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FORMULATION AND DEVELOPMENT OF CEFDINIR SUSTAINED RELEASE TABLETS USING VARIOUS RETARDING POLYMERS

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ABSTRACT

Sustained release tablets of Cefdinir were formulated by using Tamarind Gum, Carnauba Wax, and Fenugreek. The tablets were evaluated for Preformulation studies like angle of repose, blukdensity, compressibility index and physical characteristics like hardness, weight variation, friability and drug content. In-vitro release of drug was performed in phosphate buffer pH 6.8 for twelve hours. All the physical characters of the fabricated tablet were within acceptable limits. The tablet with Carnauba Wax (F6) shows a better sustained drug release (99.72%) was obtained with the matrix tablet. It is cleared through the dissolution profile of cefidinir from matrix tablets prepared using different polymers were indicated an increase in the polymer ratio retarded the drug release to a greater extent**.**

KEYWORDS: Cefidinir, Tamarind Gum, Carnauba Wax, and Fenugreek Sustained release matrix tablets**.**

1. INTRODUCTION

Oral drug delivery has been known for decades as the most widely utilized route of administered among all the routes that have been employed for the systemic delivery of drug via various pharmaceutical products of different dosage forms. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration belief that by oral administration of the drug is well absorbed. All the pharmaceutical products formulated

for systemic delivery via the oral route of administration irrespective of the mode of delivery (immediate, sustained or controlled release) and the design of dosage forms (either solid dispersion or liquid), must be developed within the intrinsic characteristics of GI physiology, pharmacokinetics, pharmacodymics and formulation design is essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form.

SUSTAINED DRUG DELIVERY SYSTEM

Over the past 30 years, as the expense and complication involved in marketing new entities have increased with concomitant recognition of the therapeutics advantages of controlled drug delivery, greater attention has been focused on development of sustained or controlled drug delivery system. Sustained release technology is relatively new field and as a consequence, research in the field has been extremely fertile and has produced many discoveries. With many, the basic goal is to achieve a steady state blood level that is therapeutically effective and non-toxic fir an extended period of time. The design of proper dosage form is an important element to accomplish this goal. Sustained release, sustained action, prolonged action, controlled release, extended action, timed release and depot dosage form are term used to identify drug delivery system that are designed to achieve prolonged therapeutic effect by continuously releasing medication over an extended period of time after administration of a single dose. In the case of oral sustained released dosage form, an effect is for several hours depending upon residence time of formulation in the GIT.

MATERIALS

Cefdinir, Tamarind Gum, Carnauba wax, Fenugreek, Micro Crystalline Analytical method development: Analytical method development:

METHODOLOGY

Formulation development of Tablets

All the formulations were prepared by direct compression. The compositions of different formulations are given in Table 7.3.The tablets were prepared as per the procedure given below and aim is to prolong the release of Cefdinir. Total weight of the tablet was considered as 200mg.

Procedure

1) Cefdinir and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.

3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method.

Table 1: Formulation composition for tablets.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cefdinir	100	100	100	100	100	100	100	100	100
Tamarind Gum	10	20	30	-	-	-	-	-	-
Carnauba wax	-	-	-	10	20	30	-	-	-
Fenugreek	-	-	-	-	-	-	10	20	30
Micro Crystalline Cellulose	30	20	10	30	20	10	30	20	10
Talc	5	5	5	5	5	5	5	5	5
Magnesium stearate	55	55	55	55	55	55	55	55	55
Total weight	200	200	200	200	200	200	200	200	200

All the quantities were in mg

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 uniformity, assay, disintegration time and in vitro drug release, disintegration testing was performed using modified methods.

DRUG EXICIPIENTS 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 Agilent spectrophotometer and the IR spectrum was recorded from 4000 cm^{-1} to 500 cm^{-1}. The resultant spectrum was compared for any spectrum changes.

8. RESULTS AND DISCUSSION

The present study was aimed to developing sustained release tablets of Cefdinir using various polymers. All the formulations were evaluated for physicochemical properties and *in-vitro* drug release studies.

Analytical Method

Graphs of Cefdinir were taken in 0.1N HCl and in pH 6.8 phosphate buffer at 286 respectively.

Table 2: Observations for graph of Cefdinir in 0.1N HCl.

Concentration (µg/ml)	Absorbance
0	0
5	0.118
10	0.224
15	0.336
20	0.437
25	0.528

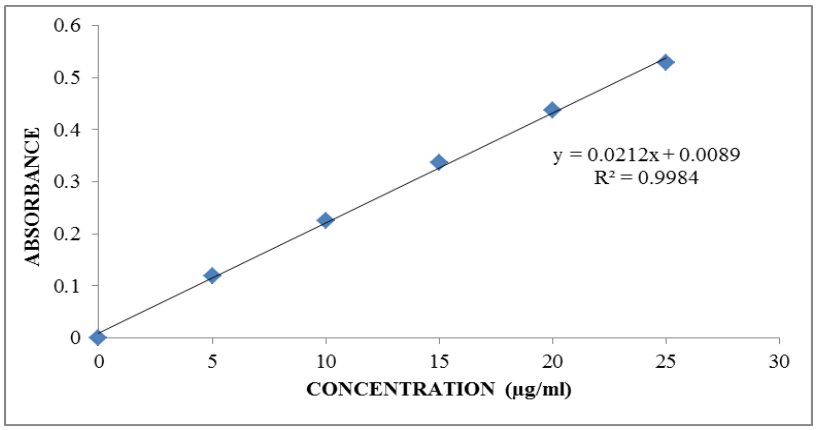

Fig 1: Standard curve of Cefdinir in 0.1N HCl.

Table 3: Standard graph values of Cefdinir pH 6.8 phosphate buffer.

Concentration (µg/ml)	Absorbance
0	0
5	0.128
10	0.249
15	0.356
20	0.479
25	0.586

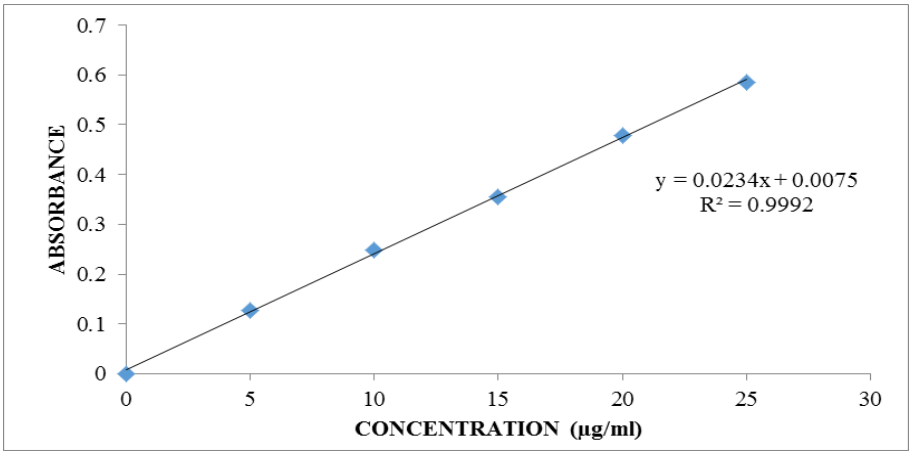

Fig 2: Standard curve of Cefdinir pH 6.8 phosphate buffer.

Preformulation parameters of powder blend

Table 4: Pre-formulation parameters of Core blend.

Formulation code	Angle of repose (Θ)	Bulk density (gms/cm^3	Tapped density(gms/cm^3)	Carr's index (%)	Hausner's Ratio
F1	23.31±0.14	0.55±0.001	0.62±0.005	11.29±0.10	1.13±0.011
F2	29.39±0.20	0.57±0.003	0.64±0.003	10.94±0.07	1.12±0.007
F3	27.55±0.13	0.59±0.004	0.69±0.004	11.94±0.09	1.14±0.011
F4	25.45±0.13	0.61±0.004	0.72±0.005	15.28±0.28	1.18±0.010
F5	29.56±0.24	0.52±0.003	0.58±0.002	10.34±0.09	1.12±0.009
F6	28.15±0.22	0.46±0.002	0.53±0.002	13.21±0.11	1.15±0.011
F7	29.56±0.23	0.57±0.004	0.63±0.003	9.52±0.050	1.11±0.010
F8	28.45±0.07	0.60±0.006	0.65±0.005	10.45±0.08	1.12±0.010
F9	25.45±0.16	0.47±0.003	0.52±0.002	14.55±0.12	1.17±0.007

All the values represent n=3

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 0.46±0.002 to 0.61±0.004 (gms/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±0.002 to 0.72±0.005 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 9.52-15.28 which show that 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 compression coated tablet.

Table 5: *In-vitro* quality control parameters for tablets.

Formulation codes	Weight variation(mg)	Hardness(kg/cm2)	Friability (%loss)	Thickness (mm)	Drug content (%)
F1	197.22	4.6	0.24	2.26	99.12
F2	198.45	4.8	0.31	2.28	98.26
F3	196.31	4.2	0.28	2.19	97.35
F4	199.84	4.5	0.19	2.22	99.22
F5	195.36	4.7	0.22	2.34	99.19
F6	200.05	4.2	0.15	2.18	100.05
F7	199.63	4.4	0.17	2.31	98.56
F8	198.37	4.9	0.26	2.24	99.37
F9	199.41	4.5	0.22	2.26	97.28

All the parameters such as weight variation (195.36 to 200.05 mg) Hardness (4.2to 4.9 kg/cm$^{2)}$, Thickness (2.18 to 2.34 mm), Friability (≥1%) Drug content (97.28 - 100.05 %) were found to be within IP limits.

***In-Vitro* Drug Release Studies**

Table 6: Dissolution Data of Cefdinir Tablets Prepared with Tamarind Gum.

TIME (HRS)	% DRUG RELEASE		
	F1	F2	F3
0	0	0	0
1	22.12	21.42	15.49
2	38.75	32.28	21.96
3	51.42	38.12	26.96
4	54.46	42.84	30.84
5	61.52	46.45	37.72
6	69.72	54.42	41.73
7	81.75	57.56	48.52
8	89.11	68.49	55.33
9	92.02	73.41	64.53
10	94.41	85.46	72.79
11	95.54	87.01	86.86
12		91.49	98.37

Fig 8.3: Dissolution profile of Cefdinir (F1, F2, F3 formulations).

Table 7: Dissolution Cefdinir Tablets Prepared With Carnauba Wax.

TIME(MIN)	% DRUG RELEASE		
	F4	F5	F6
0	0	0	0
1	12.14	14.75	19.42
2	21.67	20.42	25.56
3	28.52	29.63	28.58
4	34.53	34.68	35.43
5	39.12	39.54	41.42
6	44.85	45.12	49.53
7	50.96	42.51	53.52
8	59.43	48.63	58.94
9	67.81	53.76	65.65
10	73.76	65.13	76.21
11	80.12	82.21	87.89
12	84.15	90.18	99.72

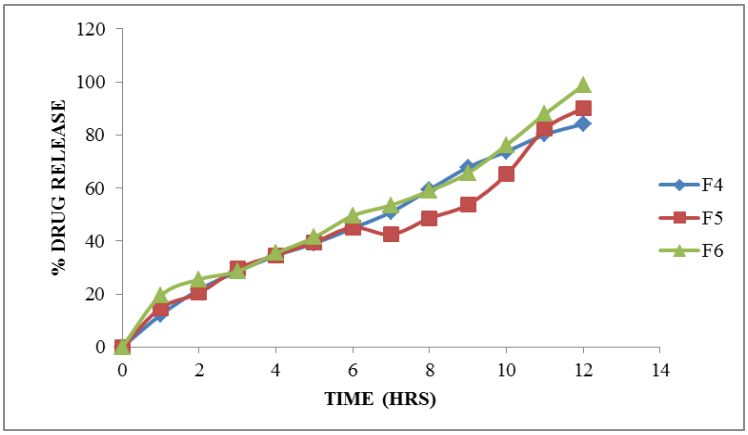

Fig 3: Dissolution profile of Cefdinir (F4, F5, F6 formulations)

Table 8: Dissolution Data of Cefdinir Tablets Prepared With Fenugreek

TIME(MIN)	% DRUG RELEASE		
	F7	F8	F9
0	0	0	0
1	25.12	23.78	21.22
2	38.12	32.85	30.42
3	48.39	48.72	45.12
4	56.52	62.52	51.68
5	60.54	68.52	56.74
6	69.46	74.86	63.42
7	80.61	79.42	71.45
8	88.51	87.51	78.52
9	94.59	92.98	83.54
10	97.52	96.83	87.76
11		97.86	91.42
12		98.53	96.37

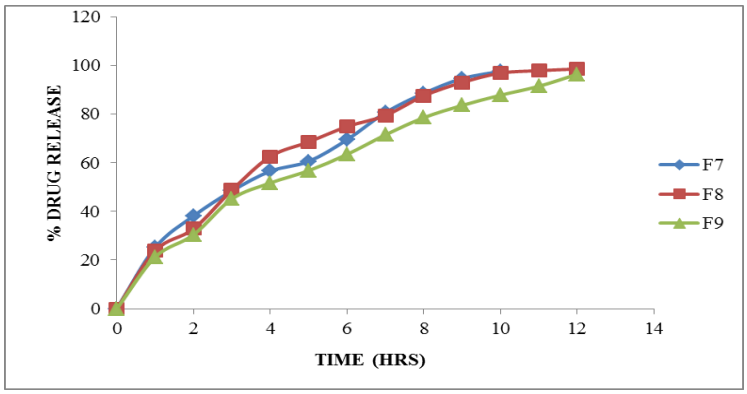

Fig 4: Dissolution profile of Cefdinir (F7, F8, F9 formulations)

From the dissolution data it was evident that the formulations prepared with Tamarind Gum as polymer were able to retard the drug release up to desired time period i.e., 12 hours.

Whereas the formulations prepared with higher concentration of Carnauba wax retarded the drug release up to 12 hours in the concentration 30 mg. In lower concentrations the polymer was unable to retard the drug release.

Whereas the formulations prepared with Fenugreek were retarded the drug release in the concentration of 20 mg (F8 Formulation) showed required release pattern i.e., retarded the drug release up to 12 hours and showed maximum of 98.53 % in 12 hours with good retardation.

From the above results it was evident that the formulation F6 is best formulation with desired drug release pattern extended up to 12 hours.

Application of Release Rate Kinetics to Dissolution Data

Various models were tested for explaining the kinetics of drug release. To analyse 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 9: Release kinetics data for optimised 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
19.42	1	1.000	1.288	0.000	1.906	19.420	0.0515	-0.712	80.58	4.642	4.319	0.322
25.56	2	1.414	1.408	0.301	1.872	12.780	0.0391	-0.592	74.44	4.642	4.207	0.435
28.58	3	1.732	1.456	0.477	1.854	9.527	0.0350	-0.544	71.42	4.642	4.149	0.493
35.43	4	2.000	1.549	0.602	1.810	8.858	0.0282	-0.451	64.57	4.642	4.012	0.630
41.42	5	2.236	1.617	0.699	1.768	8.284	0.0241	-0.383	58.58	4.642	3.884	0.758
49.53	6	2.449	1.695	0.778	1.703	8.255	0.0202	-0.305	50.47	4.642	3.696	0.946
53.52	7	2.646	1.729	0.845	1.667	7.646	0.0187	-0.271	46.48	4.642	3.595	1.046
58.94	8	2.828	1.770	0.903	1.613	7.368	0.0170	-0.230	41.06	4.642	3.450	1.192
65.65	9	3.000	1.817	0.954	1.536	7.294	0.0152	-0.183	34.35	4.642	3.251	1.391
76.21	10	3.162	1.882	1.000	1.376	7.621	0.0131	-0.118	23.79	4.642	2.876	1.766
87.89	11	3.317	1.944	1.041	1.083	7.990	0.0114	-0.056	12.11	4.642	2.296	2.345
99.72	12	3.464	1.994	1.079	0.107	8.227	0.0101	-0.006	1.28	4.642	1.086	3.556

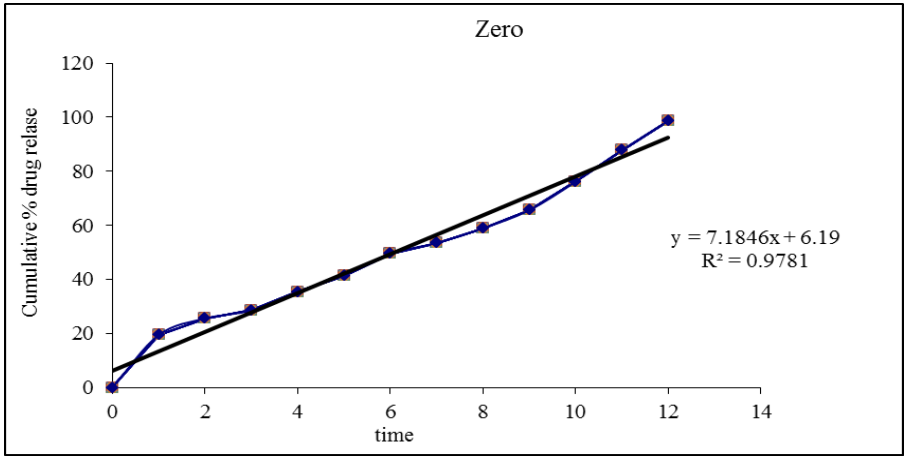

Fig 5: Zero order release kinetics graph.

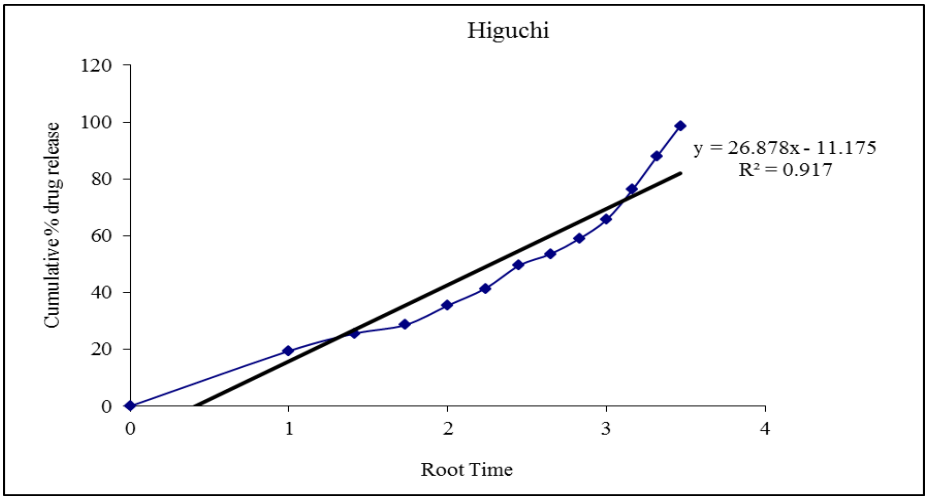

Fig. 6: Higuchi release kinetics graph.

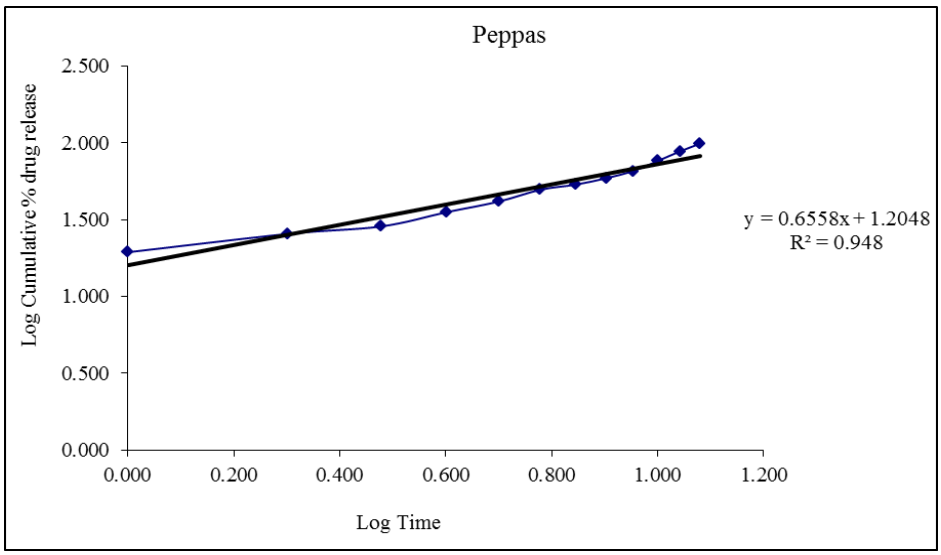

Fig. 7: Kars mayer peppas graph.

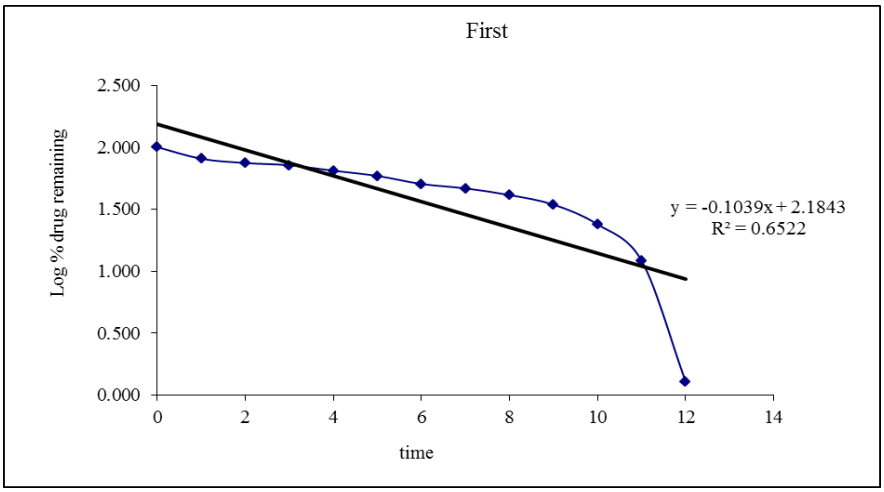

Fig 8: First order release kinetics graph.

From the above graphs it was evident that the formulation F6 was followed Zero order release kinetics mechanism.

Drug – Excipient compatibility studies

Fourier Transform-Infrared Spectroscopy

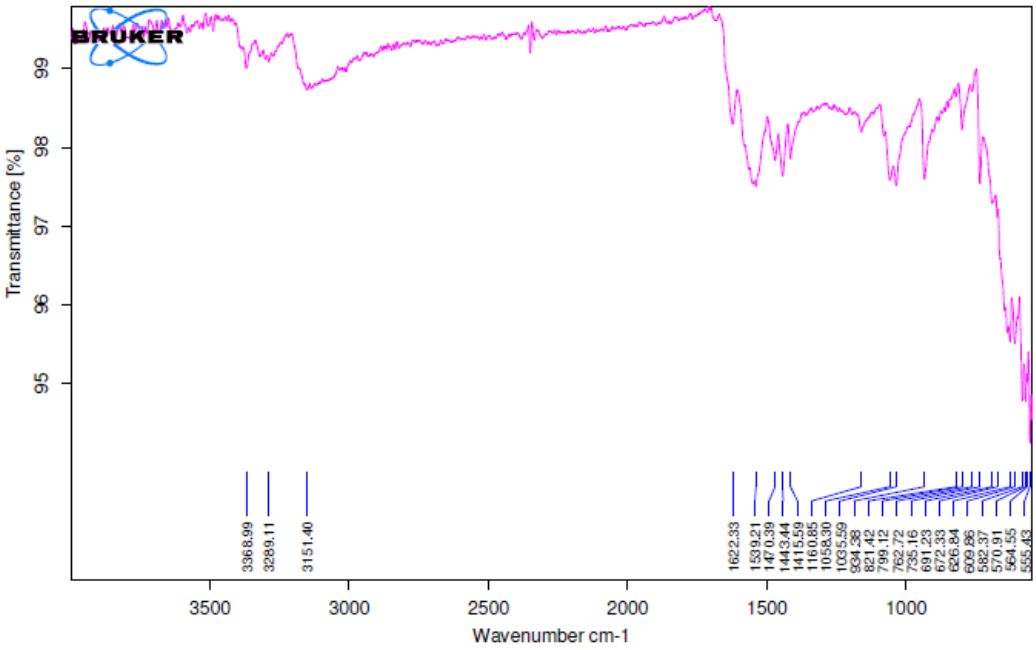

Figure 9: FT-IR Spectrum of Cefdinir pure drug.

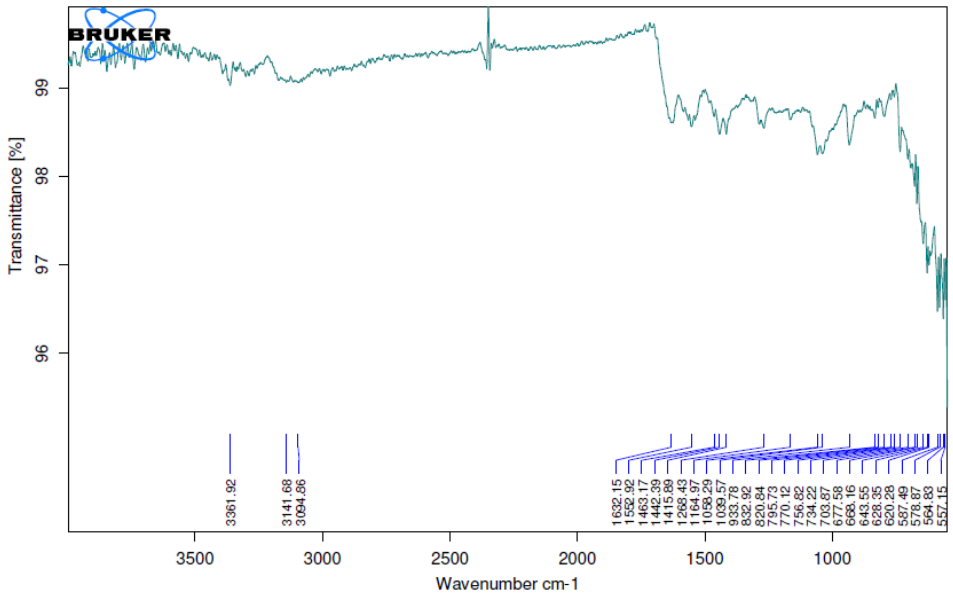

Figure 10: FT-IR Spectrum of Optimized Formulation.

From the FTIR data it was evident that the drug and excipients doses not have any interactions. Hence they were compatible.

CONCLUSION

Cefdinir sustained release matrix tablets were successfully prepared by using various polymers to retard the release and achieve the retard dissolution profile. Drug & polymer were found to be compatible as indicated by FTIR studies. From the observations it was concluded that polymers used in different concentrations differ in their ability to sustain the drug release. Further it was concluded that polymers Carnauba Wax showed better sustained release property than other polymers in the formulation of sustained release matrix tablets. Release rate of drug from the matrix was significantly influenced by proportion of swelling of Carnauba Wax. It may be concluded from the present study that slow & controlled release of Cefdinir over a period of 12 hrs. was obtained from formulation F6 using Carnauba Wax. The drug release kinetics revealed Zero order release kinetics pattern. Formulation and evaluation of sustained release matrix tablets of Cefdinir was found to be satisfactory

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