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FORMULATION, OPTIMIZATION AND *IN-VITRO* EVALUATION OF DICLOFENAC SODIUM LOADED SUSTAINED RELEASE MATRIX TABLET CONTAINING BOTH NATURAL AND SEMI-SYNTHETIC POLYMERS

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Keywords:

HPMC K4M, Guar gum, Matrix tablet, Diclofenac sodium, *In-vitro* drug release

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ABSTRACT: Objective: The persistence of this effort was to frame, evaluate and examine the impact of natural and semi-synthetic polymer in changing the release rates of matrix tablet loaded with diclofenac sodium. **Materials and method:** Matrix tablets of diclofenac sodium were made-up by varying the concentrations of both natural polymer *i.e* Guar gum and semi-synthetic polymer *i.e* HPMC K4M via straight compression method. Optimization of the tablet was completed by taking quantity of Guar gum and HPMC K4M in percentage as self-governing variable and cumulative percent of drug release at 2 hr, 6 hr and 12 hr as faithful variable using design expert Software. Optimized tablet was assessed for various pre and post compression limitations equated with marketed formulation. Drug release kinetics of the optimized tablet was evaluated by various representations of drug release kinetics. **Result:** The verdict of present investigation evidently designates that by using both natural and semi-synthetic polymer in a same tablet was given a noteworthy sustained release. The dissimilarity with the optimized formulation in software data and actual result is not diverge too much. Optimized formulation also screening talented result when linked with marketed formulation. Optimized tablet obeys zero order drug release kinetics. **Conclusion:** It was settled that blend of these natural and semi-synthetic polymer having auspicious effects on sustained release outline of drug from the matrix tablet laden with diclofenac sodium.

INTRODUCTION: The comfort of administration and the flexibility of sustained release dosage forms have been long documented in the pharmaceutical art^{1, 2}. Seeing the number of creations and processing variables^{3 - 6}, sustained release matrix tablets made-up by direct compression are the humblest and the most striking from a formulation and process development viewpoint; so, they are most commonly used expertise in controlled release dosage forms.

Sustained release dosage forms that release medication in a pH independent manner are measured to be of precise value in the area of drug delivery. Such dosage forms offer the budding benefit of reduced unpredictability of bioavailability of drugs that can result from the necessity of drug release *in-vivo* on the variable pH of the gastrointestinal tract⁷⁻⁹.

Semi-synthetic polymer such as HPMC K4M is essentially the cellulose imitative; which satisfy the key criteria of release pattern by swelling property. HPMC has molecular weight 10,000 - 1,500,000. Natural hydrophobic polymer guar gum abridged the degree and extent of drug release owing to reduced porosity of matrix. Guar gum also recognized as guaran, is a material made from guar beans. Chemically it is a polysaccharide collected sugars

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of galactose and mannose. Guar gum has density 0.8-1.0 g/ml and acidity 5-7 with molecular weight 50,000-8,000,000. Both HPMC K4M and guar gums are cellulose polymer based matrix which forms hydrogel due to real-time immigration to the matrix¹⁰.

Diclofenac sodium (2-[2, 6-dichlorophenyl) amino] phenyl) is an aryl acetic acid derivative having a non-selective COX inhibitor activity and sparingly water soluble drug. It is a non steroidal anti-inflammatory, antipyretic analgesic and also hired for long term handling of rheumatoid arthritis, osteoarthritis and further painful and inflammatory circumstances. It has a plasma half life of around 1.5 hrs which necessities frequent dosing.

The most worrying side effects are gastrointestinal distress and are dose associated. The dose of diclofenac sodium in adult persons is 100-300

mg/day. The sustained release dosage form is thus required to progress the bioavailability of drug, reduce the harshness of side effects and improve the patient obedience by giving the drug on once or twice daily basis¹¹.

Here after, the contemporary study has been commenced to formulate, evaluate and examine the effect of natural and synthetic polymer in adjusting the release rates of matrix tablet loaded with diclofenac sodium.

MATERIALS AND METHODS: The model drugs diclofenac sodium was established from Girijananda Chowdhury Institute of Pharmaceutical Science (GIPS), Guwahati, India. All other elements such as HPMC K4M, Guar gum, lactose, magnesium stearate and talc were obtained from GIPS storage. All components used were of analytical grade.

TABLE 1: CHEMICALS AND APPARATUS

Chemicals / Apparatus	Company name/supplier
Diclofenac sodium	Atlantas Height, Vadodara-10
Lactose	Merk specialist pvt limited, Mumbai-18
HPMC K4M	Balaji Drugs, Mumbai-8
Guar Gum	Merk specialist pvt limited, Mumbai-18
Talc	Balaji Drugs, Mumbai-8
Magnesium Stearate	Merk specialist pvt limited, Mumbai-18
Apparatus	Company Name
UV Spectrophotometer	Shimadju, Model no: UV 1800240V
FTIR	Bruker, Model no- 10059736
Tablet compression machine	Shakti Pharmatech, Ahmedabad, India
Dissolution test apparatus	Lab India
Verniercalipers	Alamos
Monsanto hardness tester	Rolex India
Friability tester	Rochi Fribilator
Digital weighing Balance	Denver instruments
Disintegration test apparatus	Rolex India

Assessment of Sustained Release Matrix Tablets:

Pre-formulation Studies: Differential scanning calorimetry (DSC) and Fourier Transformation infrared (FTIR) spectroscopy is used to detect any drug - excipients incompatibility¹³.

Pre-compression Parameters:

Bulk density: It is a proportion of Bulk mass and Bulk Volume is known as Bulk Density. Quantity of powder is weighed distinctly and transferred into 100 ml of measuring cylinder, initial volume of powder material is restrained and designed bulk density giving to following formula.

$$\text{Bulk density} = \text{Mass} / \text{Volume}$$

Tapped Density: It is a proportion of bulk mass and tapped volume is known as tapped density. Tapped density is significant evaluation parameter is resolute by placing a graduated cylinder containing a known mass of powder undertakes tapping in manually (100 tapes) as well as using a motorized apparatus under powder bed capacity has reached a lowest volume. The tapped density is calculated by succeeding formula.

$$\text{Tapped density} = \text{Weight of Powder} / \text{tapped volume of Powder}$$

Compressibility Index or Carr's Index: The design of compressibility index is based on the

tapped density and bulk density. It is a relation of tapped density and bulk density *i.e.* Compressibility index. The following formula for fortitude of compressibility index.

$$CI = \frac{(TD-BD)}{TD} \times 100$$

Where, TD = Tapped density BD = Bulk density

Carr's Index is less than or equal to 10 indicates poor flowing Properties.

Angle of Repose: It describes as the pile surface of powder is recognized as angle of repose. In this method of fortitude of angle of repose in which pour the powder a conical on a level, flat surface and measure the included angle. The ensuing formula for determination of angle of repose.

$$\theta = \tan^{-1}(h/r)$$

Wherever, θ = Angle of repose, h = Height of the powder cone, r = Radius of the powder cone. The Angle of repose is fewer than or equal to 40° designates free flowing properties. The angle of repose is better than 40° indicates poor flow of material.

Hausner's ratio: It is a secondary index of ease of computing of powder flow. Lower Hausner's ratio (<1.25) indicates improved flow properties than higher ones (>1.25).

Hausner's ratio = Tapped density/Bulk density¹³⁻¹⁷

Post Compression Evaluation Hardness: Five tablets since each batch were designated and hardness was measured using Monsanto hardness tester to treasure the average tablet hardness or crushing strength.

Friability (%F): 20 tablets from each bunch were chosen arbitrarily and weighed. These pre weighted tablets were subjected to friability testing utilizing Roche friabilator for 100 upsets.

The tablet to the consolidated impact of scraped area and stun in a plastic chamber rotating at 25 rpm and dropping a tablet at tallness of 6 creeps in every insurgency. Tablets were evacuated, de-tidied and weighed once more. Following recipe was utilized to ascertain the friability.

$$\%F = 1 - (\text{loss in weight} / \text{initial weight}) \times 100$$

Weight Variation: Weight variety: Weight variety was ascertained according to technique described in USP. 20 tablets were weighed independently and the normal weight is computed. The necessities are met if the weights of not more than 2 of tablets vary by more than the rate recorded in **Table 3** and no tablets contrast in weight by more than twofold that rate.

Tablet Thickness: Variety in the tablet thickness may cause issues in including and bundling expansion to weight variety past as far as possible. Tablet thickness ought to be controlled inside a $\pm 5\%$ of a standard esteem. Tablet thickness was measured by Vernier caliper.

Assay: Drug substance of the supported discharge tablet was ascertained utilizing UV Spectrophotometer. Measuring tablet powder comparable to 50 mg of diclofenac sodium. Therefore joined into 100.0 ml of volumetric jar and broke up with 0.1 N NaOH. At that point separated and disposed of the initial 10 ml of filtrate. The filtrate pipetted 2.0 ml and after that additional to the 100.0 ml volumetric carafe with 0.1 N NaOH. Measured the wavelength of most extreme absorbance (λ 276 nm). The tablet was qualified on the off chance that it contained diclofenac sodium from 95.0 to 105.0% of that expressed on the name.

In-vitro Sedate Discharge/ Disintegration Contem-plates: The tablet tests were subjected to *in-vitro* disintegration ponders utilizing USP Type II disintegration mechanical assembly at $37 \pm 2^\circ\text{C}$ and 50 rpm speed. According to the official suggestion of USFDA, 900 ml of 7.4 Phosphate Buffer was utilized as disintegration medium. Aliquot equivalent to 10 ml was pulled back at particular time interims and the disintegration media volume was complimented with crisp and equivalent volume of 7.4 Phosphate Buffer. The aliquots were separated and checked with proper weakening and measure of diclofenac sodium discharged from the tablet tests was resolved spectrophotometrically at a wavelength of 276 nm by contrasting and the standard adjustment bend¹⁸.

Optimization: Optimized detailing was chosen on the premise of supported example of medication discharge and finish measure of medication discharge toward the finish of the *in-vitro* disintegration test.

RESULTS AND DISCUSSION:

Preformulation Studies (DSC and FTIR Study):

The crests of diclofenac sodium are not modification meaningfully. So here is no drug excipients communication **Fig. 1** and **2**.

Pre-compression Parameters: Every one of the tablets were set up by dry granulation technique from Formulations F1 to F9, by taking distinctive extents of the fixings. In every one of the definitions, 100 mg of diclofenac sodium was

consolidated and last weight was made up to 400 mg. The organizations of the considerable number of definitions was given in **Table 2**.

The granules of various definitions were assessed for point of rest, mass thickness, tapped thickness, Carr's record and Hausner's proportion. Edge of rest esteems went from 15.32° - 30.33° indicates great stream property of powder. The free-streaming properties of powder were additionally affirmed by deciding Carr's file and Hausners proportion.

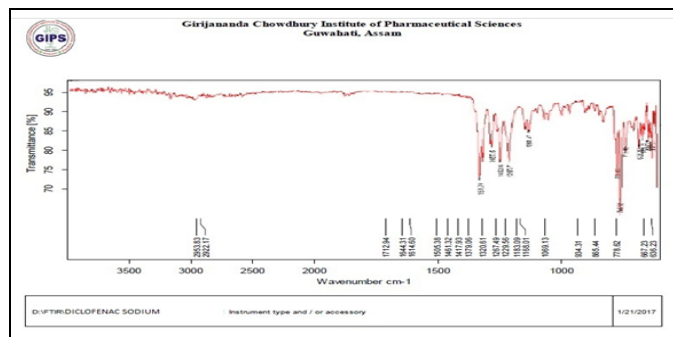


FIG. 1: FTIR OF DICLOFENAC SODIUM

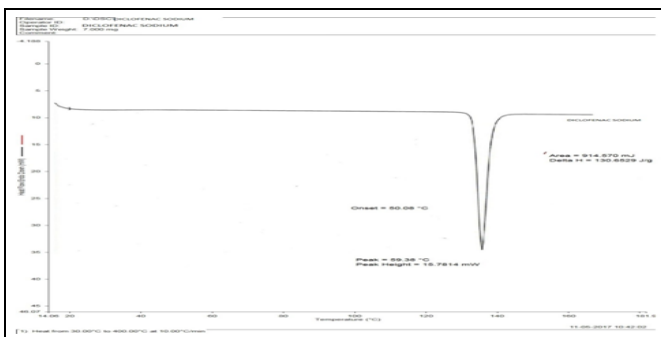


FIG. 2: DSC OF DICLOFENAC SODIUM

TABLE 2: FORMULATIONS OF SUSTAINED RELEASE MATRIX TABLETS OF DICLOFENAC

Components (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Diclofenac sodium	100	100	100	100	100	100	100	100	100
HPMC(K4M)	19	19	19	19	19	14	17	16	16
Guar gum	19	18	17	17	16	19	19	18	19
Lactose	250	251	252	252	277	255	252	254	253
Talc	8	8	8	8	8	8	8	8	8
Mag. stearate	4	4	4	4	4	4	4	4	4

TABLE 3: WEIGHT VARIATION ALLOWED AS USPXX- NF XV

Average weight of tablet (mg)	Percentage difference allowed
<130	10
130-324	7.5
>324	5

The Carr's list esteems and Hausner's proportion esteems were extended from 13.34-15.07 and 1.16-1.18 individually. The outcomes are appeared in **Table 4**. The standards of bulk density ranged from 19.00-31.00 g/ml and the values of tapped density choice since 22.00-36.66 were originate to be inside the restrictions as per USP. Tablets of entirely the formulations were exposed to many in-process estimation limits such as physical appearance, content uniformity, weight variation, hardness, friability and drug release tests are shown in the **Table 5**.

Post Compression Evaluation: Every one of the tablets was round fit as a fiddle with no unmistakable breaks and having smooth appearance.

The normal rate weight variety of 20 tablets from the normal was stayed inside $\pm 0.1\%$. Subsequently weight variety test uncovered that the tablets were inside the scope of pharmacopeia confine. Medication substance of all clusters of tablets were inside the scope of 98.2 to 99.8 % demonstrating great consistency among various plans of the tablets. Every one of the definitions indicated sensibly great hardness esteems went from 4.46-4.56 kg/cm². The rate weight reduction of the considerable number of definitions was under 0.8 %. This shows every one of the tablets withstand the mechanical stuns amid taking care of. Among every one of the Formulations; F6 indicated greatest medication arrival of $97 \pm 0.04\%$ appeared in the **Table 6**.

TABLE 4: MICROMETRICS PROPERTIES OF PRE -COMPRESSIONAL POWDER BLEND

Formulation code	Angle of repose (θ)	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index	Hausner's ratio
F1	30.33 \pm 0.98	30 \pm 0.76	34.00 \pm 0.34	15.07 \pm 0.65	1.18 \pm 0.63
F2	31.33 \pm 0.76	31 \pm 0.75	36.66 \pm 0.87	14.54 \pm 0.56	1.17 \pm 0.83
F3	30.00 \pm 0.65	30 \pm 0.76	34.66 \pm 0.56	13.34 \pm 0.63	1.15 \pm 0.96
F4	25.00 \pm 0.65	25.66 \pm 0.76	22.00 \pm 0.56	14.48 \pm 0.27	1.17 \pm 0.75
F5	19.00 \pm 0.45	19.00 \pm 0.87	22.33 \pm 0.35	14.90 \pm 0.57	1.16 \pm 0.56
F6	22.00 \pm 0.25	22.00 \pm 0.65	26.66 \pm 0.23	15.00 \pm 0.84	1.17 \pm 0.74
F7	19.12 \pm 0.64	19.13 \pm 0.75	25.42 \pm 0.59	13.43 \pm 0.48	1.19 \pm 0.75
F8	18.13 \pm 0.23	18.17 \pm 0.23	23.32 \pm 0.99	15.36 \pm 0.63	1.15 \pm 0.54
F9	15.32 \pm 0.98	15.12 \pm 0.43	27.23 \pm 0.58	14.43 \pm 0.74	1.16 \pm 0.57

TABLE 5: POST-COMPRESSIONAL STUDIES OF DICLOFENAC LOADED MATRIX TABLETS

Formulation code	Weight variation (mg)	Hardness (kg/cm ²)	Thickness (mm)	% Friability
F1	398 \pm 0.005	4.56 \pm 0.2	2.53 \pm 0.1	0.43 \pm 0.08
F2	401 \pm 0.009	4.53 \pm 0.2	2.32 \pm 0.1	0.34 \pm 0.0.05
F3	400 \pm 0.002	4.56 \pm 0.3	2.53 \pm 0.1	0.13 \pm 0.07
F4	399 \pm 0.008	4.46 \pm 0.2	2.56 \pm 0.1	0.24 \pm 0.04
F5	398 \pm 0.004	4.56 \pm 0.2	2.56 \pm 0.1	0.16 \pm 0.08
F6	397 \pm 0.008	4.46 \pm 0.3	2.58 \pm 0.1	0.15 \pm 0.02
F7	399 \pm 0.002	4.65 \pm 0.3	2.62 \pm 0.1	0.17 \pm 0.05
F8	400 \pm 0.007	4.55 \pm 0.3	2.65 \pm 0.1	0.12 \pm 0.0.1
F9	398 \pm 0.005	4.76 \pm 0.2	2.59 \pm 0.1	0.17 \pm 0.07

N.B: (Average of five formulation, n=5)

In choice of improved detailing combined % of medication discharge versus time was considered and that plan F6 has demonstrated the most

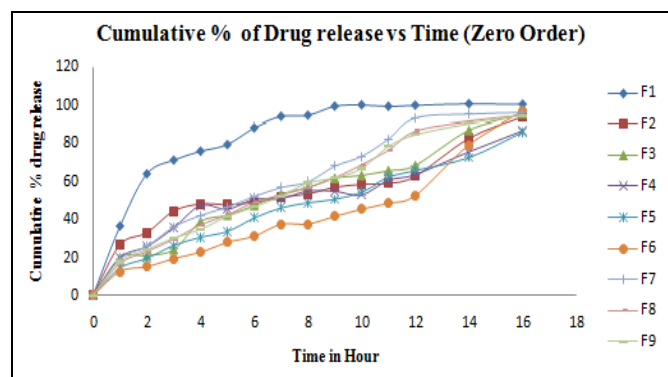
maintained and finish discharged portrayed for longer timeframe up to the 16 hour appeared in the **Table 6**.

TABLE 6: CUMULATIVE DRUG RELEASE VS TIME

Time (h)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	36.64 \pm 2.05	26.62 \pm 2.73	19.79 \pm 1.75	19.79 \pm 0.87	14.39 \pm 0.76	12.58 \pm 2.87	19.09 \pm 3.32	16.76 \pm 2.87	17.76 \pm 1.98
2	64.28 \pm 1.80	32.98 \pm 1.26	21.01 \pm 2.87	25.70 \pm 1.87	19.51 \pm 3.23	15.09 \pm 2.86	25.79 \pm 1.42	23.09 \pm 2.87	24.16 \pm 1.86
3	71.55 \pm 2.10	44.38 \pm 1.54	24.07 \pm 2.87	35.55 \pm 2.65	26.37 \pm 1.53	19.41 \pm 2.75	36.02 \pm 2.33	29.58 \pm 1.86	30.28 \pm 2.87
4	76.26 \pm 2.03	48.13 \pm 1.75	38.92 \pm 1.87	47.44 \pm 2.54	30.68 \pm 1.98	22.78 \pm 1.86	42.05 \pm 1.54	37.14 \pm 1.76	34.89 \pm 1.87
5	79.81 \pm 1.42	47.82 \pm 2.86	42.36 \pm 2.75	45.43 \pm 1.65	33.75 \pm 2.98	28.01 \pm 1.35	46.54 \pm 1.98	42.49 \pm 2.98	41.79 \pm 2.65
6	88.58 \pm 2.11	48.99 \pm 3.86	47.52 \pm 0.89	50.65 \pm 3.76	40.90 \pm 1.97	31.29 \pm 2.86	52.07 \pm 1.43	49.15 \pm 3.98	46.79 \pm 1.87
7	94.15 \pm 1.30	51.73 \pm 1.875	53.51 \pm 2.87	50.99 \pm 1.876	46.27 \pm 2.75	37.59 \pm 0.89	56.83 \pm 2.86	53.03 \pm 1.87	52.57 \pm 3.98
8	94.69 \pm 1.49	53.43 \pm 0.64	56.98 \pm 1.45	55.10 \pm 3.32	48.93 \pm 0.76	37.77 \pm 1.68	59.77 \pm 3.98	56.93 \pm 1.87	59.51 \pm 2.98
9	99.43 \pm 0.61	56.94 \pm 1.75	61.93 \pm 1.43	54.90 \pm 1.31	50.80 \pm 3.91	41.70 \pm 1.76	68.10 \pm 2.09	62.03 \pm 2.76	62.25 \pm 1.98
10	100.13 \pm 0.77	58.45 \pm 1.75	63.43 \pm 1.75	53.02 \pm 2.76	54.64 \pm .87	45.63 \pm 1.34	73.29 \pm 1.98	69.04 \pm 3.87	67.16 \pm 1.89
11	99.36 \pm 0.94	59.02 \pm 1.67	65.93 \pm 2.98	60.70 \pm 1.87	61.97 \pm 1.88	48.71 \pm 1.76	82.29 \pm 2.54	76.55 \pm 1.43	78.81 \pm 1.78
12	99.93 \pm 1.44	62.73 \pm 1.87	68.67 \pm 1.87	63.74 \pm 2.88	65.50 \pm 2.98	52.76 \pm 2.74	93.69 \pm 1.34	86.58 \pm 2.43	84.96 \pm 1.87
14	100.72 \pm 0.73	82.67 \pm .98	87.25 \pm 2.87	75.69 \pm 1.18	72.30 \pm 1.76	79.61 \pm 2.12	95.73 \pm 1.34	91.56 \pm 2.43	90.79 \pm 2.98
16	100.45 \pm 0.61	94.26 \pm 3.43	95.36 \pm 1.87	86.77 \pm 2.76	85.55 \pm 0.98	97.04 \pm 1.54	96.60 \pm 1.43	94.48 \pm 1.32	94.77 \pm 2.87

By looking at discharged profile energy of the advanced definition F6 with promoted plan it was seen that the improved detailing has preferred managed profile over showcased plan appeared in the diagram.

The various model of drug release were figure out from **Fig. 3, 4, 5** and **6** and it clearly indicated that it obeyed zero order kinetics. When % cumulative drug release of prepared formulation were compared with marketed product it showed that the formulation F6 had better drug release profile then marketed one **Fig. 7**.

**FIG. 3: CUMULATIVE % OF DRUG RELEASE VS TIME GRAPH**

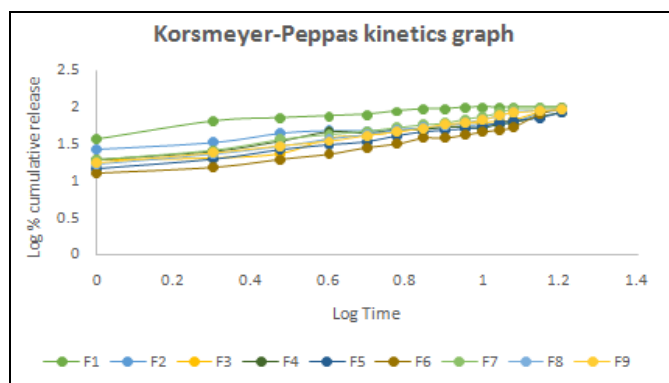


FIG. 4: KORSMEYER-PEPPAS KINETICS MODEL

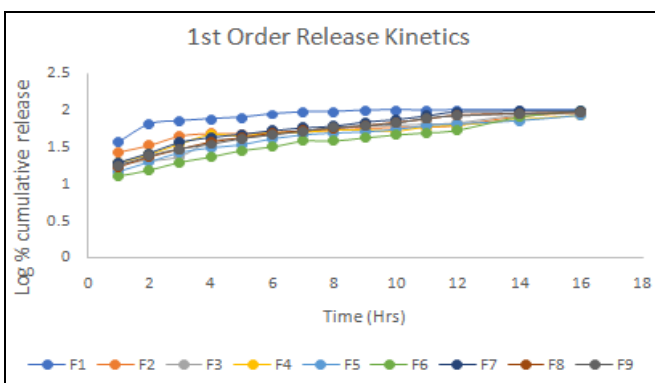
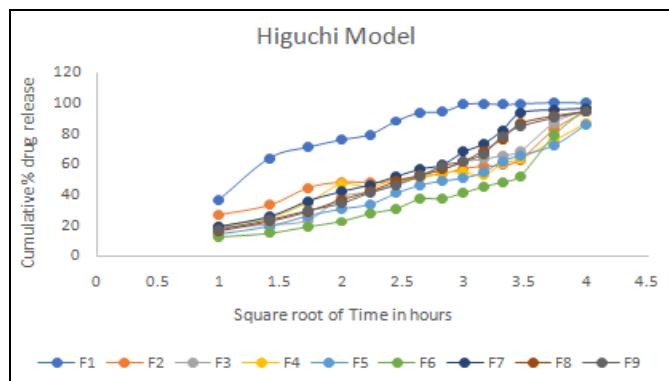
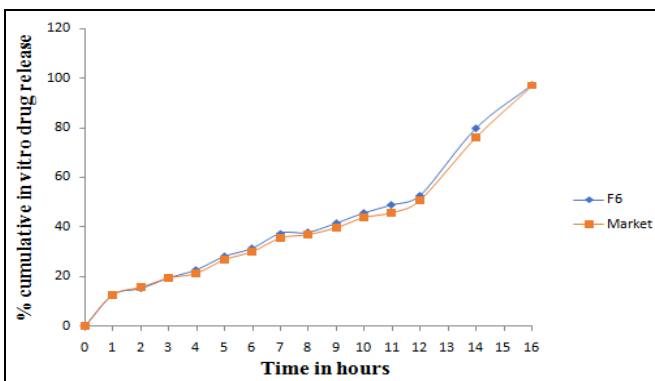
FIG. 5: 1ST ORDER RELEASE KINETICS

FIG. 6: HIGUCHI MODEL

FIG. 7: % COMPARATIVE *IN-VITRO* DRUG RELEASE OF OPTIMIZED FORMULATION F6 AND MARKETED PREPARATION

CONCLUSION: From the above examination, it was evaluated that the semi-synthetic polymer display discharge over a long stretch. Normal polymers have more discharge retardant property than semi-manufactured polymer. Accessibility of adequate time for swelling and gelling was in charge of the moderate arrival of medication. The thickness of HPMC K4M was more than the guar gum so; it was demonstrating better outcome in framework tablet. Furthermore, the hydration rate of HPMC relies upon the idea of the substituents like hydroxy-propyl a mass content.

Thus, HPMC K4M was shaped a solid thick gel in contact with fluid media which might be valuable in controlled conveyance of medication than normal polymer. At long last it was settled that mix of these regular and semi-manufactured polymer affecting supported discharge blueprint of medication from the network tablet weighed down with diclofenac sodium.

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