International Journal of Enhanced Research in Medicines & Dental Care (IJERMDC),
ISSN: 2349-1590, Vol. 9 Issue 12, December 2022, Impact Factor: 7.125

Formulation and Evaluation of Okra Gum Based Diclofenac Sodium Sustained Release Matrix Tablets Comparison with Synthetic Hydrophilic Polymers

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ABSTRACT

The present study was to extract the mucilage from the Okra plant (*Abelmoschus esculentus*) and to study the effect of okra gum on in vitro release of Diclofenac sodium from it's sustained release matrix tablets. Okra gum was extracted from the fruits of *Abelmoschus esclentus* using organic solvent Acetone. The extracted okra gum was subjected to various physiological properties for its suitability as an excipient in the preparation of tablet. Okra. FTIR of Okra shows that it has same IR spectra like other polymer such as HPMC. Diclofenac sodium sustained release tablets were prepared using Okra gum as a sustained release matrix excipient and synthetic hydrophilic polymers such as HPMC K4, HPMCE15, and HPMCK100. The formulated tablets were evaluated for post compression parameters such as weight variation, hardness, friability, and *in vitro* drug release studies. The results of *in vitro* release revealed that the release rate decreased with increase in the concentration of okra gum. The release kinetics indicated that the nature of drug release from the matrix tablets dependent on drug diffusion and polymer relaxation and therefore followed non-fickian or anomalous release. No incompatibility was observed between the drug and excipients used in the formulation of matrix tablets. The Okra gum showed promising results in terms of sustaining the release behavior of Diclofenac sodium from the matrix. The developed sustained release tablets of Diclofenac sodium, with extension of release up to 12 -18 hours, can overcome all the disadvantages of conventional Diclofenac sodium tablets.

Key words: Diclofenac sodium, Okra gum, HPMCK4, HPMCE15LV, HPMCK100, Sustained release tablets

INTRODUCTION

Sustained release tablets are commonly taken only once or twice daily, compared with counterpart conventional forms that may have to take three or four times daily to achieve the same therapeutic effect [1]. The advantage of administering a single dose of a drug that is released over on sustained period of time to maintain a near-constant or uniform blood level of a drug often translate into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use [2, 3]. Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) of the phenyl acetic acid class. When given orally the absorption of diclofenac is rapid and complete. Diclofenac binds extensively to plasma albumin. It is completely absorbed from the GI tract but likely undergoes significant first pass metabolism with only 60% of the drug reaching systemic circulation unchanged [4, 5]. Aim of the study is to formulation and evaluation of okra gum-based Diclofenac sodium sustained release matrix tablets comparison with synthetic hydrophilic polymer like HPMC K4, HPMCE15, and HPMCK100[6]. The main objective of this study is to prolong the drug release of diclofenac sodium to reduce dosage frequency [7].

MATERIALS AND METHODS

Materials

Diclofenac Sodium was gift sample from Aurobindo Labs., Hyderabad, India. Okra gum, HPMCK4, HPMCE15LV, HPMCK100 chemicals of Laboratory-grade from SD Fine chemicals Pvt. Ltd., were used.

Methods

Analytical methods development

A UV absorption maximum was determined by scanning 10µg/ml solution of Diclofenac sodium in phosphate buffer pH 6.8, in between 200-400 nm by using UV-visible spectrophotometer. Further a representative spectrum was drawn of Diclofenac sodium in phosphate buffer pH 6.8.

The absorbance of solutions of pure Diclofenac sodium drug were measured at 276 λmax and a calibration curve was plotted between concentration of drug (µg/ml) on x-axis v/s absorbance on y-axis to get the linearity and regression equation [8].

Drug -Excipient compatibility studies

Fourier transforms infrared spectroscopy (FTIR)

The physical properties of the physical mixture were compared with those of plain drug. Samples was mixed thoroughly with 100 mg potassium bromide IR powder and compacted under vacuum at a pressure of about 12 psi for 3 minutes. The IR spectrum was recorded from 3500 cm to 500 cm. The resultant spectrum was compared for any spectrum changes [9].

Preformulation parameters

There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia include angle of repose, Bulk dnsity, Tapped density, Carr's index and Hausner's Ratio [10].

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 Diclofenac sodium. Total weight of the tablet was considered as 250 mg.

Procedure: Diclofenac sodium 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 [11].

Table 1: Formulation composition for tablets

F. C	Diclofenac Sodium	HPMC K4	HPMC E15LV	HPMC K100	Okra gum	Carbopol 940	MCC pH 102	M.S	Talc
F1	75	75	-	-	-	60	80	6	4
F2	75	100	-	-	-	75	40	6	4
F3	75	125	-	-	-	90	10	6	4
F4	75	-	100	-	-	60	55	6	4
F5	75	-	125	-	-	75	15	6	4
F6	75	-	150	-	-	90	10	6	4
F7	75	-	-	125	-	60	30	6	4
F8	75	-	-	150	-	75	10	6	4
F9	75	-	-	175	-	90	10	6	4
F10	75	-	-	-	16.25	60	143.75	6	4
F11	75	-	-	-	32.5	60	127.5	6	4
F12	75	-	-	-	48.75	60	111.25	6	4
F13	75	-	-	-	75	60	80	6	4
F14	75	-	-	-	91.25	60	63.75	6	4
F15	75	-	-	-	107.5	60	47.5	6	4

All the quantities were in mg and total tablet weight was 300mg.

Evaluation of post compression parameters for prepared Tablets

Weight variation test:

The average weight of one tablet was determined from the collective weight [12]. The percent deviation was calculated using the following formula.

% Deviation = (Individual weight – Average weight / Average weight) × 100

Hardness:

The hardness of tablets was determined using Monsanto hardness tester [13].

Thickness:

Tablet thickness is an important characteristic in reproducing appearance measured by using screw guaze [14].

Friability:

Roche friabilator was used to determine the friability by following procedure [15]. The friability is expressed in percentage as

% Friability = [(W1-W2) / W] × 100

Where, W1 = Initial weight of three tablets, W2 = Weight of the three tablets after testing

Determination of drug content:

Ten tablets were finely powdered quantities of the powder equivalent to one tablet weight of Diclofenac sodium were accurately weighed, transferred to a 100 ml volumetric flask containing 50 ml water and were allowed to stand to ensure complete solubility of the drug. The solution was suitably diluted and the absorption was determined by UV –Visible spectrophotometer. The drug concentration was calculated from the calibration curve [16].

***In vitro* drug release studies**

900 ml 0f 0.1 HCl was placed in vessel and the USP apparatus –II (Paddle Method) was assembled. The medium was allowed to equilibrate to temp of 37 $\pm$ 0.5°C. Tablet was placed in the vessel and the vessel was covered the apparatus was operated for 2 hours and then the medium 0.1 N HCl was removed and pH 6.8 phosphate buffer was added process was continued from up to 12 hrs at 50 rpm. At definite time intervals of 5 ml of the receptors fluid was withdrawn, filtered and again 5ml receptor fluid was replaced. Suitable dilutions were done with receptor fluid and analyzed by spectrophotometrically at 298 nm using UV-spectrophotometer [17].

Extraction & Isolation of Okra gum

The method for extracting okra gum was based on procedure provided by Tavakoli et al. 1kg of fresh, unripe and delicate okra fruits (pods) were taken from nearby vegetable market. All the fruits were cleaned and thinly sliced using a sharp knife. Due to absence of mucilage in okra seeds, the seeds were removed from okra fruits. To isolate and extract the mucilage from okra fruits, the sliced mass of okra fruits were steeped in distilled water overnight. After soaking, the sticky gum (mucilage) was extracted; and filtered by using a white muslin cloth. Acetone was used to precipitate the gum by adding 3 part of acetone in 1 part of gum extract. In addition, the precipitated gum was then dried for about 2 weeks in desiccator containing anhydrous calcium chloride. Particle size reduction of prepared okra gum was done by using stainless steel grinder followed by passing through sieve no. 120 to obtain uniform particles of dried okra gum powder. The dried okra gum powder was stored in airtight glass containers [18].

RESULTS AND DISCUSSION

The present study was aimed to developing sustain release of diclofenac sodium using various polymers. All the formulations were evaluated for physicochemical properties and *in vitro* drug release studies.

Analytical Methods: The calibration curve of diclofenac sodium was taken in pH 6.8 phosphate buffer at 276 nm.

Drug- Excipient compatibility studies

Fourier Transform-Infrared Spectroscopy:

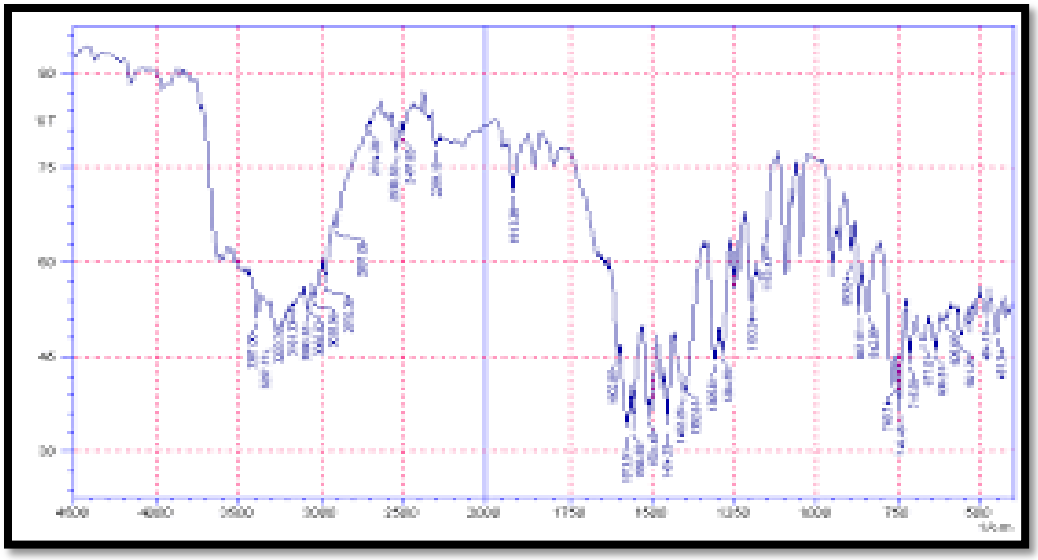

Figure 1. FT-IR spectrum of Diclofenac sodium pure drug

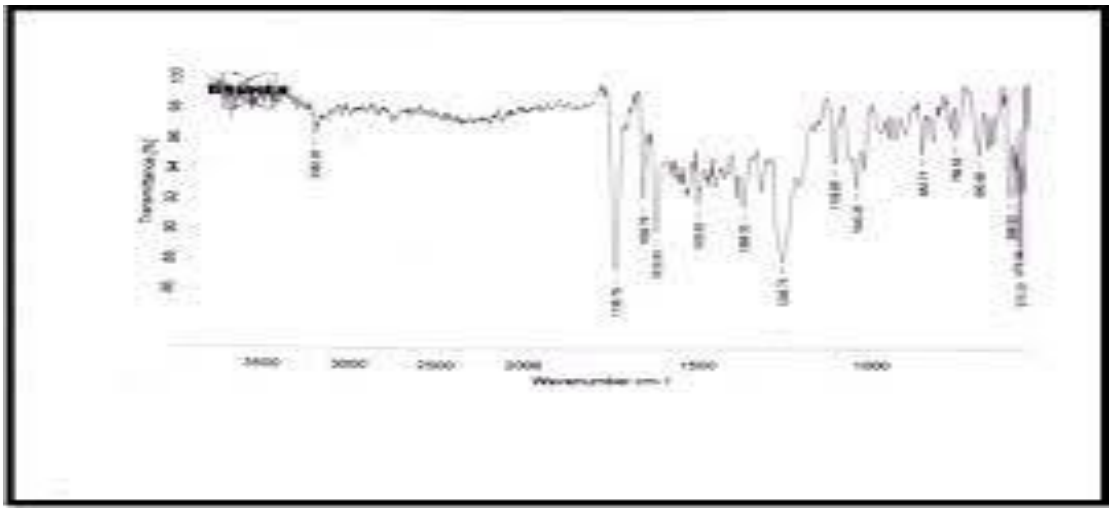

Figure2. FT-IR spectrum of optimized formulation

It is observed that the peaks of major functional groups of diclofenac which are presents in spectrum of pure drug. There was no appearance or disappearance of any characteristics peak in the FTLR spectrum of drug and the polymers used. It means that there are no interactions between drug and other ingredients in a physical mixture and drug is compatible with other ingredients.

Table 2. Preformulation parameters of powder blend

Batch	Angle of Repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's Ratio
F1	25.11	0.49	0.54	16.21	0.86
F2	25.67	0.52	0.52	16.87	0.98
F3	25.54	0.50	0.58	17.11	0.64
F4	25.43	0.51	0.54	17.67	1.12
F5	25.34	0.52	0.57	16.92	1.2
F6	24.22	0.53	0.56	17.65	1.06
F7	25.18	0.54	0.59	16.43	0.76
F8	24.22	0.58	0.67	17.97	1.15

F9	25.05	0.55	0.52	17.54	1.17
F10	26.01	0.59	0.67	11.94	1.13
F11	27.8	0.46	0.54	14.81	1.17
F12	24.7	0.62	0.74	16.21	1.19
F13	25.33	0.54	0.64	14.28	1.16
F14	26.24	0.63	0.74	14.86	1.17
F15	27.12	0.48	0.57	15.78	1.18

Pre-formulation parameters of blend

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 of be in the range of 0.54±0.08 to 0.7±0.05 showing the powder has good flow properties. The compressibility index of all formulations was found to be below 18 which show that the powder has good flow properties. All the formulations have shown the Hauser ratio below 1.2, 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 compression tablets.

Table 3. *In vitro* quality control parameters for tablets

Formulation code	Weight variation (mg)	Hardness (kg/cm^2)	Friability (% loss)	Thickness (mm)	Drug content (%)
F1	312.5±0.24	4,5±0.24	0.52±0.14	4.8±0.11	99.76±0.19
F2	305.4±0.11	4.2±0.41	0.54±0.24	4.9±0.19	99.45±0.24
F3	298.6±0.18	4.4±0.11	0.51±0.32	4.9±0.32	99.34±0.18
F4	310.6±0.21	4.5±0.18	0.55±0.19	4.9±0.22	99.87±0.36
F5	309.4±0.32	4.4±0.39	0.56±0.29	4.7±0.18	99.14±0.17
F6	310.7±0.17	4.2±0.19	0.45±0.11	4.5±0.31	98.56±0.29
F7	302.3±0.41	4.1±0.23	0.51±0.27	4.4±0.29	98.42±0.15
F8	301.2±0.38	4.3±0.31	0.49±0.18	4.7±0.21	99.65±0.41
F9	298.3±0.31	4.5±0.43	0.55±0.19	4.6±0.22	99.72±0.24
F10	299.4±0.14	4.0±0.15	0.42±0.12	4.6±0.12	98.75±0.25
F11	303.3±0.34	4.2±0.45	0.47±0.16	4.7±0.34	98.54±0.98
F12	305.4±0.23	4.5±0.24	0.49±0.34	4.4±0.23	98.35±0.27
F13	306.1±0.23	4.6±0.32	0.47±0.35	4.4±0.13	99.15±0.23
F14	307.4±0.15	4.3±0.26	0.48±0.24	4.6±0.12	99.25±0.28
F15	304.5±0.14	4.7±0.67	0.49±0.11	4.5±0.11	99.78±0.15

Weight varation test: The average weight of the tablet is approximately in range of298.3±0.18to 312.5±0.24 mg , the results of the test showed that, the tablet weight were the pharmacopoeia limit.

Hardness test: The results showed that the hardness of the tablets is range of 4.0±0.15 to4.7±0.67 kg/cm^2, which was within IP limits.

Thickness: Thew result showed that thickness of the tablet is ranging form 4.4±0.13 to 4.9 + 0.32

Friabiliity : Tablets of each batch were evaluated for percentage faribility. The faribility of all the formulations was found to be less than 1% as per official requirment of IP indication a good mechanical resistence of tablets.

***In vitro* drug release studies**

Table 4. Dissolution Data of Diclofenac sodium Tablets Prepared With HPMCK4

Time (hr)	Cumulative percent drug Released		
	F1	F2	F3
0	0	0	0
0.5	5.68	6.54	7.23

1	12.45	14.56	10.45
2	20.46	21.67	21.78
3	32.65	34.62	27.76
4	48.71	48.43	38.76
5	56.62	58.92	45.87
6	69.35	63.43	55.63
7	77.51	77.13	69.43
8	81.54	81.34	76.56
9	83.45	83.76	82.56
10	86.59	85.98	88.67
11	88.82	88.42	93.46
12	90.13	92.18	98.56
14	91.45	92.67	97.49

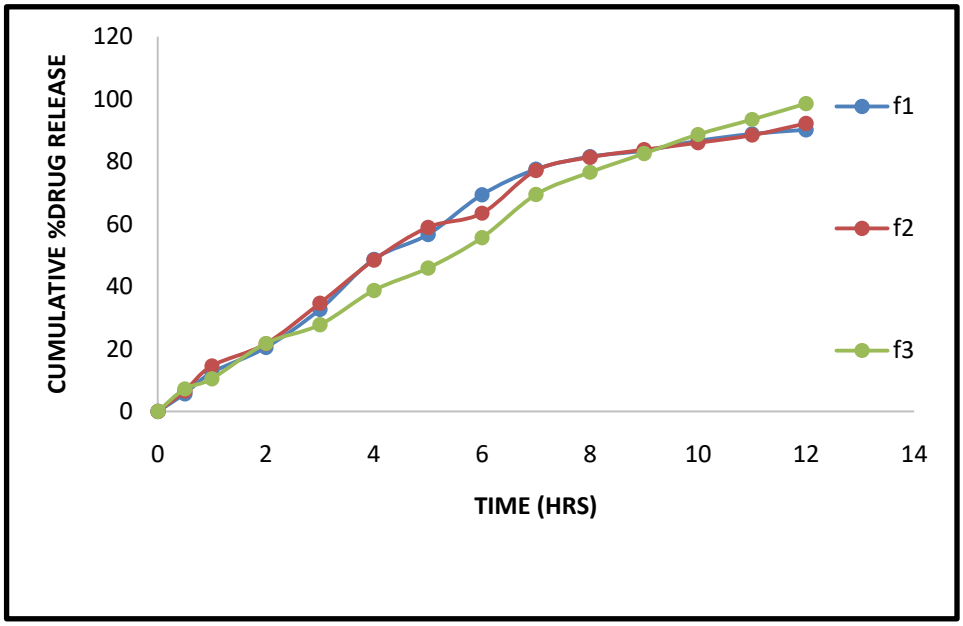

Figure 3. Dissolution profile of diclofenac sodium (F1-F3) containing HPMCK4

Table 5: Dissolution Data of Diclofenac sodium (F4, F5, F6 formulations) prepared with HPMCE15LV

Time (hr)	Cumulative percent drug Released		
	F4	**F5**	**F6**
0	0	0	0
0.5	4.71	6.32	8.29
1	13.54	11.56	13.65
2	21.56	25.75	19.78
3	29.87	37.74	28.18
4	39.1	49.54	38.89
5	44.98	56.27	48.67
6	56.92	66.75	59.91
7	68.77	79.63	69.41
8	73.65	82.75	76.98
9	78.56	84.17	81.65

10	82.19	89.32	85.71
11	85.35	91.85	89.75
12	90.12	92.89	92.57
14	90.34	94.57	92.45

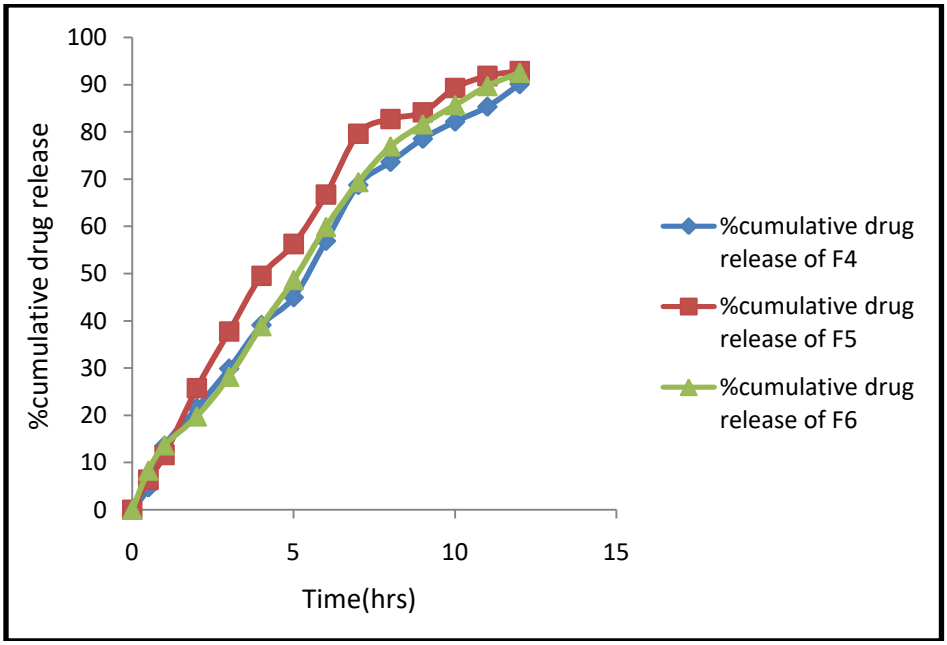

Figure 4: Dissolution profile of Diclofenac sodium (F4, F5, F6 formulations)

Table 6: Dissolution Data of Diclofenac sodium (F7, F8, F9 formulations) prepare with HPMCK100

Time (hr)	**Cumulative percent drug released**		
	F7	**F8**	**F9**
0.5	2.34	4.79	4.09
1	9.31	11.71	10.53
2	15.67	21.65	32.53
3	22.78	38.76	45.71
4	34.76	49.71	52.56
5	43.78	57.41	63.43
6	55.76	65.81	72.31
7	62.87	72.76	76.31
8	75.61	77.61	81.67
9	81.76	82.45	85.91
10	89.94	85.52	87.31
11	88.83	88.65	88.86
12	93.9	90.53	89.97
14	91.78	89.45	89.12

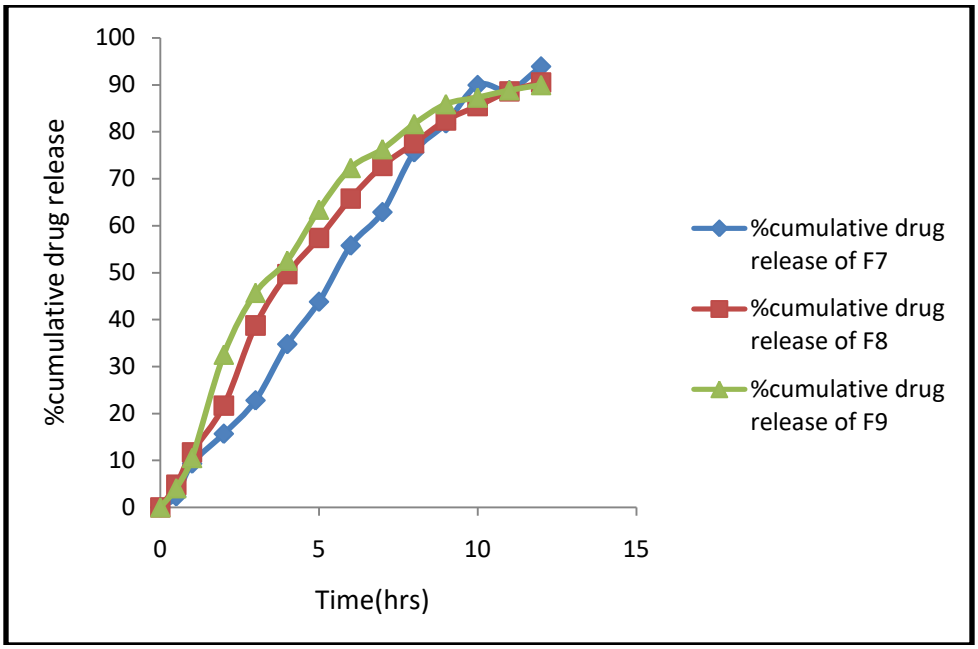

Figure 5: Dissolution profile of Diclofenac sodium (F7, F8, F9 formulations)

Table 7: Dissolution Data of Diclofenac sodium (F10, F11, F12, F13, F14 and F15 formulations) prepare with Okra gum

Time (hrs)	F10	F11	F12	F13	F14	F15
0	0	0	0	0	0	0
0.5	2.34	3.34	2.89	2.45	3.21	2.35
1	8.31	9.31	8.34	8.76	9.45	9.23
2	15.67	16.57	15.78	16.45	17.49	15.54
3	22.78	27.78	23.45	23.68	25.34	24.25
4	34.76	36.46	35.49	34.56	35.78	34.83
5	43.78	45.68	45.12	44.54	46.76	43.89
6	55.76	59.76	58.76	56.76	55.35	54.89
7	62.87	61.87	62.72	62.36	60.98	59.13
8	75.61	78.61	71.34	74.96	73.69	71.56
9	81.56	81.26	74.36	80.57	79.53	73.62
10	82.94	83.94	79.43	81.48	78.54	74.67
11	84.23	84.13	81.87	82.84	79.46	74.96
12	84.38	84.23	82.19	83.47	80.56	75.67
14	84.56	84.87	82.35	84.78	81.67	76.25

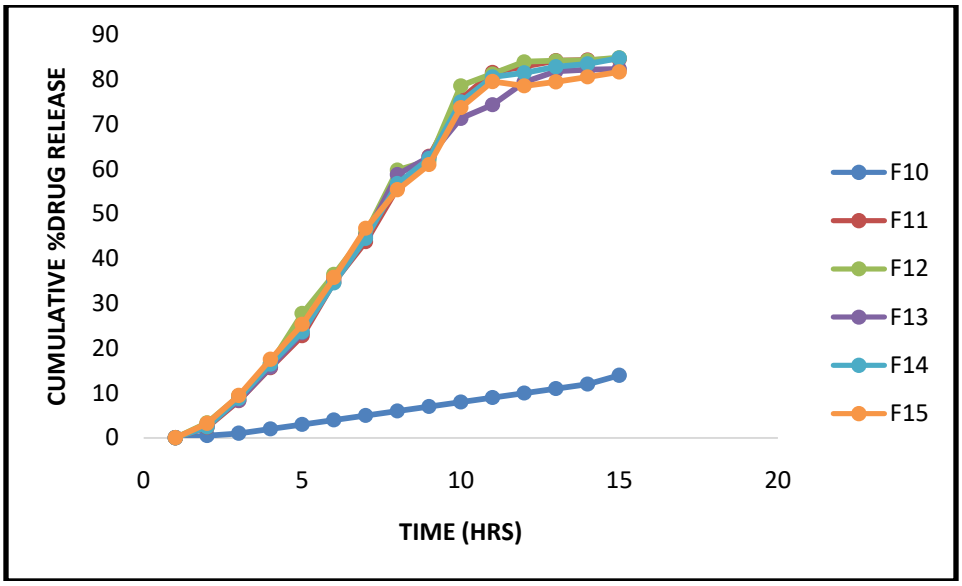

Figure 6.: Dissolution profile of Diclofenac sodium (F10, F11, F12, F13, F14 and F15 formulations)

***In vitro* drug release study**

The *in-vitro* drug release studies were carried out in simulated GIT and pH conditions (1.2 and 6.8). The formulations were subjected to dissolution studies in 0.1N HCl (1.2 pH) for 1.5h followed by 6.8 phosphate buffer until the maximum amount of drug was released. The formulations F1, F2, and F3 were prepared with HPMC K4M and Carbopol 940. The formulation F1(1:1) releases 90% of the drug which is extended up to 14h of dissolution profile which contains 20% of Carbopol as a secondary polymer to offer mucoadhesive Ness and to improve the physic-chemical characteristics of the tablet. The Formulation F2 (1:1.25) releases the same amount (85%) of the drug up to 14h of dissolution study. The Formulation F2 showed no significant difference in the dissolution characteristics with F1which is containing 25% of Carbopol. The Formulation F3 contains the maximum amount of release retarding polymer HPMC K4M and Carbopol (30%) shown the slightly improved and extend release profile in the dissolution (98%) up to 14h. Among all HPMC K4M based formulations F3 shown controlled release profile compare to other formulations. The formulations F4, F5 and F6 were prepared with HPMC E15LV and Carbopol 940. Dissolution studies were conducted until the maximum amount of drug release. The formulations F4 and F5 shown 90% and 92% of the drug release respectively, up to 14h of dissolution study. The formulation F6 released the drug bit higher than F4 indicated that the higher amount of HPMC in the preparation controlled the drug release. These formulations also contain 20, 25 and 30% of Carbopol in the formulae which also influenced the controlled the release to some extent. The formulations F7, F8, F9 controlled the drug release up to 14h. All the three formulations [F7, F8 and F9] released almost same amount of drug that is 83% up to 14h of dissolution profile. These formulations also contain 25, 30, 26% of Carbopol respectively. The formulations F10-F15 prepared with Okra gum with the ratio of 1:0.25, 1:0.5, 1:0.75, 1:1, 1:1.25, and 1:1.5. The Okra gum concentration was increased proportionately, whereas the Carbopol concentration was kept constant in all the Okra gum based formulation. The formulation design was planned to assess the impact of Okra gum on drug release. So that Carbopol concentration was kept constant. The formulations F10 and F11 released were 84% of drug for 14 h. The formulations F12 and F13 released 82% and 84% of the drug respectively. There was no significant retardation observed between F12 and F13. The formulation F15 showed highest controlled release which is 75% followed by F14 of 81%. Among all the formulations Okra gum also shown the competitive controlled release property when compared to commercial synthetic polymers. The physio-chemical properties of the Okra gum based tablets were found to be competitive and equivalent to the tablets prepared with HPMC polymers of different grades. The dissolution profile of triplicate studies was very consistent which confirmed the use of Okra gum as a controlled release polymer.

CONCLUSION

The formulated sustained release matrix tablets of diclofenac sodium. The extended release tablets showed a sustained release for up to 14h, indicating a promising potential of the diclofenac sodium tablet as an alternative to the conventional dosage form. Among the formulations (F1, F2, F3) prepared with HPMC K4M and Carbopol 940 was found to be the best among the formulations (F4, F5, F6) prepared with HPMC E15LV and Carbopol 940, F6 was found to be the best formulation. Among the formulations F7, F8 and F9 prepared with HPMC K100M and Carbopol 940, F9 was found to be the best formulation. Among the Okra gum based formulations F12 and F13 were found to be the best in terms of physio-

chemical properties of the tablets and controlling the drug release profile. Okra gum formulations also competitively showed the controlled release as like the cellulose derivative polymers and it is having the property of muco-adhesiveness, biocompatibility, which is the advantage over the HPMC based formulations. The results of the experimental study confirmed that the polymer concentration significantly influenced the drug release rate. The tablets of optimized formulation F12 (drug polymer ratio of 1:0.75) shown 84 % drug release at the end of 14h indicated that it can extend the drug release till the desired time period of 15h. Overall study report suggested that Okra gum can be successfully used as a controlled release polymer by simple industrial relevant direct compression technique. The optimized formulation was found to be F12 based on precompression and drug release parameters.

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