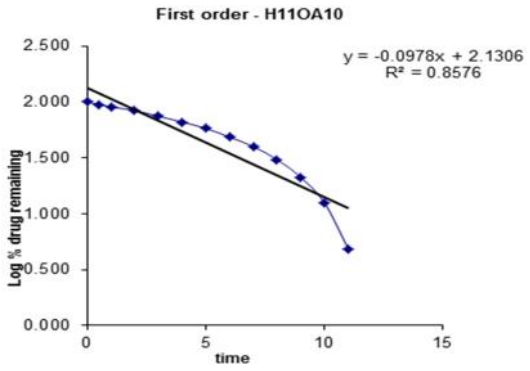

Fig 9: First order release kinetics graph

4. Conclusion

The aim of the present study was to develop sustained release formulation of Ropinirole Hydrochloride to maintain constant therapeutic levels of the drug for over 12 hrs. Various natural polymers such as Guar gum, karaya gum and locustbean gum were employed as polymers. Ropinirole Hydrochloride dose was fixed as 5 mg. Total weight of the tablet was considered as 60 mg. Polymers were used in the concentration of 10 mg, 15mg and 20 mg concentration. All the formulations were passed various physicochemical evaluation parameters and they were found to be within limits. Whereas from the dissolution studies it was evident that the formulation (F6) showed better and desired drug release pattern i.e.,97.35 % in 12 hours. It followed zero order release kinetics mechanism.

5. Reference

[1] Mayur Karvekar, Arshad Bashir KhanA Brief Review on Sustained Release Matrix Type Drug Delivery System Journal of Pharmaceutical Research Volume 16, Issue 3, Jul-Sep, 2017: 282

[2] Pundir S, Badola A, Sharma D. Sustained release matrix technology and recent advance in matrix drug delivery system: a review. International Journal of drug research and technology. 2017 Feb 28; 3(1):8.

[3] Aamir Khan, Dr. Bhuwanendra Singh, Dr. Manoj Kumar Sagar, Formulation and Evaluation of Sustained Release Nifedipine Tablets by using Matrix SystemInternational Journal of Advanced Science and Technology Vol. 29, No.02, (2020), pp. 3220-3232.

[4] Vaquar Ahmed, Saurabh Sharma and Pankaj Bhatt Formulation and Evaluation Of Sustained Release Tablet Of Diltiazem Hydrochloride IJPSR, 2020; Vol. 11(5): 2193-2198.

[5] Sonal Sahu, Rohit Dangi, Rohit Patidar, Rukhsaar, Jagdish Rathi, Vivek Asat Formulation and evaluation of sustain released matrix tablet of atenolol Journal of Drug Delivery & Therapeutics. 2019; 9(1):183-189

[6] Pradeep Kumar , Dr. Sachin Kumar , Dr. Manoj Kumar Sagar Formulation And Evaluation Of Sustained Release Matirx Tablet Of Vildagliptin Using Natural And Synthetic Polymers International Journal of Advanced Science and Technology Vol. 28, No. 16, (2019), pp. 1649-1663.

[7] K. Ravi Shankar, K. Madhan and G. Swetha Formulation and Evaluation Of Sustained Release Matrix Tablets Of Baclofen IJPSR, 2018; Vol. 9(10): 4402-4409.

[8] M. Sunitha Reddy and S. ArchanaFormulation And Evaluation Of Sustained Release Tablets Of Repaglinide Using Hydrophilic Natural And Synthetic PolymersIJPSR, 2018; Vol. 9(7): 2914-2920.

[9] BochareUmesh J , Shelke Satish P, Ambore Sandeep M, Jain Shirish P, Ghodke Amol D.Formulation And Evaluation Of Sustained Release Matrix Tablet of Glipizide By Using Combination of Natural And Synthetic PolymerJ Pharma Res, 2018;7(7):136-142

[10] Mahesh T Gaikwad , Bhagyashri S. Kanadje , Sachin Dilip Pawar Formulation and evaluation of sustained release glipizide tablet using different polymers2017 Innovations in Pharmaceuticals and Pharmacotherapy