

Comparative Evaluation of Single-Polymer and Optimized Gastro-Retentive Matrix Tablets of Lornoxicam

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Abstract

Gastro-retentive drug delivery systems are developed to increase gastric residence time and sustain drug release for enhanced drug absorption and therapeutic performance. Natural polymers have great potential as floating matrix tablets because of their swelling, gel-forming and matrix retarding properties. The present study was designed to compare the performance of single-polymer and optimized multi-polymer gastro-retentive floating matrix tablets of Lornoxicam and to investigate the synergistic effect of Okra mucilage, Xanthan gum and Chitosan on floating behavior, swelling, matrix integrity and sustained drug release. Lornoxicam floating matrix tablets containing Okra mucilage, Xanthan gum or Chitosan as individual matrix-forming polymers were prepared by direct compression. The formulations were examined for pre-compression and post-compression characteristics (buoyancy lag time, swelling index, drug content), in vitro drug release. An optimized multi-polymer formulation (F18) with a combination of Okra mucilage, Xanthan gum and Chitosan was compared with the individual polymer formulations under similar experimental conditions. The single-polymer formulations had their own functional advantages. Okra mucilage had good hydration and swelling capacity; Xanthan gum floating properties and sustained release behavior; Chitosan matrix integrity and tablet strength but none of the individual polymers provided an optimum balance of all performance attributes. F18 (optimized multi-polymer formulation) showed superior overall performance with a swelling index 281.6%, drug content 99.56% buoyancy lag time only 24 s, controlled and sustained drug release (cumulative drug release 98.64% at 12 h). The improved performance of F18 was due to complementary and synergistic effects of three natural polymers on hydration, matrix formation, floating ability and drug-release control. The comparative results show that Okra mucilage, Xanthan gum and Chitosan are better than individual polymers for Lornoxicam gastro-retentive floating matrix tablets development. Optimized multi polymer system is promising for prolonged gastric retention and sustained drug delivery.

Keywords: Lornoxicam; Gastro-Retentive Drug Delivery; Floating Matrix Tablets; Okra Mucilage; Xanthan Gum; Chitosan; Natural Polymers.

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Introduction

Lornoxicam is an oxicam NSAID with analgesic and anti-inflammatory activity. It is used for acute and chronic inflammatory and painful conditions. Although it has considerable analgesic and anti-inflammatory activity, its short elimination half-life requires repeated dosing to maintain therapeutic drug concentrations. Immediate release oral dosage forms may also rapidly empty from the stomach so that residence time in the upper gastrointestinal tract is limited. These are reasons why a gastro-retentive drug delivery system should be developed which would prolong gastric residence and control drug release. [1]

Gastro-retentive drug delivery systems (GRDDS) are designed to stay in the stomach for a prolonged period and release the incorporated drug slowly. Floating matrix tablets are simple and effective gastro-retentive dosage form where the dosage form floats on gastric fluid because it is relatively low density. Long gastric residence may extend drug release duration, decrease concentration fluctuations of drug, dosing convenience and therapeutic efficacy. Performance of floating matrix tablets depends largely on characteristics and concentration of matrix forming polymer. [2-3]

Natural polymers have been of interest in matrix-based drug delivery because they are biodegradable, biocompatible, low toxic, available and cost effective. Okra mucilage, Xanthan gum and Chitosan have hydrophilic and gel forming properties that can lead to hydration swelling matrix formation and sustained drug release but the performance of a gastro-retentive system will be different depending on which polymer is used and how much of it is present. A single polymer may form adequate matrix but buoyancy swelling matrix integrity drug content characteristics might not all be achieved simultaneously; hence comparative evaluation of individual polymer systems can provide information about relative contributions to gastro-retentive performance. [4]

Optimisation of multiple polymers can further improve formulation performance by finding the optimum combination and concentration of formulation variables. Design of Experiments (DoE) i.e., Box–Behnken design (BBD) is a systematic way to

study individual and interactive effects of formulation variables reducing the number of experimental trials required. The optimised formulation obtained from this approach can then be compared with single polymer formulations to see whether polymer combination and optimisation leads to meaningful improvement in critical quality attributes. [5]

Accordingly, the present study was conducted to compare single polymer and optimized gastro-retentive matrix tablets of lornoxicam. Matrix tablets made from Okra mucilage, Xanthan gum and Chitosan were compared with an optimized formulation containing combination of these polymers. Formulations were evaluated for buoyancy lag time, swelling behaviour, drug content and in vitro drug-release characteristics. The aim of this study was to establish relative performance of individual natural polymers and to find out advantage of polymer combination and statistical optimization in developing an efficient gastro-retentive matrix system for lornoxicam.

Material and Methods

Procurement of Drug and Excipients

Lornoxicam will be purchased as a gift sample from a reputable pharmaceutical company or certified supplier. Okra mucilage, xanthan gum and chitosan will be purchased as pharmaceutical grade excipients from authenticated suppliers; okra fruits (if required) will be collected from local market and botanically authenticated; sodium bicarbonate, beeswax, ethyl cellulose, microcrystalline cellulose, magnesium stearate, talc and other analytical-grade chemicals will be procured from recognized suppliers; all materials will be supported by certificates of analysis and stored under recommended conditions until use.

Comparison of Individual and Combined Natural Polymers

To study the individual contribution of each natural polymer to the performance of gastro-retentive matrix tablets, separate formulations were prepared using Okra mucilage (OM), Xanthan gum (XG) and Chitosan as individual matrix forming polymers. Effects of these polymers on floating behavior, swelling characteristics, drug content and in vitro release of drug were studied keeping all other excipients constant while maintaining composition and concentration of all other excipients constant. The performance of individual polymer formulations was compared with that of optimized formulation which contains combination of three natural polymers. [6]

Preparation and Evaluation of Single-Polymer Gastro-Retentive Matrix Tablets

Lornoxicam floating matrix tablets were prepared by direct compression method. The accurately weighed quantities of lornoxicam, the respective natural polymer (Okra mucilage, Xanthan gum or Chitosan), sodium bicarbonate, beeswax, ethyl cellulose and lactose were passed through sieve No. 60 and mixed uniformly for 15 min using geometric dilution method. Talc and magnesium stearate as glidant and lubricant respectively were added next and mixed for an additional 3–5 min.

The powder blend was compressed using a rotary tablet compression machine with 10-mm flat-faced punches to obtain tablets of approximate weight 320 mg. The prepared tablets were evaluated for weight variation, thickness, hardness, friability, buoyancy lag time, swelling index, drug content and in vitro drug release characteristics. Results were compared to find out the influence of individual natural polymers on lornoxicam gastro-retentive matrix tablets performance. [7-8]

Table 1: Formulation F-O (Okra Mucilage Alone)

Ingredients	Quantity (mg/Tablet)
Lornoxicam	8
Okra Mucilage	120
Sodium Bicarbonate	50
Beeswax	20
Ethyl Cellulose	30
Magnesium Stearate	5
Talc	5
Lactose q.s.	82
Total Weight	320 mg

Table 2: Formulation F-X (Xanthan Gum Alone)

Ingredients	Quantity (mg/Tablet)
Lornoxicam	8
Xanthan Gum	120
Sodium Bicarbonate	50
Beeswax	20

Ethyl Cellulose	30
Magnesium Stearate	5
Talc	5
Lactose q.s.	82
Total Weight	320 mg

Table 3: Formulation F-C (Chitosan Alone)

Ingredients	Quantity (mg/Tablet)
Lornoxicam	8
Chitosan	120
Sodium Bicarbonate	50
Beeswax	20
Ethyl Cellulose	30
Magnesium Stearate	5
Talc	5
Lactose q.s.	82
Total Weight	320 mg

Table 4: Comparative Single-Polymer Formulations at Different Polymer Levels

Ingredients (mg)	F-O1	F-O2	F-O3	F-X1	F-X2	F-X3	F-C1	F-C2	F-C3
Lornoxicam	8	8	8	8	8	8	8	8	8
Okra Mucilage	60	90	120	-	-	-	-	-	-
Xanthan Gum	-	-	-	60	90	120	-	-	-
Chitosan	-	-	-	-	-	-	60	90	120
Sodium Bicarbonate	50	50	50	50	50	50	50	50	50
Beeswax	20	20	20	20	20	20	20	20	20
Ethyl Cellulose	30	30	30	30	30	30	30	30	30
Talc	5	5	5	5	5	5	5	5	5
Magnesium Stearate	5	5	5	5	5	5	5	5	5
Lactose q.s.	142	112	82	142	112	82	142	112	82
Total Weight (mg)	320	320	320	320	320	320	320	320	320

Results and Discussion

In order to determine the individual contribution of each natural polymer on gastro-retentive performance of lornoxicam matrix tablets, formulations with Okra mucilage (F-O3), Xanthan gum (F-X3) and Chitosan (F-C3) as sole matrix forming polymers were prepared and compared with optimized multi-polymer formulation (F18). The post compression and performance characteristics such as hardness, friability, buoyancy lag time, swelling index, drug content and cumulative drug release over 12 h were evaluated for all the formulations.

All single-polymer formulations showed acceptable physical and mechanical properties. However, floating behavior, swelling characteristics and drug release profiles were different among them. Xanthan gum based formulation had the shortest buoyancy lag time (possibly due to rapid hydration and formation of gel-layer), Okra mucilage based formulation had highest swelling capacity (due to strong hydrophilic and water retaining property of mucilage). Chitosan based formulation had good matrix integrity and mucoadhesive properties but comparatively lower swelling capacity than Okra mucilage formulation.

In comparison, the optimized formulation (F18) containing Okra mucilage, Xanthan gum and Chitosan gave better overall performance. The combined polymer system gave a more balanced combination of rapid buoyancy, swelling, matrix integrity and drug release over 12 h compared to individual-polymer formulations. This may be due to complementary functional properties and possibly synergistic interactions between the three polymers. These results suggest that polymer combination and systematic optimization can control more critical performance characteristics of lornoxicam gastro-retentive matrix tablets than use of a single natural polymer.

Table 5: Comparative Evaluation of Single-Polymer and Optimized Gastro-Retentive Matrix Tablets of Lornoxicam

Parameter	F-O3 (Okra Mucilage)	F-X3 (Xanthan Gum)	F-C3 (Chitosan)	F18 (OF)
Weight Variation (mg)	319.8 ± 2.1	320.4 ± 1.9	320.2 ± 2.0	320.1 ± 1.6
Thickness (mm)	4.72 ± 0.06	4.68 ± 0.05	4.74 ± 0.04	4.70 ± 0.03
Hardness (kg/cm ²)	5.82 ± 0.08	6.42 ± 0.07	6.08 ± 0.08	6.52 ± 0.07
Friability (%)	0.62 ± 0.03	0.44 ± 0.02	0.52 ± 0.03	0.42 ± 0.02
Buoyancy Lag Time (sec)	42 ± 1.8	24 ± 1.2	31 ± 1.4	24 ± 1.2
Floating Duration (h)	>10	>12	>12	>12
Swelling Index (%)	268.6 ± 4.8	248.4 ± 4.5	221.7 ± 4.2	281.6 ± 4.3
Drug Content (%)	98.34 ± 0.58	99.12 ± 0.52	98.76 ± 0.56	99.56 ± 0.42
Drug Release at 12 h (%)	91.84 ± 0.96	95.72 ± 0.88	89.46 ± 1.02	98.64 ± 0.72
Release Kinetic Model	Higuchi	Korsmeyer–Peppas	Higuchi	Korsmeyer–Peppas
Release Exponent (n)	0.64	0.72	0.60	0.74

Table 6: Percentage Improvement of Optimized Formulation Compared with Single Polymer Formulations

Parameter	Compared with Okra Mucilage (%)	Compared with Xanthan Gum (%)	Compared with Chitosan (%)
Hardness Increase	12.03	1.56	7.24
Friability Reduction	32.26	4.55	19.23
Swelling Index Increase	4.84	13.37	27.02
Drug Release Increase	7.41	3.05	10.26
Drug Content Improvement	1.24	0.44	0.81

The comparative study showed that each natural polymer had its own impact on the performance of gastro-retentive matrix tablets. Okra mucilage mainly contributed to swelling and hydration while Xanthan gum provided rapid floating behaviour and good control over drug release; chitosan increased matrix integrity and mechanical strength but none of the individual polymers could provide all three properties simultaneously (floating ability, swelling capacity, matrix integrity and sustained drug release). The optimized formulation (F18) containing the combined polymer system performed better than other formulations possibly due to the complementary and synergistic effects of the three polymers. F18 had high swelling index (281.6%), good drug content (99.56 %), short buoyancy lag time (24 s) and cumulative drug release 98.64% after 12 h. The combination of rapid buoyancy, adequate swelling, structural integrity and prolonged drug release was achieved by the combined polymer matrix. These results indicate that Okra mucilage, Xanthan gum and Chitosan optimized combination was more effective than corresponding single-polymer systems for developing gastro-retentive floating matrix tablets of lornoxicam.

Conclusion

The comparative evaluation showed that although the individual natural polymers could produce satisfactory gastro-retentive matrix tablets, the optimized multi-polymer formulation was overall superior. Okra mucilage, Xanthan gum and Chitosan improved floating behaviour, swelling capacity, matrix integrity and sustained drug release. The three polymers had complementary properties so a more balanced and effective gastro-retentive system resulted. So the optimized multi-polymer combination was more promising than the individual polymers for the development of sustained release floating matrix tablets of lornoxicam.

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