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Research Article

FLOATING DRUG DELIVERY SYSTEM OF NSAIDS TO INCREASE GASTRIC RETENTION TIME IN UPPER PART OF GASTROINTESTINAL TRACT

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ABSTRACT

The purpose of the present work is to prolong the gastric residence time of Lornoxicam by developing gastric floating drug delivery system. Lornoxicam is non-steroidal anti-inflammatory drugs. Its short half life 2 to 3 hrs and maximal absorption of upper part of gastrointestinal tract. The residence time of the dosage form in the stomach depends upon various factors like pH, size of the dosage form, food intake, and biological factors which include age, body weight gender, posture, and diseased states Floating tablet prepared by melt granulation techniques, using bees wax as a binder and the other polymers include HPMC 50cPs,15cPs,5cPs and Sodium Alginate. The Prepared granules were then evaluated for Precompression Properties. The best batches were then tabulated, and Evaluation was carried out for the following parameters with in vitro release, buoyancy, Floating Lag timed. Batch F12 and F13 Showed best Floating time of 12hrs and Floating Lag time of 60 second.

Keywords: Floating tablet, Lornoxicam, Melt granulation techniques, lag time, in-vitro release.

INTRODUCTION

The primary objective of the design of an oral managed drug delivery system should be to achieve a more predictable and improved bioavailability of drugs. However, some physiological issues, such as the inability to restrain and localize the drug delivery mechanism inside desired regions of the gastrointestinal tract and the highly complex existence of the gastric emptying process, preclude the production process. The most convenient and significant means of administering medications for systemic effect is the oral route of drug administration. Due to patient acceptance and ease of administration, these systems provide more benefits. [1]

By prolonging the gastric residence period and improving patient compliance, the overall gastrointestinal residence time of the dosage type is increased. The floating drug delivery device offers stomach buoyancy for a prolonged period of time, thereby offering optimum bioavailability with extended gastric residence time for the dosage type. The residence time of the stomach dosage form depends on various variables such as pH, dosage form size, food intake, and biological variables including age, gender of body weight, posture, and diseased states (hepatic failure, diabetes).[2]

BASIC GASTROINTESTINAL TRACT PHYSIOLOGY:[3]

It is well known that the stomach can be used in both human and veterinary applications as a depot for sustained release dosage types. Three sections of the fundus, body, and pylorus are anatomically separated into the stomach. The proximal stomach, consisting of the regions of the fundus and body, acts as a reservoir of food materials. The gastrointestinal motility is characterized by a cyclic pattern that consists of four distinct phases:

Phase I (Basal phase): It lasts from 30-60 minutes with rare contractions.

Phase II (Pre-burst phase): It lasts for 20-40 minutes with intermittent action potential and contractions. As the phase progresses the intensity and frequency also increase gradually.

Phase III (Burst phase): It lasts for 10-20 minutes. It includes intense and regular contractions for short period. It is due to this wave that all the undigested material is swept out of the stomach down to the small intestine. It is also known as the housekeeper wave.

Phase IV: It lasts for 0-5 minutes and occurs between phases III and first second consecutive cycles.

TYPES OF GASTRORETENTIVE FORMS: [4-6]

- Floating systems
- High density systems
- Expandable systems
- Super-porous hydrogel
- Mucoadhesive or bioadhesive systems

Floating Systems

Floating drug delivery systems have a lower bulk density than gastric fluids and therefore remain buoyant in the stomach for a prolonged period of time without impacting the gastric emptying rate. While the system floats on the gastric material, the drug is

slowly released from the system at the desired rate, the floating system mechanism is shown in figure No. 1.[3]
For medications, floating dosage type is highly desirable with prolonged residence time in the stomach:

- Active in stomach locally.
- Have absorption window in stomach or in upper small intestine
- It is unstable in colonic or intestinal environment and has low solubility at high pH value.

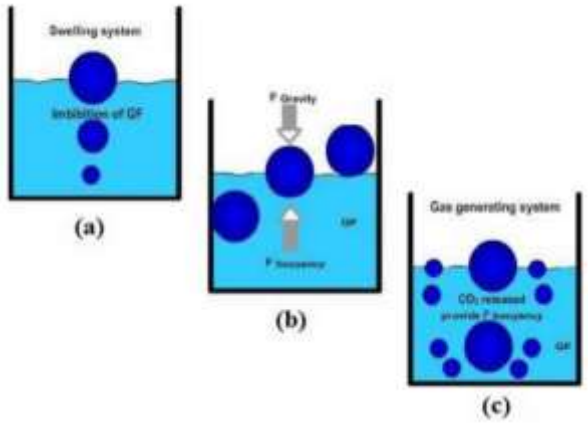

Figure 1: Mechanism of floating system[7,8,9]

High density systems

The density of the gastric material is similar to water (1.004 g/cm3). Tiny high-density pellets fall to the bottom of the stomach while the patient is standing, where they become stuck in the antrum folds and endure the stomach wall's peristaltic waves. For substantial prolongation of gastric residence time, a density close to 2.5 g/cm3 seems appropriate, and barium sulphate, zinc oxide, iron powder and titanium dioxide are used as excipients.

Expandable systems: [10,11,12]

If it is larger than the pyloric sphincter, a dose type in the stomach can tolerate gastric transit. The dosage type, however, must be sufficiently small to be swallowed and must not cause gastric obstruction on its own or by accumulation. Three configurations are therefore required: a small oral intake configuration, an extended gastro-retentive form and a final small form allowing evacuation after drug release. Un-foldable and swellable structures have been studied. Un-foldable structures are made of polymers which are biodegradable. The idea is to create a carrier that integrates a compressed structure that reaches into the stomach, such as a capsule.

Super-porous Hydrogels

These are swellable systems, which vary adequately from traditional styles. With pore sizes between 10 nm and 10 am the absorption of water by traditional hydrogel is a very slow operation, and it may take several hours to achieve an equilibrium state during which the dosage type may be prematurely evacuated. Super-porous hydrogels, average pore size > 10 am, swell within a minute to equilibrium size, due to rapid water absorption through multiple interconnected open pores by capillary wetting. Moreover, they swell to a large size and are intended to provide ample mechanical strength by gastric contraction to withstand strain.

Mucoadhesive or bioadhesive systems: [12,13,14,15]

The basis of mucoadhesion is that various mechanisms will bind to the mucosal surface of a dosage type. To explain these processes, distinct hypotheses are invoked. First, between the glycoprotein mucin network and the bioadhesive material, the electronic theory proposes attractive electrostatic forces. Secondly, the principle of adsorption indicates that bioadhesion is due to secondary forces like the forces of Van der Waals and the bonding of hydrogen. The wetting principle is based on the ability to spread and establish intimate contact with the mucus layer of bioadhesive polymers.

Classification of floating drug delivery system

FDDS can be classified into two systems based on the mechanism of buoyancy:

- Effervescent system (gas-generating system).
- Non-effervescent system.

Effervescent system

A gas producing agent, typically sodium bicarbonate or sodium carbonate, is mixed with matrices prepared with swelling polymers in effervescent systems when the systems come into contact with gastric fluids, the carbon dioxide is released by the acidity of the gastric contents and the gas is retained in the viscous hydrocolloid. Thus, the device produces an upward motion that maintains buoyancy. [16]

Non-effervescent system

The drug combines with a gel shaped hydrocolloid, polymers such as polycarbonates, polyacrylates etc. in non-effervescent FDDS. After oral administration, the hydrocolloid forming gel swells in contact with gastric fluid and retains a relative integrity of the shape and bulk density of less than one in the gastric setting.

Advantages of floating drug delivery system [17]

- For medications ingested through the stomach, for example, ferrous salts, antacids, the gastro-retentive mechanisms are beneficial.
- When they come into contact with it, acidic substances like aspirin cause inflammation of the stomach wall. The formulation of HBS can also be beneficial for the administration of aspirin and other related medications.
- Gastro-retentive mechanisms are useful for medications intended for local action in the stomach, e.g. From antacids.

Disadvantages of floating drug delivery system

- For certain drugs that have solubility or stability issues in G.I., the floating system is not feasible. Yeah. Tract.
- One of the drawbacks of floating systems is that they need a sufficiently high volume of fluids in the stomach to float in it and function effectively with the medication dosages.
- Only desirable candidates are drugs that are greatly absorbed in the gastrointestinal tract, which undergo extensive first pass metabolism.
- Many medicines present in the floating system cause gastric mucosa irritation.

Applications of floating drug delivery system [18]

1. Enhanced bioavailability
2. Sustained Drug Delivery
3. Site-Specific Drug Delivery

4. Absorption Enhancement
5. Minimized adverse activity at the colon
6. Reduced fluctuations of drug concentration

MATERIALS AND METHODS

Precompression parameters:[18]

Angle of repose: The maximum angle possible between the surface of a pile of the powder and the horizontal plane.

Procedure: The angle of repose of granules was determined by the funnel method. The accurately weight powder was taken in the funnel. The height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder. The powder was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured, and angle of repose was calculated by using the following formula:

$$\text{Tan } \theta = h/r$$

where, h = height of pile, r = radius of the base, and ɵ = angle of repose

Compressibility Index: Compressibility is indirectly related to the relative flow rate, cohesiveness and particle size of a powder. The compressibility of a material can be estimated from the tap and bulk density measurements.
Carr's Compressibility Index for the prepared granules was determined by the following formula:

$$\text{Carr's Index (\%)} = TBD - LBD/TBD \times 100$$

$$\text{Hausner Ratio} = Vb/Vt$$

where, Vb = initial or bulk volume and Vt = final or tapped volume

Bulk density and Tapped density: Bulk density is the ratio between a powder's weight and the volume it occupies. As gm/ml, it is expressed. The volume of the solid component of the particle and the voids between the particles are filled by the powder. In determining the size of the container required for handling and processing, bulk density is essential.

$$\text{Bulk density} = W/V_o$$

where,W= weight of the powder, V_o= initial volume, V_f= final volume

Post Compression Parameters

***in vitro* buoyancy studies:** Floating lag time has been calculated by *in vitro* buoyancy. The tablets were put in a 0.1N HCL-containing 100 ml glass beaker. Floating lag time was calculated to be the time needed for the tablet to rise to the surface and float. It also calculated the overall floating time.[19]

Hardness test: Hardness demonstrates a tablet's ability to resist mechanical shocks during handling. Tablet hardness was measured using a validated hardness tester of the dial type. This is expressed in terms of kg/cm2. From every sample three tablets were randomly selected and analyzed for hardness. It also measured the mean and standard deviation.

Weight variation test: Twenty tablets were randomly chosen and individually measured. Calculate the average weight and equate the weight of each tablet to the average weight. Not more than two of the individual weights deviate by more than the percentage shown in the table and not more than twice the percentage deviates from the average weight.

Friability test: Friability was accomplished by the use of the Roche friabilator; six tablets were typically pre-weighed and put in the plastic friabilator chamber. This was run for 100 revolutions afterward. The tablets would then be dusted and measured again. Weight loss of less than 1% is deemed to be healthy.

$$F = (\text{initial weight} - \text{final weight}) \times 100$$

Drug content uniformity: They weighed and took five tablets in a mortar and ground them into powder. In a 100 ml volumetric flask, a quantity of powder weighing equal to 40 mg of Lornoxicam was taken and 0.1N HCL was applied. It was then heated for 30 minutes at 60^0C. Using What Man filter paper, the solution was filtered and then its absorption was measured at 379nm. Using the calibration curve, the volume of medication was measured.

***in-vitro* Dissolution studies:** In the dissolution basket, one tablet was inserted. The analysis was conducted for 6 hours (75 rpm) at 900ml of 0.1N HCl; the temperature was maintained at 37±2 ?? C. Aliquots of 1 ml at particular time intervals were removed. The dissolution flask was replaced with 1ml of fresh medium at each time of withdrawal. [20]

RESULTS AND DISCUSSION

Physical Examination/ organoleptic properties: Organoleptic properties were evaluated on the basis of colour, odour, taste and appearance of the drug.

Drug-Excipient Compatibility Studies: Fourier transform infrared spectroscopy (FTIR) studies were performed from CDRI, Lucknow, U.P. The FTIR spectra of the mixture of the drug and HPMC 50 cps was recorded from 400-4000cm^{-1} at room temperature by Perkin Elmer Spectrum Version 10.03.06, compatibility studies FTIR graph shown in figure 2.

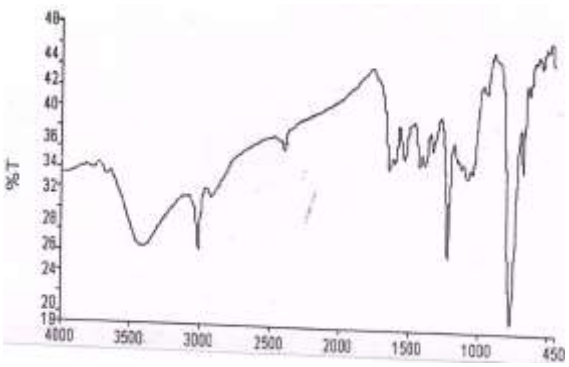

Figure 2: FTIR Spectra of Lornoxicam +Polymer HPMC 50cPs(1:1)

The IR spectra of Lornoxicam was compared with the IR spectra of Lornoxicam +HPMC 50cPs, no considerable changes were found.

Table 1: Formulations for Selection of Polymer

S. No.	Ingredients	Batch (weight in mg)				
		F1	**F2**	**F3**	**F4**	**F5**
1	Sodium Alginate	-	80	-	-	-
2	E C	25	-	-	-	-
3	HPMC (50 cPs)	75	-	-	-	80
4	HPMC (5cPs)	-	-	80	-	-
5	HPMC (15cps)	-	-	-	80	-
6	NaHCO3	75	60	60	60	60
7	Bees wax	80	80	80	80	80
8	Mg stearate	2.5	10	10	10	10
9	Talc	2.5	10	10	10	10

Table 2: Formulation Optimization

Ingredients	**F6**	**F7**	**F8**	**F9**	**F10**	**F11**
HPMC 50cPs	60 mg	100 mg	80 mg	80 mg	80 mg	80 mg
NaHCO3	60 mg	60 mg	40 mg	80 mg	60 mg	60 mg
Bees wax	80 mg	80 mg	80 mg	80 mg	40 mg	60 mg
Mg stearate	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg
Talc	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg

Table 3: Formulations for Floating Tablet of Lornoxicam

S. No.	Ingredients	Batch (weight in mg)		
		F12	**F13**	**F14**
1	Lornoxicam	12	18	24
2	HPMC 50cPs	80	80	80
3	NaHCO3	60	60	60
4	Bees wax	80	80	80
5	Mg stearate	10	10	10
6	Talc	10	10	10

Table 4: Evaluation Parameters of Powder Blend

Formulation Code	**Polymer**	**Bulk Density (g/ml)**	**Tapped Density (g/ml)**	**Compressibility Index (%)**	**Angle of Repose (ɵ)**
F1	Ethyl cellulose and HPMC	0.581	0.730	28.33	26.35
F2	Sodium alginate	0.582	0.732	27.33	28.31
F3	HPMC 5cPs	0.580	0.735	30.30	28.30
F4	HPMC 15cPs	0.570	0.729	29.30	27.69
F5	HPMC 50cPs	0.576	0.728	27.30	27.75

Table 5: Post-Compression Evaluation Parameters of Tablets

Formulation Batch Code	**Hardness (kg/cm^2)**	**Friability (%)**	**Average weight (mg)**	**Floating Lag time (*in vitro*buoyancy)**	**Floating time (hrs)**
F1	5.6	0.485	251.0	60 secs	4 hrs
F2	5.5	0.487	252.1	No floating observed	No floating observed
F3	5.8	0.481	252.2	300 mins	12 hrs
F4	5.3	0.485	251.1	300 mins	12hrs
F5	5.4	0.492	252.3	180secs	12hrs

Table 6: Evaluation Parameters of Powder Blend of Selected Formulations

Formulation Code	**Polymers**	**Bulk Density (g/ml)**	**Tapped Density (g/ml)**	**Compressibility Index (%)**	**Angle of Repose (ɵ)**
F6	HPMC 50cPs	0.585	0.732	32.80	29.28
F7	HPMC 50cPs	0.582	0.742	36.24	28.46
F8	HPMC 50cPs	0.474	0.585	18.93	33.99
F9	HPMC 50cPs	0.582	0.740	38.23	28.04
F10	HPMC 50cPs	0.350	0.440	20.45	33.69
F11	HPMC 50cPs	0.481	0.564	20.18	30.36

Table 7: Evaluation Parameters of Selected Formulations

Formulation Code	Hardness (kg/cm^2)	Average weight (mg)	Friability (%)	Floating Lag time (min)	Floating time (hrs)
F6	5.5	252.2	0.490	120	5
F7	5.3	252.1	0.489	120	8
F8	5.2	252.2	0.486	60	12
F9	5.1	252.3	0.488	120	12
F10	5.5	252.1	0.491	120	12
F11	5.6	252.2	0.488	60	12

Table 8: Evaluation Parameters of Powder Blend

Formulation Code	Polymers	Bulk Density (g/ml)	Tapped Density (g/ml)	Compressibility Index (%)	Angle of Repose (ɵ)
F12	HPMC 50cPs	0.550	0.640	14.60	28.51
F13	HPMC 50cPs	0.510	0.550	9.09	29.21

Table 9: Evaluation Parameters of Formulations

Formulation Code	Hardness (kg/cm^2)	Friability (%)	Weight variation (mg)	Drug Content Percentage	Floating Lag time secs)	Floating time (hrs)
F12	5.5	0.487	251 ± 1.35	93	60	12
F13	6.0	0.525	256± 1.52	94	120	12
F14	5.6	0.489	262±1.56	94	No floating observed	No floating observed

FORMULATION AND DEVELOPMENT OF FLOATING TABLETS[21,22,23]

Preparation of floating tablets by melt granulation techniques
Required quantity of beeswax was weighed and melted in a large china dish over a water bath. The drug was added to the molten wax and mixed well. Previously weighed quantities of HPMC 50cPs and $NaHCO_3$ were added to the mixture and mixed well. The coherent mass was then scrapped from the china dish and was passed through sieve no.18. The granules were then lubricated with talc and Magnesium stearate was added. The lubricated granules were then passed through sieve no.22. The granules were then compressed using a multi-station tablet punch machine (Proton Mini Press). Table 1 shows the different formulations.

Five Batches F1, F2, F3, F4 and F5 were prepared using melt granulation techniques. Using polymers sodium alginate, Ethyl cellulose and HPMC 50cPs, HPMC 5cPs and HPMC 15cPs respectively. Precompression and post compression parameters were evaluated for all the batches.

Optimization of concentration of HPMC 50cPs
Six more batches were prepared where in the concentration of HPMC and $NaHCO_3$ and bees wax were optimized as given in table 2 and 3. Pre-compression and post-compression parameters were evaluated for all the batches. (Table 3 & 4)

The Precompression parameters obtained for five formulations are tableted in the table 4. The value of range of angle of repose was found to be in the range of 26.35 to 28.31.99. This indicates good flow property of powder blend. Carr's index value range between 27.30 to 30.30% indicates that the powder blend has the required flow property for melt granulation techniques and were further tableted.

Results for the formulations were as follows:

- All the batches possessed good hardness and the friability percentage was less than 1.
- Batch F1 showed a floating lag time of 60 secs but floating time of only 4hrs was observed. This formulation also exhibited sink problem that is, the tablets after floating for some time, used to sink and again float. This problem exhibited that proper floating was not obtained using Ethyl cellulose and HPMC 50cps combination.
- Batch F2: The tablets did not float. It can be concluded that sodium alginate together with beeswax did not provide enough buoyancy to float.
- Batch F3: The tablets exhibited a floating lag time of 300 min but floating time observed was remarkably good of 12 hrs. It can be concluded that although the HPMC 5cps was providing buoyancy for the tablets to float but buoyancy was achieved after a long time.
- Batch F4: The tablets exhibited a floating lag time of 300 min but floating time observed was remarkably good of 12 hrs. It can be concluded that although the HPMC 5cps was providing buoyancy for the tablets to float but buoyancy was achieved after a long time.
- Batch F5: The tablets exhibited a floating lag time of 180 secs but and floating time observed was remarkably good of 12 hrs. It can be concluded that although the HPMC 50cps was providing enough buoyancy for the tablets to float and floating lag time observed as also less.
- Hence, HPMC 50cPS was selected as the polymer of choice.

The Precompression parameters obtained for six formulations are tableted in the table 6. The value of range of angle of repose was found to be in the range of 28.04 to 33.99. This indicates good flow property of powder blend. Carr's index value range between 18.93 to 38.23% indicates that the powder blend has the required flow property for melt granulation techniques.

Post compression parameters, hardness, friability, floating lag time and floating time was of the above batches was determined. Results shown in table 7.

- The measured hardness for the tablets for each batch arranged between 5.1 to 5.6 kg/cm^2, this ensures the good handling characteristics of the batches.
- The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.
- Floating lag time was least in Batch F8 and F11.Both the batches exhibited floating time of 12 hrs.

The precompression parameters obtained for two formulations are tableted in the table 8. The value of range of angle of repose was found to be in the range of 28.51 to 29.21. This indicates good flow property of powder blend. Carr's index value range between 9.09 to 14.60% indicates that the powder blend has the required flow property for melt granulation techniques.

The F12 and F13 formulations shows floating time up to 12 hours and it shows good buoyancy.

Batch F12 and F13 exhibited floating lag time of 60 secs and 120 secs respectively. However, in Batch 14 no floating was observed. Thus, it can be concluded that when the dose of Lornoxicam is being increased, there is significant effect on the floating lag time**.** (Table 9)

***in vitro* Dissolution Study**

Table 10: Percentage Drug Release of Formulation F12

S. No.	Time (min)	Absorbance	Amt. (mg)	F12 % DR
1	0	0	0	0
2	30	0.059	0.075	6.04
3	60	0.152	0.197	15.91
4	90	0.305	0.399	32.17
5	120	0.573	0.752	60.55
6	150	0.743	0.975	78.45
7	210	0.844	1.109	89.28
8	270	0.885	1.162	93.51
9	330	0.985	1.182	94.42

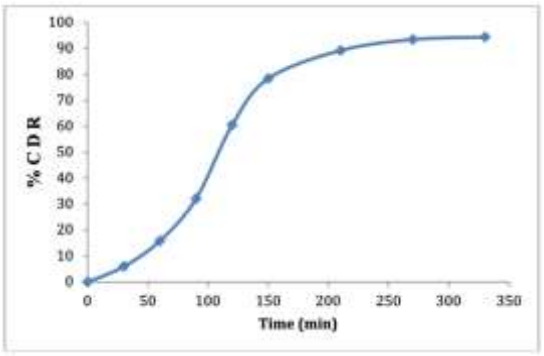

Figure 3: Dissolution Profiles Lornoxicam Floating tablet Batch F12

Table 11: Percentage cumulative drug released from formulation F13

S. No.	Time (min)	Absorbance	Amt. (mg)	F13 % CDR
1	0	0	0	0
2	30	0.084	0.107	8.86
3	60	0.224	0.292	24.08
4	90	0.363	0.474	39.08
5	120	0.601	0.788	64.95
6	150	0.771	1.012	83.38
7	210	0.832	1.092	90.02
8	270	0.859	1.129	93.05
9	330	0.935	1.148	94.09

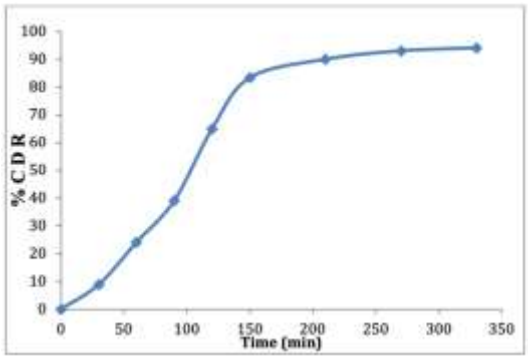

Figure 4: Percentage cumulative drug released from formulation F13

Table 12: Percentage drug release of Batch F12 and Batch F13

S no	Batch no	Percentage drug release at the end of 5.5 hrs
1	F12	94.42
2	F13	94.09

Batch F12 and Batch F13 showed percentage drug release of 94.42 % and 94.09% at the end of 5.6 hrs. It can be anticipated from above data and floating time (12hrs) that the remaining amount shall be exhausted within 12 hrs.

CONCLUSION

Lornoxicam's floating drug delivery system was successfully developed and evaluated to increase gastric retention time in the upper part of GIT for the desired time span, the tablet prepared by melt granulation techniques, all the prepared batches were tested for pre-compression and post-compression parameters, it was observed that the batch F12 and F13 had the best floating time of 12 hours and lag time.

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