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Formulation and Evaluation of Extended Release Tablets of Lornoxicam

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ABSTRACT
The short half- life of lornoxicam, a potent non-steroidal anti-inflammatory medicine, makes the development of extended- release (ER) forms extremely profitable. still, due to its weak acidic nature, its release from ER delivery systems is limited to the lower gastrointestinal tract which accordingly leads to a delayed onset of its analgesic action. Consequently, the end of this study was to develop lornoxicam ER matrix tablets that give complete medicine release that starts in the stomach to fleetly palliate the painful symptoms and continues in the intestine to maintain prolonged analgesic effect as well as meets the reported ER specifications. The proposed strategy was grounded on preparing directly compressed hydroxypropylmethylcellulose matrix tablets to extended lornoxicam release. Basic pH- modifiers, either sodium hydroxide or Potassium dihydrogen orthophosphate, were incorporated into these matrix tablets to produce introductory micro environmental pH inside the tablets favourable to medicine release in acidic conditions. All the set matrix tablets containing introductory pH modifiers showed respectable physical parcels before and after storehouse. Release studies, performed in dissembled gastric and intestinal fluids used in sequence to mimic the GI conveyance.

KEYWORDS- Lornaxicam, NSAID, extended-release Tablet, hydroxypropyl methyl cellulose matrix tablets

I. INTRODUCTION

Utmost conventional oral medicine products, similar as tablets and capsules, are formulated to release the active medicine incontinently after oral administration, to gain rapid-fire and complete systemic medicine immersion. similar immediate- release products affect in fairly rapid-fire medicine immersion and onset of accompanying pharmacodynamic goods. still, after immersion of the medicine from the lozenge form is complete, tube medicine attention decline according to the medicine's pharmacokinetic profile. ultimately, tube medicine attention fall below the minimum effective tube attention, performing in loss of remedial exertion. Before this point is reached, another cure is generally given if an extended remedial effect is asked An volition to administering another cure is to use a lozenge form that will give extended medicine release, and thus maintain tube medicine attention, beyond what's generally seen using immediate- release lozenge forms. In recent times, colorful modified- release medicine products have been developed to control the release rate of the medicine and/ or the time for medicine release.[1]

MODIFIED DRUG DELIVERY

The term modified-release product is used to describe products that alter the timing and/or the rate of release of the drug substance. A modified release form is defined “as one for which the drug-release characteristics of time course and/or location are chosen to accomplish therapeutic or convenience objectives not offered by conventional dosage forms such as solutions, ointments or promptly dissolving dosage forms as presently recognized”. Modified drug delivery systems are divided into four categories. These systems are those that use repetitive, intermittent dosing of a drug from one or more immediate release units incorporated into a single dosage form. Examples of delayed release systems included repeat action tablets, capsules and enteric-coated tablets where timed release is achieved by a barrier coating.

International Journal of Pharmaceutical Research and Applications
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These system are includes any dosage form that maintains therapeutic blood or tissue levels of the drug for a prolonged period. It is considered as a controlled drug delivery system. These systems refer to targeting of a drug to a certain biological location. In this case the target is adjacent to the effected organ or tissue. These systems refer to targeting of a particular drug receptor within an organ or tissue. Site specific targeting and receptor targeting systems satisfy the spatial aspect of drug delivery and are also considered to be controlled drug delivery systems.

II. MATERIALS AND METHODS

Sr. No.	Name of drug/excipients	Name of manufacturer / supplier and address
1.	Lornoxicam	Aurobindo pharma ltd, Hyderabad, India
2.	Locust bean gum[2]	Indichem international, Mumbai
3.	Xanthan gum [3]	Elim chemicals jeedimetla, Hyderabad
4.	HPMC K100 [3]	Dr.Reddy's laboratories, Hyderabad, India.
5.	Microcrystalline cellulose	Loba chemicals pvt. ltd, Mumbai.
6.	Rosin [3]	Dycon chemicals pvt. ltd, Mumbai
7.	Talc	Qualikems fine chemicals pvt. ltd, New Delhi.
8.	Magnesium stearate	Qualikems fine chemicals pvt. ltd, New Delhi
9.	Potassium dihydrogen orthophosphate purified	S.D. fine chemical pvt. ltd, Mumbai
10.	Sodium hydroxide pellets	Finar chemicals limited, Ahmedabad.

Table No.1: List of materials

PREFORMULATION STUDIES

The organoleptic properties of the drug sample were observed for appearance, color, and any peculiar odor by placing 1.0g of the sample in a watch glass. The melting range was determined using the glass capillary method, where a capillary filled with the drug was tied to a thermometer and placed in a thielstube containing liquid paraffin as a heating medium. The solubility study of the drug involved shaking 10mg of the sample in a beaker with a solvent and visually observing its solubility. The loss on drying test was conducted by weighing 1g of the sample, keeping it in an oven at 105oc for 6 hours, and measuring the percentage of drug loss. These tests help in judging the purity of crude drugs and selecting the appropriate solvent for the drug

Sr. No.	Test	Reported value	Observed value
1.	Physical test Appearance Colour Odour	Crystalline powder Faint yellow Odourless	Crystalline powder Faint yellow Odourless
2.	Melting point	225-230^{o}C	228-230^{o}C
3.	Solubility Water Ethanol Choroform	Poorly soluble Soluble Less soluble	Poorly soluble Soluble Less soluble
4.	LOD	NMT 0.5%	0.3%

Table No. 2 : Evaluation of lornoxicam.

NMT= Not More Than

Inference= the observed value are in good agreement with reported value.

International Journal of Pharmaceutical Research and Applications
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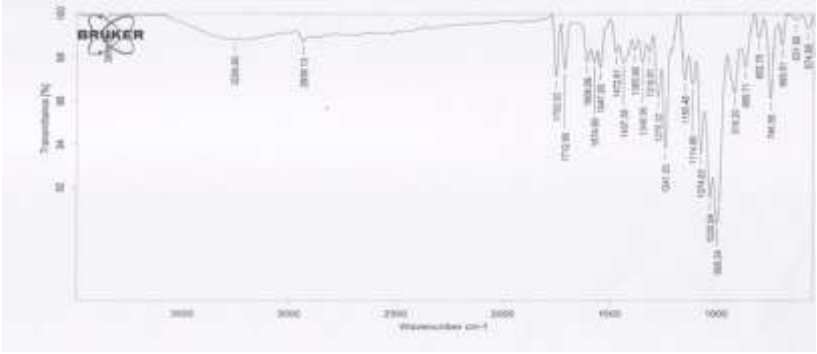
Fourier transform infrared spectroscopy studies

The Fourier transform infrared spectroscopy studies were carried out for pure drug. The results are summarized are follows.



FTIR spectra of lornoxicam

Sr. No.	Frequency	Assignment	Functional group
01	3259	OH shifted	Hydroxyl present
02	2930	OH shifted	2^o Amine
03	996	CO shifted	C-a group

The above peaks are considered as characteristic peaks of lornoxicam.

CONSTRUCTION OF STANDARD GRAPH OF LORNOXICAM

Preparation of Standard Solution of lornoxicam in 0.1 N HCl.

100mg of Lornoxicam was accurately weighed and placed in a 100ml volumetric flask, followed by the addition of 50ml of 0.1 N HCl to dissolve the drug. The volume was then made up to 100ml with HCl, resulting in a solution with a concentration of 1000 µg/ml. Aliquots of 0.2, 0.4, 0.6, 0.8, and 1ml of the lornoxicam standard solution (100mcg/ml) were taken and diluted to 10ml with 0.1 N HCl to obtain concentrations ranging from 2 to 10µg/ml. The absorbances of these solutions were determined at 380nm against respective media solutions as blank, and a standard curve was plotted based on the obtained data.

Preparation of standard solution of lornoxicam in phosphate buffer pH 6.8

A 100mg lornoxicam solution was dissolved in 50ml of pH 6.8 phosphate buffer to create 1000 µg/ml of solution. Different concentrations of lornoxicam standard solution were diluted to 10ml, resulting in concentrations ranging from 2 to 10µg/ml. The absorbances of the solutions were determined at 380nm against the media solutions, and a standard curve was plotted.

Preparation of pH 6.8 phosphate buffers

Accurately measured 50 ml of 0.2M potassium dihydrogen orthophosphate was transferred to a 200ml volumetric flask and 22.4 ml of 0.2 M sodium hydroxide was added to it. Volume was made up to 200 ml with distilled water, mixed and pH was adjusted to 6.8 with 0.2 M sodium hydroxide or 0.2 M othophosphoric acid.

Preparation of 0.2 M potassium dihydrogen phosphate solution

Accurately weighed 27.218 g of monobasic potassium dihydrogen phosphate was dissolved in 1000 ml of distilled water and mixed.

Preparation of 0.2 M sodium hydroxide solution

Accurately weighed 8 g of sodium hydroxide pellets were dissolved in 1000 ml of distilled water and mixed.

Preparation of 0.1N HCl

An 8.65 ml of Conc. HCl was placed in a 1000 ml volumetric flask and the volume was made up with water and pH was adjusted to 1.2 [4]

Standard calibration curve of lornoxicam

A standard graph of lornoxicam was constructed using 0.1N HCl, with concentrations ranging from 2 to 8µg/ml. The absorbance of these

International Journal of Pharmaceutical Research and Applications
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concentrations was measured at 380 nm by adjusting to zero with a blank sample. A graph was plotted with concentration on the x-axis and absorbance on the y-axis, and a best fit line was drawn. The regression value and equation were calculated and represented.

Concentration(µg/mL)	Absorbance
0	0
1	0.158
2	0.254
4	0.485
6	0.758
8	0.962

Table No 3: Calibration curve of lornoxicam in 0.1N HCl

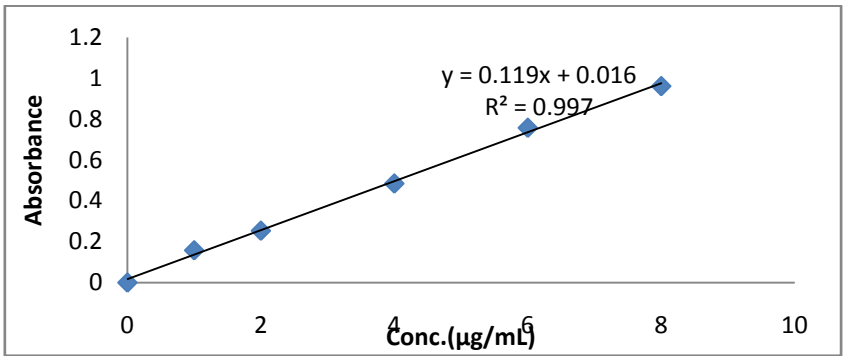

Fig No 1: Calibration curve of lornoxicam at 0.1N HCl

Calibration curve of lornoxicam in 6.8pH

A standard graph of lornoxicam was created using a 6.8 pH phosphate buffer. Different concentrations ranging from 2 to 8µg/ml were prepared. The absorbance of each concentration was measured at a wavelength of 380nm, adjusted to zero using a blank sample. Using the concentrations and absorbance values, a graph was plotted with concentration on the x-axis and absorbance on the y-axis. A best fit line was drawn on the graph and a regression value and equation were calculated to represent the relationship between concentration and absorbance.

Concentration(µg/mL)	**Absorbance**
0	0
2	0.221
4	0.487
6	0.715
8	0.902

Table No 4: Calibration curve of lornoxicam at 6.8 pH

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 6 Nov-Dec 2023, pp: 2540-2549 www.ijprajournal.com ISSN: 2249-7781

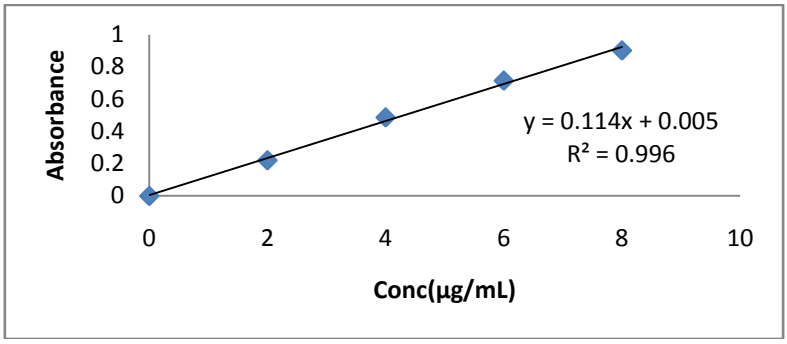

Fig No. 2: Calibration curve of lornoxicam phosphate buffer 6.8 pH.

The standard calibration curve for lornoxicam was determined in 0.1N HCl and phosphate buffer pH 6.8. The curve was found to be linear over the concentration range of 2 to 8 µg/ml, with R2 values of 0.997 and 0.9969 for 0.1N HCl and phosphate buffer pH 6.8, respectively. This suggests that the lornoxicam standard curve follows Beer-Lambert's law within the concentration range of 2-10 µg/ml.

PREPARATION OF LORNOXICAM MATRIX TABLETS BY WET GRANULATION METHOD

Lornoxicam matrix tablets were prepared using the wet granulation technique. The ingredients listed in table 6.14 were weighed and passed through 40 mesh. HPMC K100, Xanthan gum, and Lucast bean gum were used either alone or in combination in varying proportions as matrix polymers. After mixing all the ingredients in ascending order of weight, a small amount of water was added to prepare the dough mass, which was then passed through 10 meshes. The resulting coarse granules were dried at a constant temperature of 60^{o}C to remove moisture and then shifted through 34 mesh to ensure uniform size. Talc and magnesium stearate were added and mixed for 5 minutes, before the granules were compressed into tablets using a 12 station tablet compress machine (Rimek MT II, 12 station).

Ingredient (mg)	**Formulation Code**											
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
Lornoxicam	8	8	8	8	8	8	8	8	8	8	8	8
HPMC K100	10	-	-	15	-	-	20	-	-	10	-	10
Xanthum gum	-	10	-	-	15	-	-	20	-	10	10	-
Locust bean gum	-	-	10	-	-	15	-	-	20	-	10	10
Macrocrystaline Cellulose	76	76	76	72	72	72	68	68	68	68	68	68
Rosin	3	3	3	2	2	2	1	1	1	1	1	1
Talc	2	2	2	2	2	2	2	2	2	2	2	2
Magnesium Stearate	1	1	1	1	1	1	1	1	1	1	1	1
Total	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Table No 5: Composition of matrix tablets

EVALUATION OF PRECOMPRESSION PARAMETERS

Prior to development of tablet dosage form it is necessary to check the flow and compressibility properties of prepared granules. Following test were perform to check the flow and compressibility properties of granules.

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 6 Nov-Dec 2023, pp: 2540-2549 www.ijprajournal.com ISSN: 2249-7781

a. Angle of repose

The height of the funnel was adjusted in such a manner that the tip of the funnel just touched the apex of the heap of the powder blend. The powder blend was allowed to flow through the funnel freely onto the surface. θ = tan-1h/r Where, h and r are the height and radius of the powder cone, θ is the angle of repose.

S.NO	Angle of Repose	Properties
1	<25	Excellent
2	25-30	Good
3	30-40	Passable
4	>40	Poor flow

Table No 6: Angle of repose values

b) Bulk density and tapped density

An accurately weighed quantity of the granules/ powder (W) was carefully poured into the graduated cylinder and volume (V0) was measured. Then the graduated cylinder was closed with lid and set into the tap density tester (USP).

Bulk density = W/V_0

Tapped density = W/V_f

Where, W= Weight of the powder

V_0 = Initial volume

V_f = final volume

c) Compressibility index (Carr's Index)

Carr's index (CI) is an important measure that can be obtained from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is.

CI = (TD-BD) x 100/TD Where, TD is the tapped density and BD is the bulk density.[5]

Sr.No.	Carr's Index	Properties
1	5-12	Free flowing
2	13-16	Good
3	18-21	Fair
4	23-35	Poor
5	33-38	Very poor
6	>40	Extremely poor

Table No 7: Carr's index values

d) Hausner's ratio

It is the ratio of tapped density and bulk density. Hausner found that this ratio was related to interparticle friction and, as such, could be used to predict powder flow properties. Generally a value less than 1.25 indicates good flow properties, which is equivalent to 20% of Carr's index

Hausner's Ratio= Tapped density/ Bulk density

Precompression parameters

Formulation Code	Bulk Density (g/cc)	Tapped Density (g/cc)	Carr's Index	Hausner Ratio	Angle of Repose (θ)
F1	0.55	0.65	15.38	1.18	23.45
F2	0.54	0.62	12.90	1.14	19.65
F3	0.56	0.64	12.5	1.14	22.35

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 6 Nov-Dec 2023, pp: 2540-2549 www.ijprajournal.com ISSN: 2249-7781

F4	0.54	0.63	14.28	1.16	20.69
F5	0.55	0.63	12.69	1.14	20.82
F6	0.53	0.62	14.51	1.16	20.72
F7	0.56	0.67	16.41	1.19	20.89
F8	0.55	0.68	19.11	1.23	20.78
F9	0.56	0.68	17.64	1.21	22.6
F10	0.52	0.66	21.21	1.26	22.3
F11	0.51	0.62	17.74	1.21	24.6
F12	0.52	0.63	17.46	1.21	25.8

Table No 8: Precompression parameters of prepared lornoxicam granules

The bulk density and tapped density were found in the range of 0.52-0.56 g/cc and 0.62-0.69 g/cc respectively. The values of Hausner's ratio and carrs index were in the range of 1.16-1.25 and 12.5 to 21.21 respectively, indicating good flow and compressibility properties.

EVALUATION OF FORMULATED BATCHES

i) Appearance

The tablets were observed by nacked eyes to check colour and shape.

ii) Thickness

Twenty tablets from the representative sample were randomly taken and individual tablet thickness was measured by using vernier caliper.

iii) Hardness

Tablet hardness was measured by using Monsanto hardness tester. From each batch six tablets were measured for the hardness and average of six values was noted along with standard deviations.

iv) Friability test

Apparatus was operated at 25 rpm for 4 minutes and tablets were observed while rotating. The friability was calculated as the percentage weight loss. %Friability was calculated as follows % Friability = (W1 – W2) x 100/W1 Where W1 = Initial weight of the tablets. W2 = Final weight of the tablets after testing.

v) Weight variation test

% weight variation = (WA–WI) x 100/ WA¬ As the total tablet weight was 250 mg, according to IP 1996, out of twenty tablets ±7. 5 % variation can be allowed for not more than two tablets. According to USP 2004, ±10% weight variation can be allowed for not more than two tablets out of twenty tablets.

vi) Drug content (Assay)

Three tablets were weighed and taken into a mortar and crushed into fine powder. 8 pH Phosphate buffer solution and the volume was made up to the mark. From this resulted solution 1 ml was taken, diluted to 10 ml with 6. 8 pH Phosphate buffer solution and absorbance was measured against blank at 380 nm.

6.6.1 Post compression parameters

Formulation Code	Thickness (mm)	Average wt. of tablet (mg)	Friability (%)	Hardness (kg/cm^2)	%Drug Content
F1	2.41	100.65	0.16	5.4	96.19
F2	2.45	99.67	0.18	5.5	99.69
F3	2.43	98.89	0.17	5.3	99.77
F4	2.35	101.05	0.25	5.6	100.38

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 6 Nov-Dec 2023, pp: 2540-2549 www.ijprajournal.com ISSN: 2249-7781

F5	2.54	99.41	0.22	5.3	99.38
F6	2.60	96.81	0.3	6.0	96.5
F7	2.63	98.99	0.48	5.6	99.49
F8	2.72	99.62	0.25	5.5	98.17
F9	2.46	99.23	0.42	5.0	99.38
F10	2.62	98.45	0.02	5.5	97.3
F11	2.54	99.81	0.12	6	96.4
F12	2.20	99.46	0.14	5.5	98.6

Table No 9 : Post compression parameters

The average weight of all the 12 formulations was found to be in between 96. The thickness of tablets was found between 2. Hardness of all the tablets was maintained at 5 to 6 kg/cm2. Assay was performed and percent drug content of all the tablets were found to be in between 96.

vii) Dissolution test

Temperature of media : 37oC Speed of rotating paddle : 50rpm Sample volume : 5ml Sample interval : 1,2,4,6,8,10,12h Duration of test : 12h Lornoxicam tablets were placed in dissolution medium From each vessel at definite time interval 5ml of sample was withdrawn, filtered through whatmann filter paper (No. 41), diluted and analyzed spectrophotometrically at 380nm. An equal volume of fresh medium which was prewarmed at 37oC replaced into the dissolution medium after each sampling to maintain. The constant volume throughout the test.

time h	**% Drug Release**											
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
0	0	0	0	0	0	0	0	0	0	0	0	0
1	18.45	15.92	12.6	14.05	9.2	10.64	14.25	8.56	6.45	10.5	10.6	12.6
2	28.2	28.15	23.4	26.41	18.15	22.85	22.1	15.5	12.4	26.7	19.8	24.8
4	55.6	50.24	46.9	49.66	39.24	46.98	49.6	28.24	26.92	41.8	46.4	52.4
6	80.4	76.5	67.34	77.47	54.5	68.34	70.02	49.76	48.34	55.3	60.8	66.9
8	97.6	88.92	83.52	88.9	78.28	80.5	82.65	68.8	64.52	78.4	72.6	78.4
10	-	97.74	90.2	95.32	91.74	89.44	98.9	76.52	78.3	90.4	85.3	87.6
12	-	-	-	-	-	-	-	96.2	92.4	98.4	91.2	95.3

Table No 10 : In vitro release profile of drug with various polymers containing ratio 1:1,1:2,1:3

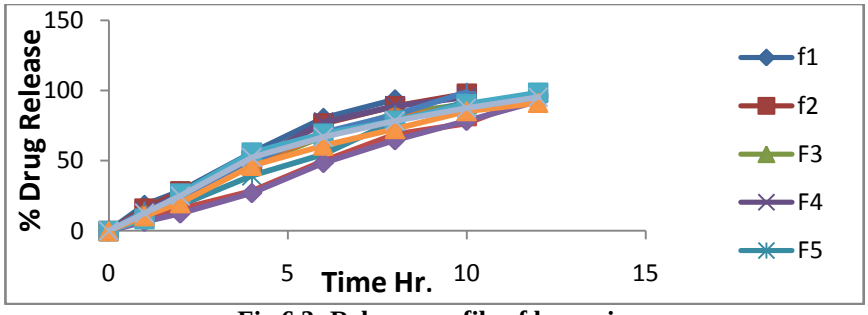

Fig 6.3: Release profile of lornoxicam

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The in-vitro release data suggested the slow release of drug from all the formulated batches. Batch F1 released 97.6% drug at the end of 8h study. Batch F2,F3,F4,F5,F6,F7 release 97.74,90.2,95.32,91.74,89.44,98.9% drug respectively at the end of 10h study. Batch F8, F9, F10, F11, F12 release 96.2, 92.4, 98.4, 91.2,95.3% drug at the end of 12h. It was observed that batch F10 containing 10mg HPMC K and 10mg Xanthan gum released 10.5% and 98.4% drug at the end of 1h and 12h respectively.

viii) Swelling studies

The dissolution jars were marked with the time points of 0. One tablet was placed in each dissolution jar containing 900 ml of phosphate buffer pH 6. The tablets were taken out after completion of the respected stipulated time span as mentioned above and weighed after the excess of water at the surface had been removed with filter paper. It was estimated according to following equation Q = 100(Ww – Wi) / Wi Where, Q is the percentage swelling, and Ww and Wi are the masses of the hydrated samples before drying and the initial starting dry weight, respectively.[6]

Formulation code	Swelling index
F1	22.4
F2	24.07
F3	23.67
F4	28.63
F5	29.76
F6	31.80
F7	38.69
F8	29.45
F9	30.12
F10	31.2
F11	32.5
F12	34.4

Table No 11: Swelling index

It was observed that batch F10 containing 10mg HPMC K 100 and 10mg Xanthan gum released 10.5% and 98.4% drug at the end of 1h and 12h respectively. Batch F10 Passed the weight variation and friability test, showed hardness, swelling index and percent drug content 5.5kg/cm^2, 31.2 and 97.3% respectively. Batch F 10 showed good physical properties so selected for further experiment

III. DISCUSSION

The present investigation was under taken to formulate and evaluated extended release tablets of lornoxicam. Using various polymers like HPMC K100 and Xanthan gum, tablets were prepared along with other additives. Wet granulation method was used for the preparation of tablets. A total 12 formulations were prepared and evaluated.

Precompression studies

The bulk density and tapped density were found in the range of 0.52-0.56 g/cc and 0.62-0.69 g/cc respectively. The values of Hausner's ratio and Carrs index were in the range of 1.16-1.25 and 12.5 to 21.21 respectively, indicating good flow and compressibility properties. Values of angle of reposewas found in the range of 19.65-25.8 showing that blend of powder mass have excellent flow properties.

Evaluation of tablets

The average weight of all the 12 formulations was found to be in between 96.7 to 101.3 mg. Not a single table was outside the ±7.5% range prescribed by IP. The thickness of tablets was found between 2.4 to 2.72mm. Friability values were less than 1%. Hardness of all the tablets was maintained at 5 to 6 kg/cm^2. Assay was performed and percent drug content in all the

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 6 Nov-Dec 2023, pp: 2540-2549 www.ijprajournal.com ISSN: 2249-7781

tablets were found to be in between 96.5% and 100.38%, which was within the acceptable limits.

In-vitro dissolution

The in-vitro release data suggested the slow release of drug from all the formulated batches. Batch F1 released 97.6% drug at the end of 8h study. Batch F2,F3,F4,F5,F6,F7 release 97.74,90.2,95.32,91.74,89.44,98.9% drug respectively at the end of 10h study. Batch F8, F9, F10, F11, F12 release 96.2, 92.4, 98.4, 91.2, 95.3% drug at the end of 12h. It was observed that batch F10 containing 10mg HPMC K and 10mg Xanthan gum released 10.5% and 98.4% drug at the end of 1h and 12h respectively. It was observed that batch F10 containing 10mg HPMC K 100 and 10mg Xanthan gum released 10.5% and 98.4% drug at the end of 1h and 12h respectively. Batch F10 Passed the weight variation and friability test, showed hardness, swelling index and percent drug content 5.5kg/cm^2, 31.2 and 97.3% respectively. Batch F 10 showed good physical properties so selected for further experiment

IV. CONCLUSION

Success of the in-vitro drug release studies recommends the product studies, which may improve patient compliance. From the results, formulation F10 containing lornoxicam 8mg, HPMC K1100 10mg and xanthan gum10mg evolved as the optimized formulation and it releases more than 98% drug in 12h. IR spectroscopic studies was indicated that there no drug-excipient interactions in the optimized formulation. The optimized formulation F10 can be considered as a promising extended drug delivery system of lornoxicam providing nearly drug release over a period of 12 h.

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CONFLICT OF INTEREST

The authors declare no conflict of interest

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