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## Research Article

# Formulation and Evaluation of Sustained Release Matrix Tablets of Quetiapine Fumarate

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### Abstract

The objective of this present investigation was to develop matrix tablets of Quetiapine fumarate (QF) for sustained release (SR). Different batches of Quetiapine fumarate sustained release tablets were prepared by direct compression technique using different polymers and to elucidate the release pattern of drug from SR matrix tablets, and compare with the theoretical sustained release profile. Xanthan gum, guar gum, karaya gum were used as natural polymers and HPMC K15, HPMC K100, Ethyl cellulose, Sodium CMC were used as synthetic polymers and by comparing the combination of different polymers was found to provide better-controlled release characteristics with excellent drug release. The prepared tablets were evaluated for weight variation, friability, hardness, thickness and in vitro dissolution studies. From the In vitro dissolution studies it is clear that as the concentration of polymer increased, drug release was found to be retarded. Formulation Q1 and Q15 gave better-controlled drug release in comparison to the other formulations. FTIR study of pure Quetiapine fumarate and formulations showed that there is no drug polymer interaction.

## 1. INTRODUCTION

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms<sup>1-8</sup>. Oral controlled release drug delivery is a system that provides continuous oral delivery of drugs at predictable and reproducible kinetics for a predetermined period throughout the course of GI transit and also the system that target the delivery of a drug to a specific region within the GI tract for either a local or systemic action<sup>3,4,9-12</sup>. Sustained-release systems include any drug-

delivery system that achieves slow release of drug over an extended period of time. If the systems can provide some control, whether this be of a temporal or spatial nature, or both, of drug release in the body, or in other words, the system is successful at maintaining constant drug levels in the target tissue or cells, it is considered a controlled-release system<sup>5,6,13-16</sup>.

Quetiapine Fumarate (QF) is an atypical anti-psychotic agent, widely used for bipolar disorder as well as schizophrenia management. Quetiapine fumarate (QF) (bis [2-(2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl)]ethoxy)ethanol] fumarate, a dibenzothiazepine derivative, is a recent antipsychotic drug with an atypical neuropharmacological profile. Quetiapine is the antipsychotic that has the highest serotonin/dopamine binding ratio, being the serotonin type 2(5-HT<sub>2</sub>)-receptor blocking effect about twice as strong as the dopamine D<sub>2</sub>-receptor blocking effect. Due to this binding pattern, quetiapine causes minimal extrapyramidal side effects. It is readily absorbed from the gastrointestinal tract with oral bioavailability of about 83% and a plasma elimination half life ranging from 6-7 hours<sup>17-25</sup>. Administration of QF in the sustained release dosage form as once daily would be more desirable as this formulation is intended to be given to schizophrenic patients and moreover there was no literature available for sustained release matrix formulation of Quetiapine Fumarate using HPMC K15M and

HPMC K100M<sup>25-32</sup>

Thus, an attempt has been made to formulate the sustained release matrix tablet dosage forms of Quetiapine Fumarate using various low-density and natural polymers.

## 2. MATERIALS AND METHODS

### 2.1 Materials

Quetiapine Fumarate was obtained as a gift sample from Dr. Reddy's Pharmaceuticals, Hyd and other excipients HPMC K100M, HPMC K15M obtained as a gift sample from Dr. Reddy's Pharmaceuticals, Hyd and Karaya gum and Xanthan gum purchased from Himedia Laboratories, Mumbai; Guar gum from Qualikems Pvt. Ltd. All other chemicals and reagents were of analytical grade and used without any further purification.

### 2.2 Spectrophotometric determination of quetiapine fumarate

The standard graphs and whole analysis was performed in the ionized water, USP P<sup>H</sup> 1.2 (0.1N HCl). The wavelength selected was 250nm.

### 2.3 Construction of Theoretical release profile

Theoretical release profile of a drug is constructed when marketed preparations are not available, in order to check whether the formulations are releasing the drug similar to the predicted profile. Theoretical release profile of a drug is plotted on the basis of the loading dose and the drug availability rate.

The total dose of Quetiapine fumarate for sustained release formulation was calculated by the following equation

$$Dt = \text{Dose} (1 + 0.693 \times t / t_{1/2})$$

Where, Dt = total dose of drug (40mg)

Dose = dose of immediate release part

t = time during which sustained release is desired i.e. 24hr

t<sub>1/2</sub> = half life of the drug (6hr)

The results are shown in table 3.

### 2.4 FORMULATION METHOD

Different formulations of Quetiapine fumarate were prepared by direct compression method using varying proportion of polymers either alone or in combination. The composition of various formulations of the tablets are listed in table. Calculated amount of the drug, polymers and filler (Avicel 102) was mixed thoroughly. Then the lubricated blend was added and subjected to compression

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on a sixteen station rotary tablet punching machine using 9mm circular standard flat faced punches. The tablet weight was fixed for

300 mg. The formulation composition is shown in table 1.

**Table 1:** Composition of formulations of sustain release tablets of Quetiapine Fumarate

Formulations	Quetiapine Fumarate	HPMC K100M	HPMC K15M	EC	Xanthan gum	Guar gum	Karaya gum	SCMC	Avicel P <sup>H</sup> 102	Talc	Magnesium stearate
Q1	50	150		-	-	-	-	-	92	4	4
Q2	50	175		-	-	-	-	-	67	4	4
Q3	50	200		-	-	-	-	-	42	4	4
Q4	50	150		50	-	-	-	-	92	4	4
Q5	50	150		-	50	-	-	-	92	4	4
Q6	50	150		-	-	50	-	-	92	4	4
Q7	50	150		-	-	-	50	-	92	4	4
Q8	50	150		-	-	-	-	50	92	4	4
Q9	50	-	150	-	-	-	-	-	92	4	4
Q10	50	-	175	-	-	-	-	-	92	4	4
Q11	50	-	200	-	-	-	-	-	92	4	4
Q12	50	-	150	50	-	-	-	-	92	4	4
Q13	50	-	150	-	50	-	-	-	92	4	4
Q14	50	-	150	-	-	50	-	-	92	4	4
Q15	50	-	150	-	-	-	50	-	92	4	4
Q16	50	-	150	-	-	-	-	50	92	4	4

All the weights of ingredients are taken in mg.

### 2.5 Evaluation of matrix tablet

The physical properties such as friability, weight variation, thickness, and assay of compressed matrix tablet for each formulation were determined. Preweighed, randomly selected twenty tablets were placed in a Roche friability tester and operated for 4 min at 25 rpm. Compressed tablets should not lose more than 1% of their weigh. The thicknesses of tablets was measured by Vernier callipers (Mitatoyo, Japan). The drug content in terms of assay of each batch was determined in triplicate and all the results of these were shown in table 4.

### 2.6 In vitro drug release studies

The release rate of matrix tablets of Quetiapine Fumarate was determined using USP Type 2 Apparatus. The dissolution test was performed in triplicate, using 900ml of 0.1 N HCl at 37±0.5°C at 50 rpm for 24 hrs. A 5ml sample was withdrawn from the dissolution apparatus at specified time points and the samples were replaced with fresh dissolution medium. The samples were filtered through a 0.45-µm membrane filter and diluted if necessary. Absorbance of these solutions was measured at specified wave length of 250nm by U.V-Visible Spectrophotometer.

### 2.7 Kinetic analysis of dissolution data

To analyze the in vitro release data various kinetic models were used to describe the release kinetics. The zero order rate describes the systems where the drug release rate is independent of its concentration. The first order describes the release from system where release rate is concentration dependent. Higuchi described the release of drugs from insoluble matrix as a square root of time dependent process based on Fickian diffusion. Korsmeyer–Peppas model described mechanism of drug release from a polymeric system.

### 2.8 Calculation of similarity factor (f2)

Different dissolution profiles were compared to establish the effect of formulation or process variables on the drug release as well as comparison of test formulations to the theoretical release profile. The data were analyzed by the following formula.

$$f_2 = 50 \log \left\{ \left[ 1 + \frac{1}{N} \sum (R_i - T_i)^2 \right]^{-0.5} \times 100 \right\}$$

Where N = number of time points

R<sub>i</sub> = % release from marketed product or Theoretical release profile

T<sub>i</sub> = % release from test formulation at time i

If f<sub>2</sub> value is in between 50-100, it is to be considered that 2 products share similar drug release behaviors.

### 2.9 Drug-excipient compatibility studies

#### 2.9.1 Fourier Transform Infrared (FTIR) Spectroscopy

To investigate the possibility of chemical interaction between drug and polymer, FTIR spectra of pure QF, pure polymers and optimised formulations were analyzed over the range 400–4000 cm<sup>-1</sup>. The result was shown in fig 6,7.

#### 2.9.2 Differential Scanning Calorimetry (DSC)

DSC study was conducted on Pure drug and two optimized formulations containing HPMC K100M, combination of HPMC K15M and karaya gum respectively. DSC thermogram of pure

drug ( Quetiapine fumarate ) exhibits maximum peak at 178.1<sup>o</sup> C. The results were given in fig 8.

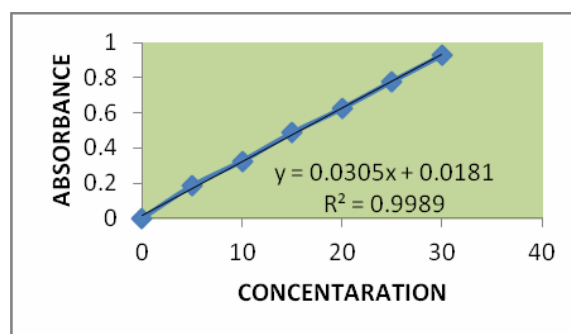
## 3. RESULTS AND DISCUSSION

### 3.1 Standard graph of Quetiapine fumarate in 0.1NHCl at 250nm

The standard graph of Quetiapine fumarate in 0.1N HCl showed a good linearity with R<sup>2</sup> of 0.9989, in the concentration range of 0-30 µg/ml.

**Table 2:** Calibration data

Concentration (µg/ml)	Absorbance
0	0
5	0.185
10	0.326
15	0.486
20	0.625
25	0.779
30	0.927



**Fig 1:** Standard graph of Quetiapine fumarate

**Table 3:** Theoretical release profile of Quetiapine fumarate

Time in hrs to be released	Amount of Quetiapine fumarate (mg)	% drug released
0	0	0
1	13.25	26.51
2	14.84	29.68
4	18.02	36.04
6	21.2	42.4
8	24.38	48.76
10	27.56	55.12
12	30.74	61.48
20	43.46	86.92
24	49.82	99.64

**3.2 Evaluation of the quetiapine fumarate tablets for physical parameters**

The Hardness of the tablets was found in the range of 4.0-5.5 Kg/cm<sup>2</sup> indicating satisfactory mechanical strength. The thickness of the tablets was found to be between 3.50 and

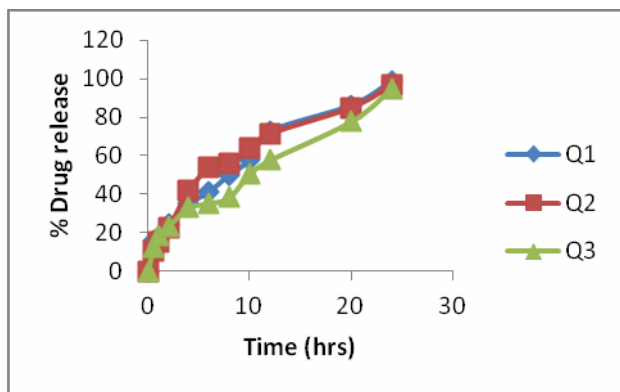
3.84mm. The friability was below 1% for all the formulations, which is an indication of good mechanical resistance of the tablet. Assay of the prepared matrix tablets was found in the range of 98-100%, clearly indicating the good content uniformity. This study indicated that all the prepared formulations were good.

**Table 4:** Physical parameters of the prepared formulation

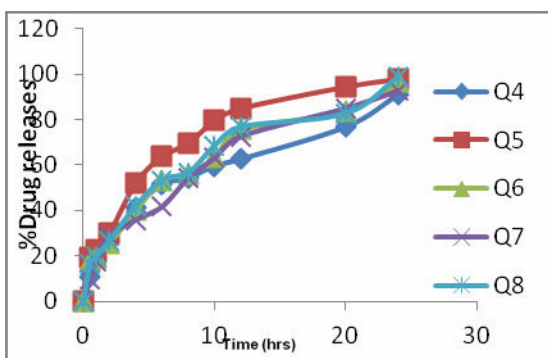
Formulation code	Weight variation (mg)	Hardness (kg/cm <sup>2</sup> )	Thickness (mm)	Friability (%)	Assay (%)
Q1	350±3	4.5±0.3	3.84±0.05	0.32±0.04	98.23±0.89
Q2	348±2	4.6±0.5	3.76±0.06	0.19±0.05	99.65±0.68
Q3	346±3	5.0±0.5	3.50±0.04	0.29±0.06	98.45±0.47
Q4	347±2	4.0±0.5	3.76±0.04	0.33±0.06	98.44±0.69
Q5	348±3	4.5±0.2	3.63±0.06	0.29±0.07	99.23±0.53
Q6	349±3	4.2±0.5	3.50±0.04	0.29±0.03	98.45±0.42
Q7	346±2	4.5±0.4	3.86±0.03	0.26±0.04	99.12±0.39
Q8	348±2	5.0±0.2	3.55±0.06	0.23±0.07	98.65±0.78
Q9	343±3	5.2±0.5	3.50±0.04	0.29±0.08	98.45±0.67
Q10	347±3	5.5±0.5	3.50±0.04	0.29±0.05	98.45±0.54
Q11	344±3	5.0±0.5	3.50±0.04	0.29±0.03	98.45±0.65
Q12	348±2	4.5±0.2	3.60±0.04	0.24±0.07	99.72±0.52
Q13	343±2	4.2±0.5	3.50±0.04	0.29±0.05	98.45±0.46
Q14	345±2	4.2±0.5	3.76±0.06	0.19±0.04	99.65±0.76
Q15	350±3	5.0±0.5	3.50±0.04	0.29±0.07	98.45±0.86
Q16	348±3	5.2±0.5	3.50±0.04	0.29±0.06	98.45±0.65

**3.3 In vitro drug release studies of quetiapine fumarate matrix tablets**

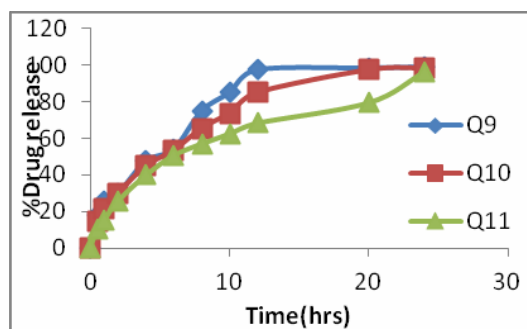
All the matrix formulations Q1-Q16 showed the drug release up to 24 hrs in controlled manner without changing their physical integrity in dissolution medium. The In Vitro dissolution data was fitted to different kinetic models such as Zero order, First order, Higuchi and Korsmeyer-peppas equation. All the release profiles of 16 formulations were given in fig. below.



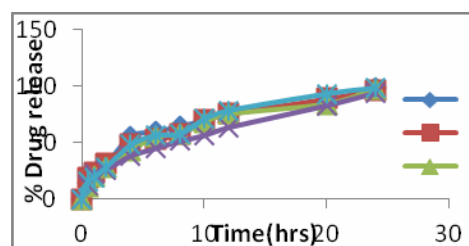
**Fig: 2:** Drug release profiles of Q1, Q2, Q3



**Fig 3:** Drug release profiles of Q4, Q5, Q6, Q7, Q8



**Fig 4:** Drug release profiles of Q9, Q10, Q11



**Fig 5:** Drug release profiles of Q12, Q13, Q14, Q15, Q16

**Table 5:** Cumulative percentage drug release for 24 hours

Formulation	Time(hrs)									
	0	1	2	4	6	8	10	12	20	24
Q1	0	17.82±1.35	24.54±1.46	35.17±0.85	41.31±1.67	50.22±1.54	57.83±0.98	72.53±1.76	86.10±1.89	98.50±0.90
Q2	0	15.40±1.25	22.60±1.86	42.07±2.13	53.64±1.28	56.01±0.68	63.68±1.53	71.35±1.67	84.92±2.41	96.50±1.46
Q3	0	18.82±1.05	23.48±1.10	33.10±0.98	35.23±1.97	38.41±2.14	50.75±1.69	57.78±2.65	77.84±0.67	94.96±1.27
Q4	0	17.76±1.43	26.43±1.20	41.36±1.48	51.40±1.59	54.24±1.13	59.55±1.07	62.50±1.66	76.66±0.35	90.83±1.10
Q5	0	22.83±3.12	30.15±2.61	52.11±0.87	63.68±1.70	69.58±1.59	79.61±1.06	84.92±1.27	94.37±1.31	97.80±1.35
Q6	0	19.12±1.37	25.49±1.24	40.13±0.53	53.23±1.24	56.01±1.11	63.09±1.19	75.48±1.91	83.74±0.89	96.73±0.24
Q7	0	17.76±1.46	28.74±1.34	35.82±1.64	41.66±0.45	54.24±0.77	63.09±0.67	72.53±1.31	84.92±1.21	92.60±1.36
Q8	0	19.71±1.11	26.85±1.18	42.01±0.68	53.29±0.96	56.60±0.21	68.40±1.28	76.66±1.31	82.56±1.38	98.68±0.43
Q9	0	25.37±0.98	29.68±1.32	47.50±1.28	54.05±1.57	74.89±1.44	84.92±1.24	97.32±1.68	98.25±0.55	98.89±0.54
Q10	0	21.48±0.86	30.03±1.81	44.91±2.04	53.52±2.33	65.45±1.08	73.71±1.54	84.92±1.32	97.32±0.89	98.34±0.86
Q11	0	15.34±1.24	25.84±1.07	39.95±1.11	50.75±2.08	57.06±1.53	62.50±0.86	68.40±1.11	79.61±1.45	96.50±1.12
Q12	0	19.88±1.13	33.39±1.21	55.76±0.65	59.55±0.75	64.86±1.32	69.58±1.51	76.66±1.34	87.29±1.11	98.78±0.46
Q13	0	23.25±1.30	32.04±1.81	48.51±0.78	53.64±1.35	57.19±1.51	69.58±1.21	75.48±1.19	89.06±1.36	96.73±1.12
Q14	0	20.24±0.98	27.97±1.28	42.60±1.34	55.76±0.56	57.78±1.98	68.40±0.77	75.48±1.31	84.33±0.89	97.35±0.64
Q15	0	22.42±1.23	26.20±1.11	38.47±1.45	44.96±0.86	51.46±0.87	58.60±1.98	63.68±1.36	83.15±1.23	94.37±1.54
Q16	0	19.29±1.43	28.56±0.94	47.97±1.78	56.47±1.64	57.78±1.34	70.76±1.76	78.43±1.47	93.19±0.89	98.50±0.23

The formulations Q1, Q3, Q6, Q8, Q11, Q14 and Q15 followed Zero order kinetics as indicated by their high regression values compared to first order kinetics whereas formulation Q2, Q4, Q5, Q7, Q9, Q10, Q12, Q13 and Q16 followed first order kinetics. All the formulations (Q1 to Q16) showed good correlation in Higuchi kinetics clearly indicating that the drug release mechanism was predominantly diffusion controlled. Peppas release exponent

(n) values indicated that the drug release from formulations Q1, Q2, Q6, Q7, Q8, Q11 and Q16 followed non-fickian diffusion (n>0.5) whereas formulation Q3, Q4, Q5, Q9, Q12, Q13, Q14 and Q15 followed Fickian diffusion (n<0.5).

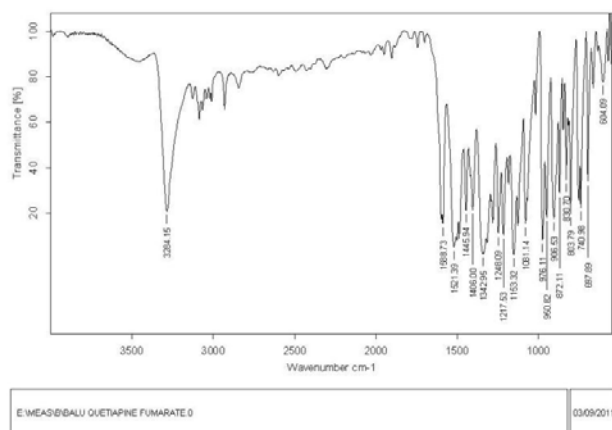
The f2 values for all the formulations were higher than 50 indicating the sameness of release profiles.

**Table 6:** Regression coefficient (R<sup>2</sup>) values of all formulations for different kinetic models

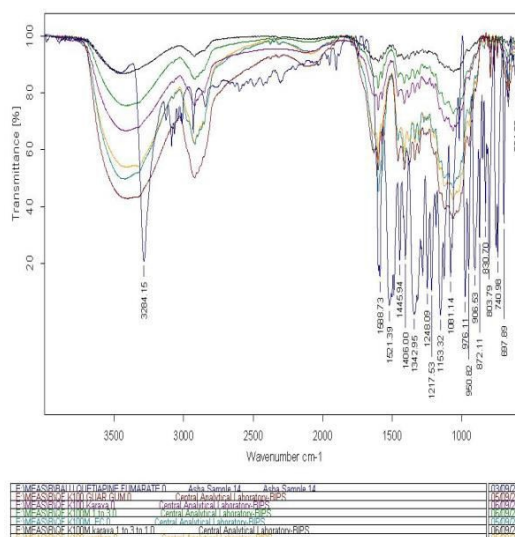
Formulation code	Zero order R <sup>2</sup>	First Order R <sup>2</sup>	Higuchi R <sup>2</sup>	Korsmeyer R <sup>2</sup>	Korsmeyer n	Similarity factor f2
Q1	0.966	0.863	0.986	0.990	0.545	64.062
Q2	0.907	0.927	0.982	0.977	0.576	54.725
Q3	0.990	0.865	0.954	0.954	0.497	58.514
Q4	0.917	0.938	0.980	0.983	0.490	57.79
Q5	0.816	0.993	0.939	0.964	0.481	39.462
Q6	0.915	0.911	0.981	0.988	0.518	55.430
Q7	0.935	0.984	0.984	0.985	0.518	60.060
Q8	0.901	0.828	0.974	0.986	0.508	52.64
Q9	0.780	0.917	0.898	0.949	0.489	36.019
Q10	0.882	0.982	0.970	0.987	0.505	44.306
Q11	0.934	0.874	0.982	0.982	0.550	57.099
Q12	0.851	0.859	0.951	0.954	0.483	44.92
Q13	0.921	0.956	0.986	0.990	0.447	51.33
Q14	0.901	0.900	0.978	0.987	0.495	52.14
Q15	0.982	0.933	0.993	0.987	0.460	73.16
Q16	0.899	0.955	0.979	0.981	0.515	48.25

**3.4 FTIR studies**

The IR spectrum of pure QF showed strong absorption bands at wave numbers of 3284, 2941, 1741, 1597, 1371 and 1070 cm<sup>-1</sup> due to -OH stretching, C-H bend in plane and C-C stretching respectively



**Fig 6:** FT-IR Spectra of Quetiapine Fumarate



**Fig 7:** FT-IR Spectra of optimised formula

### 3.5 DSC studies

Similar peaks were observed for the formulation prepared with HPMC K100M at 173.5°C and at 171.2°C for formulation prepared using HPMC K15M and karaya gum. Polymers used in the optimized formulations can be considered compatible with Quetiapine fumarate as there was no much change in the drug peak.

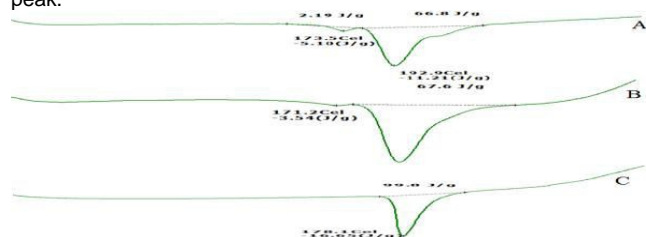


Fig 8: A) QF,HPMC K100M B) QF,HPMC K15,Karaya gum C) QF

### 4. CONCLUSION

Finally, concluded that different swelling polymers such as HPMC K100M, HPMC K15M individually and in combination with other polymers such as Xanthan gum, Guar gum, karaya gum, Sodium CMC and Ethyl cellulose can be successfully employed in the preparation of sustained release tablets of Quetiapine Fumarate. The research study provided useful information for the formulation scientists on formulation, characterization during development of controlled drug delivery systems of Quetiapine Fumarate using these polymers.<sup>33-37</sup>

### 5. ACKNOWLEDGMENTS

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