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FORMULATION AND EVALUATION OF SUSTAINED RELEASE MATRIX TABLET OF LORNOXICAM USING ACACIA AND HPMC K15M

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ABSTRACT

The work aims at investigating different types and levels of hydrophilic matrixing agents like Acacia and HPMC K15M, is an attempt to formulate sustained release matrix tablets containing Lornoxicam. Lornoxicam, a potent non-steroidal anti-inflammatory drug which has short half-life, makes the development of sustained release forms extremely advantageous. The standard curve of Lornoxicam was prepared in phosphate buffer pH 6.8 at 376 nm. Nine formulations were developed by wet granulation method. The *in vitro* release studies were carried out using USP type II apparatus i.e. paddle type. The *in vitro* dissolution studies were carried out in pH 1.2 buffer (0.1 N HCl) for the first two hours and afterwards the medium was phosphate buffer pH 6.8 for next 12 hours. From among all the developed formulations, batch F9 was found to show better release profile and hence formulation F9 was optimized. In the above view of findings it can be concluded that the combination of hydrophilic polymers that are retardant in nature are better suited for sustained and controlled drug delivery system than the hydrophilic polymer alone.

KEYWORDS

Lornoxicam, Acacia gum, HPMC K15M, Wet granulation method and Sustained release.

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INTRODUCTION

Oral route is very admired and commodious route of a drug administration. Oral route of administration has been used for both conventional and novel drug delivery system. In the modern era, sustained release dosage form is suppressing the use of conventional dosage form[1]. The sustained release or controlled release tablet provides uniform release of drug over extended period of time. Controlled release dosage form covers a wide range of prolonged action formulation which provides

continuous release of their active ingredient at a predetermined rate and time[2]. Sustained release drug delivery system is used to reduce the frequency of drug dosing or to increase the effectiveness of drug, providing continuous drug delivery, reduce incidence of adverse effect and maintain drug concentration in system[1,3]. Matrix tablet serve as an important tool for oral extended release dosage forms. Hence, various problems like patient compliance, drug targeting, local side effects, frequent administration and fluctuations in blood concentration levels, associated with their counterparts, therefore the conventional dosage forms restricted. A matrix tablet is the oral solid dosage form in which the drug or active ingredient is homogeneously dispersed throughout matrices which serve as release rate retardants[4].

The term arthritis means "joint inflammation" but is generally used to describe inflammatory and degenerative conditions of the joints. There are hundred different kinds of arthritis, the most common of which is the osteoarthritis, rheumatoid arthritis and gout[5]. Lornoxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class. It has analgesic, anti-inflammatory and antipyretic properties. Lornoxicam drug is used in relieving symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute sciatica and low back pain. It inhibits prostaglandin biosynthesis by blocking the enzyme cyclo-oxygenase (both COX-1 and COX-2). Maximum plasma concentrations are achieved after approximately 1 to 2 hours. The absolute bioavailability of Lornoxicam is 90-100%. After administration, Lornoxicam is found in the plasma in unchanged form and as it's needed for Lornoxicam because of its short biological half-life of 3 to 5 hours and also to minimize the gastro-intestinal disturbances such as peptic ulceration with or without bleeding if present in larger concentration in gastro-intestinal tract[6].

MATERIAL AND METHODS

Materials

Lornoxicam, HPMC K15M, Acacia and Microcrystalline cellulose were obtained as a gift sample from Alkem Laboratories Ltd, Mumbai, India. Magnesium stearate, Polyvinyl pyrrolidone K30 and Talc were purchased from S.D. Fine-Chem Limited, Mumbai, India. All other reagents used in this experiment were analytical grade.

Method

Different tablet formulations were prepared by wet granulation method. Matrix tablet each containing 8 mg of Lornoxicam were prepared by mixing natural (Acacia) and synthetic (HPMC K15M) polymers in different concentration as per the formula given in the Table No.1. The total weight of tablet was kept at 100mg.

The powder were mixed with sufficient quantity of polyvinyl pyrrolidone K30, the granulating solution i.e. purified water was added and mixed thoroughly to form dough mass. The mass was passed through mesh no. 12 to obtain wet granules. The wet granules were dried at 40°c for 2 hr. The dried granules were passed mesh no. 16 to break the aggregates. The granules were mixed with required quantities of talc and magnesium stearate. The required amount of granules for sustained release layer was compressed into tablets on a single punch tablet machine using 6 mm round and convex punches of a rotary multi station tablet punching machine[7].

EVALUATION PARAMETERS

Pre-formulation Studies

Fourier Transform Infra-red spectroscopy

The Fourier transform infra-red analysis was conducted for the structure characterization. FTIR spectra of the pure drug, polymers and formulations were recorded by using Prestige 21 SHIMADZU FTIR instrument. The drug sample was scanned over the range of 4000-400 cm^{-1}.

Pre-compression studies of sustained release tablet granules[8]

Angle of repose

The angle of repose was determined by the fixed height cone method suggested by Newman. The accurately weighed granules (3 gm) were taken in a funnel. The height (h) of the funnel was adjusted such a way that the tip of the funnel just touched the

apex of the heap of the granules. The granules were allowed to flow through the funnel freely onto the graph paper placed on the surface. The diameter of the power cone was measured and angle of repose was calculated using the following equation.

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

Where, θ = Angle of repose, h = Height of the cone, r = Radius of cone base

Bulk density and Tapped density

Both loose bulk density (LBD) tapped bulk density (TBD) were determined. 3 gm of granules were weighed separately from each individual formula and introduced into 10 ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2 seconds intervals. The tapping was continued until no further change in volume was noted. The loose bulk density (LBD) and tapped bulk density (TBD) were calculated using the following formulae

LBD = weight of powder/volume of the packing

TBD = weight of powder/tapped volume of the packing

Compressibility index

The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content and cohesiveness of materials because all of these can influence the observed compressibility index. The compressibility index is determined by measuring both the bulk density and the tapped density of a powder. The following equation is used to find the compressibility index.

Compressibility Index = [(Tapped Density – Bulk Density) / Tapped Density] x 100

Hausner's ratio

It indicates the flow properties of the powder and ratio of tapped density to the bulk density of the powder or granules.

Hausner's Ratio = Tapped Density/ Bulk Density

Post compression studies of Lornoxicam sustained release matrix tablet

Hardness

Hardness of each tablet was determined using the Monsanto hardness tester. The tablet to be tested was held between a fixed and a moving jaw and reading of the indicator adjusted to zero. The force applied to the edge of the tablet is gradually increased by moving the screw knob forward until the tablet breaks. The reading is noted from the scale which indicates the pressure required in kg or lb to break tablet. The hardness of 6 tablets, from each batch was determined and mean hardness was taken[9,10].

Thickness

The thickness of the tablets was determined by using vernier callipers. Ten tablets from each batch were used. Thickness values are reported in millimetres. Mean and SD values were also calculated[9].

Friability

Friability of tablet was determined using Roche friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and dropping the tablets at a height of 6 inches in each revolution. Preweighed sample of tablets was placed in the friabilator and were subjected to 100 revolutions. Tablets were de dusted using a soft muslin cloth and reweighed[10]. The friability is given by the formula:

Friability (%) = (Initial weight – Final weight / Initial weight) x 100

Weight variation test

Weight variation study was carried out as per USP. Twenty tablets were randomly selected. The average weight and standard deviation was calculated[8].

Drug uniformity content

For determination of drug uniformity content at least 10 tablets were accurately weighed and average weight is calculated. All tablets were crushed and powder equivalent to 8 mg of powder was taken and diluted upto 100 ml with pH 6.8 phosphate buffer. Then aliquot of the filtrate was diluted suitably and analysed spectrophotometrically at 376 nm against blank. Drug content was calculated using standard curve[9].

***In-vitro* release profile of formulated tablets:**

In-vitro drug release study was carried out for all the formulation using USP- XXI dissolution test

apparatus. The study was conducted at 37±0.5^0 C and stirred at 50 rpm for 2 hr in 900 ml buffer (simulated gastric fluid pH 1.2). Then the dissolution medium was replaced with 900 ml (simulated intestinal fluid pH 6.8). 5 ml of samples were withdrawn at different time intervals and an equal amount of medium was replaced to maintain sink conditions. The aliquots were diluted suitably and the amount of drug released was determined spectrophotometrically at 376 nm using reagent blank. The concentration of drug in sample solution was determined from calibration curve[11].

Swelling characteristics of fabricated tablet:

The extent of swelling was measured in terms of % weight gain by the tablets. The swelling behaviour of formulations was studied. One tablet from each formulation was kept in a petri dish containing phosphate buffer pH 6.8. At the end of 2 hr, the tablet was withdrawn, kept on tissue paper and weighed, repeated for every 2 hr till the end of 12 hr[6].

The % weight gain by the tablet was calculated by following equation:

$S.I = \{(M_t-M_0)/M_0\} \times 100$

Where, S.I = Swelling Index, M_t = Weight of tablet at time't' and M_0 = Weight of tablet at time '0'.

RESULTS AND DISCUSSION

Pre-formulation Studies

Fourier Transform Infra-red spectroscopic studies

The Fourier transform infra-red analysis was conducted for the surface structure characterization. FTIR spectrum of the pure drug, polymers and formulations was recorded. The Fourier transform infra-red spectroscopy study reveals that there is no interaction between the pure drug, polymers and formulations. Then all the functional groups of Lornoxicam, polymers and optimized batch (f9) were found in the IR spectrum.

Pre-compression studies of sustained release tablet granules

Angle of Repose

The data obtained from angle of repose for the all formulations were found to be in the range of 26.91° and 29.51°. All the formulations prepared showed the angle of repose less than 30°, which revels good flow property. The results are shown in Table No.5.

Bulk density and Tapped density

The bulk density of various granules blends were measured by graduated cylinder. Loose bulk density (LBD) and tapped bulk density (TBD) for the blend was performed. The bulk densities and tapped densities for the formulations were in the range of 0.32 to 0.46 and 0.36 to 0.53 g/cc respectively. The results are given in Table No.5.

Compressibility index

The compressibility index for the all formulation blend ranged from 11.61 to 13.53. It indicates good flow properties of the granules. The results are given in Table No.5.

Hausner's ratio

Hausner's ratios of formulations were found to be in the range of 1.13 to 1.16. It indicates good flow properties of the granules. The results are given in Table No.5.

Post compression studies of Lornoxicam sustained release matrix tablet

Hardness

The hardness of all the tablets prepared by the wet granulation method was maintained within the range of 5.57±0.30 to 5.89±0.64 kg/cm^2. In all the formulations the hardness test indicates good mechanical strength. The mean hardness test results are tabulated in Table No.6.

Thickness

The thicknesses of all the formulation were ranged from 3.06±0.13 to 3.18±0.03 mm. The results of thickness for tablets were shown in Table No.6.

Friability

The sustained release tablets friability values are found to be less than 1% in all cases and considered to be satisfactory. The results are shown in Table No.6.

Weight variation test

All this sustained release tablets passed weight variation test as the % weight variation was within the pharmacopoeia limits. The weight variation was found in the range of 100.46±0.30 mg to 104±0.15

mg. The weight variation results revealed that average percentage deviation of 10 tablets of each formulation was less than ±7.5%. The mean weight variation test results are tabulated in Table No.6.

Drug uniformity content

Drug content of all the batches are within the acceptable range which shows the proper mixing of the drug with the excipients. The results are shown in Table No.6.

***In-vitro* release profile of formulated tablets**

In-vitro drug release study of Lornoxicam sustained release matrix tablet were carried out by using phosphate buffer pH 6.8 at temperature 37±0.5°c with paddle rotation at 50 rpm for 12 hrs. In order to find out the release and mechanism, which was predominantly influence the drug release from the tablet, *in vitro* dissolution data was subjected to graphical treatment i.e. % cumulative drug release *Vs* time. The results are shown in Table No.7.

The *in-vitro* release data obtained were fitted into various kinetic models. The regression values (R^2) of zero order kinetics of formulations ranges from 0.9937 to 0.9987 and the regression values (R^2) of first order kinetics of formulations ranges from 0.9001 to 0.9412. The regression values (R^2) of higuchi model of formulations ranges from 0.9782 to 0.9900 and the regression values (R^2) korsmeyer-peppas model of formulations ranges from 0.9777 to 0.9963. So we can say that after study of dissolution of all formulations follows Anomalous transport it means formulations shows extended release. The results are shown in Table No.8.

Swelling characteristics of fabricated tablet

The sustained release tablets of Lornoxicam were evaluated for water uptake study (% Swelling index), the results are given in Table No.9.

DISCUSSION

Sustained release tablets of Lornoxicam were prepared using synthetic and natural polymers by wet granulation method. FTIR spectrum of the pure drug, polymers and formulations was recorded. The Fourier transform infra-red spectroscopy study reveals that there is no interaction between the pure drug and composition of polymers. The granules were evaluated for pre compression studies and the values of angle of repose, bulk density, tapped density, compressibility index and hausner's ratio are within limits, indicating that the granules have the required flow property and the post compression studies values have within the acceptable range such as hardness, thickness, friability and weight variation profile of sustained release tablets from each batch was carried in phosphate buffer pH (6.8) for 12 hours by using the *in vitro* dissolution data. Depending upon swelling index formulation F9 results more gel formation and forms a gelatinous barriers, which may retard the drug release in the formulation. So it demonstrates that drug release from matrix tablet decreases with increases in the concentration of polymers. From *in-vitro* drug release profile, formulation F9 showed better release profile i.e. 99.42% drug release at the end of 12 hrs and F9 formulation showed that the 'n' values of formulation F9 was in between 0.864 shows Non-Fickian diffusion as a release mechanism.

Table No.1: Formulation of different batches of Lornoxicam sustained release matrix tablet

S.No	Ingredients (mg/tablet)	Formulation code								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Lornoxicam	8	8	8	8	8	8	8	8	8
2	HPMC K15M	8	16	24	---	---	---	4	8	12
3	Acacia	---	---	---	8	16	24	4	8	12
4	MCC	72	64	56	72	64	56	72	64	56
5	PVP K30	6	6	6	6	6	6	6	6	6
6	Purified Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
7	Magnesium stearate	2	2	2	2	2	2	2	2	2
8	Talc	4	4	4	4	4	4	4	4	4

Table No.2: Angle of Repose I.P. limits

S.No	Flow Property	Angle of Repose
1	Excellent	25–30
2	Good	31–35
3	Fair	36–40
4	Passable	41–45
5	Poor	46–55
6	Very poor	56–65
7	Very, very poor	>66

Table No.3: Compressibility Index (%) and Hausner's Ratio I.P. limits

S.No	Compressibility Index (%)	Flow property	Hausner's Ratio
1	≤10	Excellent	1.00–1.11
2	11–15	Good	1.12–1.18
3	16–20	Fair	1.19–1.25
4	21–25	Passable	1.26–1.34
5	26–31	Poor	1.35–1.45
6	32–37	Very poor	1.46–1.59
7	>38	Very, very poor	>1.60

Table No.4: Weight variation tolerance for uncoated tablets

S.No	Average weight of tablets (mg)	Maximum % Deviation Allowed
1	130 mg or less	10%
2	130 mg to 324 mg	7.5%
3	More than 324	5%

Table No.5: Pre-compression studies of sustained release tablet granules

S.No	Formulation code	Angle of repose (degree)	Bulk density (gm/cc)	Tapped density (gm/cc)	Compressibility index (%)	Hausner's Ratio
1	F1	27.57	0.35	0.40	11.86	1.13
2	F2	27.64	0.34	0.39	12.24	1.14
3	F3	27.34	0.37	0.42	11.61	1.13
4	F4	29.51	0.36	0.41	12.42	1.14
5	F5	26.91	0.39	0.45	12.84	1.15
6	F6	28.27	0.39	0.45	12.46	1.15
7	F7	28.73	0.46	0.53	13.53	1.16
8	F8	29.19	0.33	0.38	13.14	1.15
9	F9	29.12	0.32	0.36	12.66	1.15

Table No.6: Post compression studies of Lornoxicam sustained release matrix tablets

S.No	Formulation code	Hardness (kg/cm2) ±SD (n=3)	Thickness (mm) ±SD (n=3)	Friability (%) ±SD (n=3)	Weight variation (mg) ±SD (n=3)	Drug content (%)
1	F1	5.78±0.35	3.16±0.03	0.68±0.14	100.63±0.60	98.48
2	F2	5.89±0.64	3.12±0.05	0.65±0.12	100.53±0.30	98.24
3	F3	5.58±0.32	3.18±0.03	0.78±0.15	100.76±0.60	97.28
4	F4	5.76±0.22	3.06±0.13	0.69±0.06	100.83±0.64	96.84
5	F5	5.57±0.30	3.14±0.03	0.76±0.09	100.46±0.30	98.92
6	F6	5.64±0.37	3.16±0.06	0.57±0.12	101.16±0.75	96.44
7	F7	5.87±0.48	3.11±0.03	0.71±0.14	104.7±0.15	99.24
8	F8	5.67±0.11	3.13±0.04	0.81±0.11	100.66±0.68	94.20
9	F9	5.89±0.42	3.11±0.02	0.69±0.07	101.23±0.32	98.72

Table No.7: Cumulative % drug release of Batch F1 to F9

S.No	Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	00.00	00.00	00.00	00.00	00.00	00.00	00.00	00.00	00.00
2	1	5.26	10.57	11.95	4.57	7.57	8.26	8.03	12.18	12.87
3	2	15.56	19.00	15.10	16.25	18.77	21.30	16.93	17.62	19.46
4	3	26.65	24.14	19.81	24.83	25.06	29.85	25.97	26.20	27.34
5	4	35.13	29.23	30.82	35.58	30.14	34.45	33.77	34.90	35.58
6	5	39.22	37.41	43.05	43.51	36.96	39.44	38.99	46.67	47.57
7	6	51.79	47.97	46.63	46.85	48.42	53.13	46.85	51.11	52.46
8	7	58.18	55.51	54.39	54.39	59.52	57.96	61.31	56.62	61.31
9	8	65.39	60.95	59.18	64.95	68.50	66.50	70.49	64.95	68.94
10	9	66.78	68.32	66.78	76.70	72.51	70.31	75.38	75.82	77.58
11	10	74.28	82.18	75.38	80.64	77.35	78.01	78.89	87.22	84.81
12	11	81.48	89.11	87.80	86.27	84.53	88.45	93.90	94.77	96.30
13	12	92.48	93.35	94.22	96.38	96.60	96.82	97.90	98.55	99.42

Table No.8: Kinetic model fitting

S.No	Formulation code	R^2				'n' value
		Zero order	First order	Higuchi model	Korsmeyer-Peppas model	
1	F1	0.9937	0.9403	0.9830	0.9885	0.987
2	F2	0.9968	0.9377	0.9814	0.9886	0.896
3	F3	0.9955	0.9168	0.9782	0.9777	0.898
4	F4	0.9966	0.9171	0.9890	0.9870	0.891
5	F5	0.9960	0.9017	0.9861	0.9897	0.990
6	F6	0.9965	0.9249	0.9885	0.9882	0.928
7	F7	0.9964	0.9217	0.9858	0.9859	0.895
8	F8	0.9973	0.9001	0.9847	0.9949	0.888
9	F9	0.9987	0.9412	0.9900	0.9963	0.864

Table No.9: % Swelling Index of Batch F1 to F9

S.No	Time in hrs	% Swelling Index								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	1	22.57	26.80	36.04	28.56	32.12	42.80	48.05	58.29	67.14
2	2	35.52	39.91	39.32	39.90	43.38	51.76	63.89	72.35	80.84
3	3	47.63	49.43	52.28	50.12	58.48	67.34	75.77	86.34	92.27
4	4	59.51	62.02	59.52	57.35	69.11	78.43	87.83	97.20	106.01
5	5	72.63	76.01	77.44	73.42	77.92	87.76	98.70	111.22	119.31
6	6	81.92	84.06	86.70	79.43	88.81	104.21	109.81	120.29	131.78
7	7	79.72	80.73	81.89	76.23	84.31	99.08	105.21	114.66	126.07
8	8	75.78	74.56	75.33	73.36	79.27	95.07	100.79	111.52	120.80
9	9	73.03	71.61	73.02	69.61	75.58	90.22	94.10	108.70	116.62
10	10	68.71	66.44	69.83	67.66	71.77	87.75	91.09	104.85	114.03
11	11	63.69	61.50	66.83	65.46	68.63	83.32	87.46	99.78	110.91
12	12	59.52	55.93	63.53	61.14	65.51	78.62	84.42	95.46	104.92

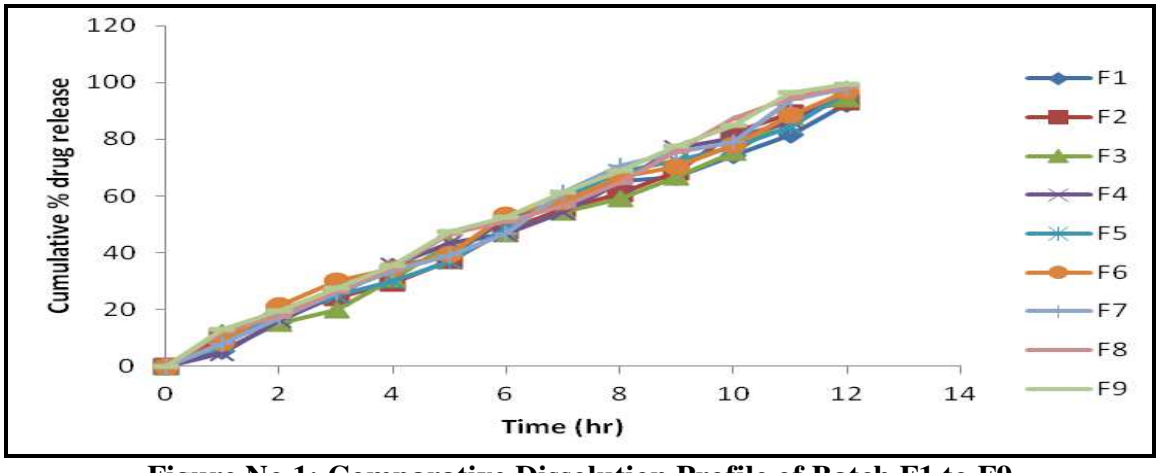

Figure No.1: Comparative Dissolution Profile of Batch F1 to F9

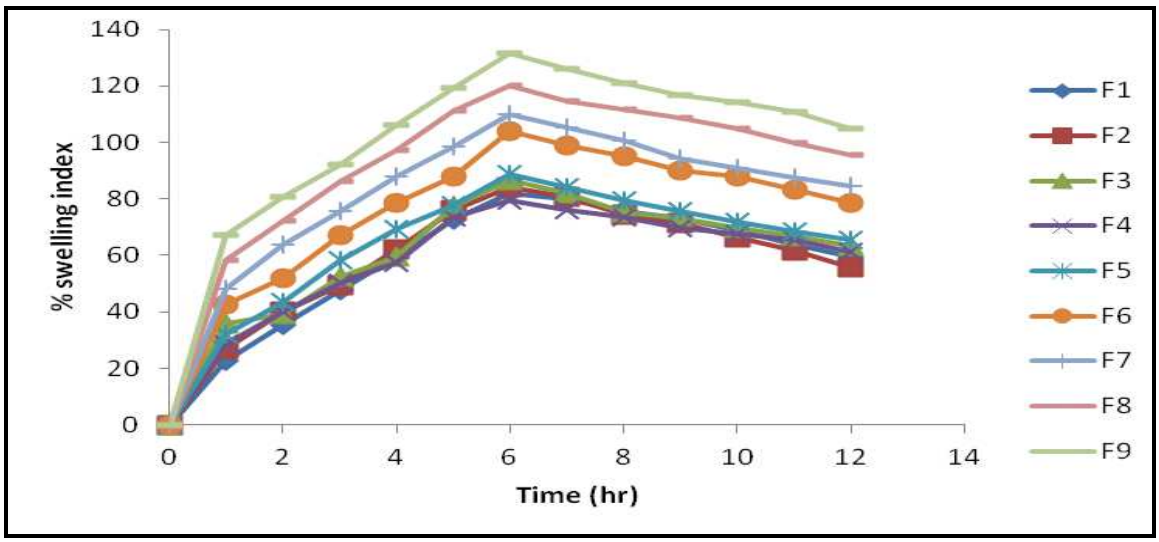

Figure No.2: Comparative % swelling index of Batch F1 to F9

CONCLUSION

Development of sustained release matrix tablet of Lornoxicam can be prepared because extended release formulation can reduce frequency of dose administration, can reduce side effects and improve patient compliance. Therefore in the present study, matrix tablets of Lornoxicam were prepared using combination of HPMC K15M and Acacia by wet granulation method. From the studies it was concluded that batch F9 was showed satisfactory results upto 12 hours.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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