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Formulation Development and Evaluation of Mefenamic Acid Floating Tablet Using Natural Polymer

Dhiraj Choudhary*, Narendra Vyas, Ashok Koshta, Aayushi Sharma, Sapna Malviya and Anil Kharia

Modern Institute of Pharmaceutical Sciences, Indore (M.P.) - India

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Abstract

Floating tablets of Mefenamic acid were developed with different concentrations of guar and Xanthan gum by direct compression methodology. The parameters such tapped density, bulk density, Carr's index, Hausner's ratio and angle of repose was found to be in the range and the thickness, weight, variation, hardness, friability of the tablets were found to be in the rang Tablets containing higher amount of guar gum & Xanthan gum usually showed longer total floating time. It ranged from 06 to 6.5 h. At the end of 6 h, F4 showed the best drug release 93.20%. F1, F2, F3, F5, and F6 showed 90.3, 91.7, 89.29, and 83.3% F6 showed the foremost effective sustained release behavior (73.2%) because of the polymer concentration was increased with increased viscosity grade, the percentage drug release got decreased resulting in a sustained drug release pattern over a period of more than 6.5h due to enhance Floatation, Based on present study it absolutely was concluded that floating tablets of mefenamic acid can increase the bioavailability additionally as gastric residence time, and so batter patient compliance may be achieved. It can be concluded that floating tablets are often used as a SR matrix. Due to their superior characteristics.

Key words: Mefenamic Acid, Floating Tablet, Natural Polymer, Bioavailability, guar gum, Xanthan gum

Introduction

Gastro retentive drug delivery systems are those systems in which the tablet is forced to remain inside the stomach for long duration, thereby increasing the absorption of the poorly absorbed drug in stomach and upper part of intestine. Increasing the duration for which the drug or the tablet remains in the stomach increases the bioavailability of the drug, increases the drug released in stomach, an also increases the gastric residence time in the stomach. Mefenamic Acid is an anthranlic acid and (NSAID) with antipyretic, anti-inflammatory and analgesic activities. Mefenamic acid inhibits the activity of the enzymes cyclooxygenase I and cyclooxygenase II, resulting in a decreased formation of precursors of prostaglandins and thromboxane. The resulting decrease in prostaglandin synthesis Mefenamic acid also causes a decrease in the formation of thromboxane A2 synthesis, by thromboxane syntheses, thereby inhibiting platelet aggregation the elimination half-life of mefenamic acid is approximately 2 hours and Volume of Distribution 1.06 L/kg and bioavailability of mefenamic acid is 90 %, Protein Binding is 99%, PKa is 4.2. [1]

***Corresponding Author**
E.Mail: dhirajc7370@gmail.com

Rational of Controlled Drug Delivery System

The fundamental reason for sustained / controlled drug delivery systems (CDDS) is to alter the pharmacokinetics and pharmacodynamics of pharmacologically active groups through the use of new drug delivery systems or by modifying the molecular structure and / or physiological Parameters inherent to an administration path selected. [2]

Approaches of GRRDS [3-4]

Several techniques are being studied and presented in the literature to increase the duration of dosage form for longer time in the stomach.

High Density Systems

This system which has a density greater than that of water the density of these systems is greater than 1g/cm3. As a result of their high density they are retained in the rogue of stomach for longer duration. A high degree of cross-linking retards the swelling ability of the system and maintains its physical integrity for prolonged period.

Mucoadhesive &Bio adhesive Systems

Bio adhesive drug delivery systems are used to keep the drug delivery dosage form within the inner lining of the stomach to increase the absorption of drug. These systems involve the use of bio adhesive and Mucoadhesive polymers in order to keep it in contact with the inner lining of the stomach. Some of the Excipients with bio adhesive and mucoadhesive properties are CMC, lectins, Carbopol, chitosan, polycarbophil & gliadin, etc.

Low Density Systems/ Floating Drug Delivery Systems

Floating Drug Delivery Systems are those systems in which the drug or Dosage form have the density less the 1 i.e. they float on the surface of the gastric fluid thereby increasing the duration in the stomach n increase the bioavailability if the drug.

Swelling and Expanding Systems

These are basically "Plug type system", because they get swelled to a large extent in the stomach fluid as a result a locked the pyloric sphincters due to their large size. These polymeric matrices remain in stomach for several hours.

Effervescent Floating Dosage Forms

Effervescent floating drug delivery systems generate gas carbon di oxide thus reduce the density of the system, and remain buoyant in the upper part of stomach for a prolonged period of time and release the API slowly at a desired rate. The main ingredients of effervescent system include polymers like methyl cellulose Chitosan and effervescent compounds such as sodium bicarbonate, citric acid, citric acid and tartaric acid.

Non-Effervescent Floating Dosage Forms

Non-effervescent floating dosage forms use a gel forming or sellable cellulose type of hydrocolloids, polysaccharides, and matrix forming polymers like polyacrylates polycarbonate, polystyrene and polymethacrylate. The formulation method includes a simple approach of thoroughly mixing the drug and the gel-forming hydrocolloid.

The fundamental reason for sustained / controlled drug delivery systems (CDDS) is to alter the pharmacokinetics and pharmacodynamics of pharmacologically active groups through the use of new drug delivery systems or by modifying the molecular structure and / or physiological Parameters inherent to an administration path selected.

The aim of the present work is to formulate development and evaluate floating tablet of Mefenamic acid using natural polymers. To develop floating tablet of Mefenamic acid using natural polymer in order to achieve an extended retention in upper part of GIT for desired time period. Naturally occurring polymers is preferred for controlled formulation because of its low cost, naturally available, and biocompatible and better patient tolerance as well as public acceptance.

Here we form the floating tablet of Mefenamic acid because it has short half-life and repidly eliminates from body, and it also has low absorption window. So, to overcome all these disadvantages we prepare gastro-retentive floating tablet which is stomach specific and release the drug in a controlled manner.

Material and Methods

Materials

Mefenamic acid and Excipients like Sodium bicarbonate, Citric acid, Cross povidone K30, dicalcium phosphate, Magnesium stearate and Polymers Xanthan gum and Guar gum was a gift from modern laboratories . All the ingredients

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used were of pharmaceutical grade

Methods

All ingredients were taken according the formulation. Mefenamic acid with polymers (Xanthan gum, guar gum) were sifted and passed through sieve #60 and then the remaining Excipients (sodium bicarbonate, citric acid and dicalcium phosphate, PVP K30 were rinsed over after pre-blending all ingredients in mortar for 15 minutes. The entire mixture was blended for 5 minutes. Then cross povidone and magnesium stearate was added and blended again for 5-6 minutes, the blends were taken for compression activity on compression machine. The Composition of Each Formulated Tablets Are shown In Table 1.[5-6]

Evaluation of Mefenamic acid floating tablets [8-12]

The powder was evaluated for bulk density, tapped density, Carr's index, angle of repose and Hausner's ratio. The prepared tablets were evaluated for hardness, thickness, friability, weight variation test, drug content, in vitro buoyancy, swelling index, and in vitro release studies.

a) Hardness

Hardness is amount of strength of tablet to be able to withstand various shocks during manufacturing to shipping. The hardness of ten tablets was measured using Monsanto hardness tester. The mean and standard deviation were computed and reported. It is expressed in kg/cm^2.The limit for hardness of the tablet ranges from 3 to 4 kg cm^{-1}

b) Thickness

This test is used to calculate the thickness of the tablet. It was evaluated by Screw Gauge.

c) Friability

The friability of the tablets was determined using electro lab friabilator. It is expressed in percentage (%). Ten tablets were initially weighed and transferred into the friabilator. The friabilator was operated at 25rpm for 4min. After 4 min the tablets were weighed again. The friability was then calculated using the formula, general acceptance limit is 0.5-1%

$$\text{Friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} * 100$$

d) Weight Variation

10 tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 10 tablets was calculated. The batch passes the test for weight variation test if not more than 2 of the individual tablet weights deviate from the average weight.

e) Drug content

10 tablets were weighed, and average weight was calculated. All the 10 tablets were crushed in mortar. The powder equivalent to 100mg of Mefenamic acid was dissolved in 100 ml of 0.1N hydrochloric acid and shaken for 20 min. Solution was filtered and 5ml of the filtrate was diluted to 100 ml using 0.1N hydrochloric acid. Absorbance of resultant solution was measured at 285 nm using 0.1N hydrochloric acid as a blank. The amount of drug present in one tablet wascalculated.

f) Swelling Index (SI)

The swelling Index of the tablets was determined by following procedure. In order to calculate the swelling index, tablets were initially weighed, kept in 100 ml of 0.1N HCl solution and were drawn out of the solution at determined time points, dried and their weights were taken. Swelling indices was calculated by the formula:

$$\% \text{ SI} = \frac{(W2 - W1)}{W1} * 100$$

g) Floating Lag Time

Three individual tablets from each formulation were put in an individual flask containing 400ml of 0.1(N) HCL solutions. Then note time in minutes for each tablet to go from the bottom to the top of the flask is called as floating lag time was measured.

h) Floating Time

Three individual tablets from each formulation were put in an individual flask containing 400ml of 0.1(N) HCL solutions. Then note the time for which tablets float on the surface of water.

i) In Vitro Release Study of Tablet [13]

Drug dissolution testing is routinely used to provide critical in vitro drug release info for both quality control purposes, In-vitro release studies were carried out by using United States of Pharmacopoeia (USP) Dissolution Testing Apparatus II. The 900 ml of the media (0.1N HCl) is taken in the flask by using paddle type apparatus at 50 rpm at 37 ^{0}c various times interval the 5ml of sample was withdrawn and sink

condition was maintained and all the samples were filtered and 1ml solution is pipette out and volume is made by appropriate solvent and was analyzed by U.V visible spectrophotometer.

j) Kinetics study

As per standard procedure

Drug-Excipients compatibility study [15-16]

The physical compatibility was observed visually. The study reveals that the drug and the excipients were physically compatible with each other as there was no change of color. The excipients are compatible with the drug selected for the formulation.

Table 1: Composition of Mefenamic acid Floatin

S. No.	Ingredients	F1	F2	F3	
1	Mefenamic acid	250 mg	250 mg	250 mg	2
2	Xanthan gum	20 mg	30 mg	40mg	5
3	Guar gum,	20 mg	30 mg	40 mg	5
4	Sod. Bicarbonate	80 mg	80 mg	80 mg	8
5	Citric acid	15 mg	15 mg	15 mg	1
6	Cross Povidone	10 mg	10 mg	10 mg	1
7	PVP K30	20 mg	20 mg	20 mg	2

Table 3: Physical Compatibility of Mefenamic acid and Excipients

S.No.	Drug + Excipients	Description and Condition	Room Temperature and 40ºC/75% RH in days	
			15th	30th
1	**Mefenamic acid**	White crystalline powder	NC	NC
2	**Drug + Xanthan gum**	White colored	NC	NC
3	**Drug + Guar gum**	White to yellowish powder	NC	NC
4	**Drug + Sod. Bicarbonate**	White powder	NC	NC
5	**Drug + Citric acid**	White powder	NC	NC
6	**Drug + Cross Povidone**	White powder	NC	NC
7	**Drug + PVP K30**	White powder	NC	NC
8	**Drug + Magnesium Stearate**	White powder	NC	NC
9	**Drug + Dicalcium phosphate**	White powder	NC	NC

The Chemical compatibility was determined using TLC. The study reveals that the drug and the Excipients were chemically compatible with each other as there was no significant change in the Rf values. The Excipients are compatible with the drug selected for the formulation

Table 4: Chemical Compatibility of Mefenamic acid and Excipients

S.No.	Mefenamic acid + Excipients	Room Temperature 40ºC & 75% RH in days			Observation
		Initial	15th	30th	
		Rf	Rf	Rf	
1.	**Mefenamic acid**	0.54	0.52	0.55	NC
2.	**D*+Xanthan gum**	0.53	0.55	0.53	NC

3.	**D*+Guar gum**	0.53	0.55	052	NC
4.	**D*+Sod. Bicarbonate**	0.52	0.54	0.53	NC
5.	**D*+Citric acid**	0.56	0.55	0.56	NC
6.	**D*+Cross Povidone**	0.47	0.46	0.48	NC
7.	**D*+PVP K30**	0.76	0.72	0.73	NC
8.	**D*+Magnesium striate**	0.52	0.51	0.51	NC
9.	**D*+Dicalcium phosphate**	0.45	0.44	0.44	NC

D* =Mefenamic acid Rf= sample value NC* =No Change
Mobile phase: Chloroform: Methanol (9.9: 0.1 V/V) Indicator: phenol red

Results and Discussion

Table 5: Study of BD, TD, Angle of repose, car's index, Hausner's ratio

Formulation code	Angle of Repose ±S.E.M	Bulk Density (gm/cm$^{2)}$ ±S.E.M	Tapped Density (gm/cm$^{2)}$ ±S.E.M	Carr's Index (%)	Hausner's Ratio (HR) ±S.E.M
F1	35.78±0.06	0.51±0.13	0.56±0.05	14.51	1.16±0.19
F2	27.35±0.05	0.43±0.01	0.50±0.02	12.96	1.14±0.18
F3	26.20±0.12	0.31±0.18	0.36±0.01	12.94	1.14±0.06
F4	26.95±0.02	0.40±0.04	0.46±0.04	13.46	1.15±0.12
F5	26.77±0.22	0.42±0.14	0.48±0.04	12.50	1.14±0.05
F6	25.30±0.21	0.33±0.05	0.38±0.12	13.16	1.15±0.10

Result are presented in mean ±S.E.M = (n=3)

The parameters such tapped density, bulk density, Carr's index, Hausner's ratio and angle of repose, were determined and the results were reported, as shown in Table.14 The bulk density and tapped density were tabulated and was found to be 0.31±0.18 to 0.51±0.13 and 0.36±0.01 to 0.56±0.05 respectively. Carr's index or compressibility index and Hausner's ratio was found to be in between 12.50% to 14.51% and 1.14±0.05 to 1.16±0.19. The angle of repose for different formulations was less than 35, which indicates passable flow properties of the powder. The values were found to be in between 25.30±0.21 to 35.78±0.06.

All these results indicate that the powder possessed satisfactory flow properties. The results were found to be within the limits and satisfactory. The pre-compression parameters of the powder blend (F1-F6) were shown in **table 5**

Post compression parameters

The properties of tablets such as thickness, hardness, friability, weight variation, Floating Lag Time (sec), Floating Time, drug content for the formulations F1 to F6 were determined and the results were reported **Table 6.**

Table 6: Evaluation Test for Floating Tablets

Evaluation Test & Formulation Code	Hardness (kg/cm^2) ±S.E.M	Thickness ±S.E.M	Friability (%) ±S.E.M	Weight Variation (mg) ±S.E.M	Floating Lag Time (sec)	oating time (h)	Drug content (%)
F1	7.3±0.15	3.96± 0.15	0.71±0.09	530±1.22	265 sec	06	99.63±0.03
F2	6.8±0.13	3.96± 0.06	0.60±0.10	532±1.82	300 sec	06	99.56±0.02
F3	6.6±0.09	3.98±0.03	0.50±0.07	532±1.61	230 sec	06	98.85±0.01
F4	6.5±0.05	3.97±0.17	0.66±0.06	535±1.12	260 sec	6.5	99.12±0.03
F5	6.5±0.05	3.92±0.19	0.53±0.08	532±0.91	240 sec	6.5	99.16±0.02
F6	7.0±0.19	3.91±0.19	0.5±0.10	533±1.23	205 sec	6.5	99.46±0.03

Result are presented in mean ±S.E.M = (n=3)

The thickness of the tablets was found to be in the range of 3.91±0.19 mm to 3.96±0.06. According to the weight variation test in U.S.P, the percentage deviation of the tablets weighing in the range of >324 mg is ±10%. The weight of all tablet formulations was as per the official requirements. Good uniformity in drug content was found among different formulations and the drug content was more than 97%. The hardness of the tablets was found to be in the range of 6.5-7.3 kg/cm^2.Tablet hardness isn't an absolute indicator of strength. Another measure of tablet's strength is friability. Conventional compressed tablets that lose less than 1% of their weight are generally considered accepted. In the present study, the friability for all the formulations was below 1% indicating that the friability was within the prescribed limit.

Table 7: Swelling Index for Floating tablet

Time in hours	Formulation and Swelling index (%)					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
1	20±0.12	18±0.66	28±0.21	21±0.33	26±0.32	35±0.55
2	75±0.13	71±0.32	31±0.32	126±0.55	117±0.65	166±0.55
3	11.9±0.12	99±0.45	90±0.23	166±0.65	193±0.25	210±0.54
4	13.2±0.15	102±0.12	185±0.32	175±0.33	221±0.25	230±0.55
5	155±0.22	112±0.21	196±0.54	199±0.66	237±0.32	245±0.54
6	170±0.22	134±0.33	202±0.36	202±0.55	240±0.12	262±0.25
7	172±0.32	137±0.33	207±0.12	203±0.66	245±0.12	274±0.21

The swelling index of the tablets from each formulation F1 to F6 was evaluated and the results of swelling index were shown in table 16. In the present study, the higher swelling index was found for tablets of batch F6 containing higher amount of combination of Xanthan gum and guargenerally showed longer total floating time. It ranged 6.0 to 6.5 hours. F6 had Total Floating Time 6.5 h due to the synergistic effect of Xanthan and guar gum. Higher amount of polymer that made dosage form excellently buoyant due to maximum swelling.

Swelling ratio describes the amount of water that is contained within the hydrogel at equilibrium and is a function of the network structure, hydrophilicity and ionization of the functional groups. While the plot of swelling index against increases with time because polymer gradually absorbs water due to its hydrophilicity. The outermost layer of polymer hydrates swells, and a gel barrier is formed at the outer surface. As the gelatinous layer progressively dissolves and dispersed, the hydration swelling release process is repeated towards new exposed surfaces, thus

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maintaining the integrity of the dosage form

Table 8: Drug Release Profile of Floating Tablet

Cumulative drug release profile of F1-F6.						
Time (h)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
0.5	5.44	8.86	7.35	6.24	7.55	6.14
1	16.5	11.6	9.62	14.5	11	13.98
1.5	24.9	27.4	12.42	26.5	18.6	19.66
2	30.5	39.7	25.33	35.7	24.2	24.52
2.5	51	57.2	35.23	47	35.12	34.94
3	60.2	60.54	50.13	57.6	49.5	41.95
3.5	70.6	71.9	57.52	70.7	55.6	46.27
4	73	80.8	63.26	77.8	72.5	50.53
4.5	79.2	83.6	72.14	83.6	74.6	52.74
5	85	85.4	80.24	88.9	80.6	57.17
5.5	88.4	90	86.25	92.9	85.9	67.5
6	90.3	91.7	89.29	93.2	88.3	73.2

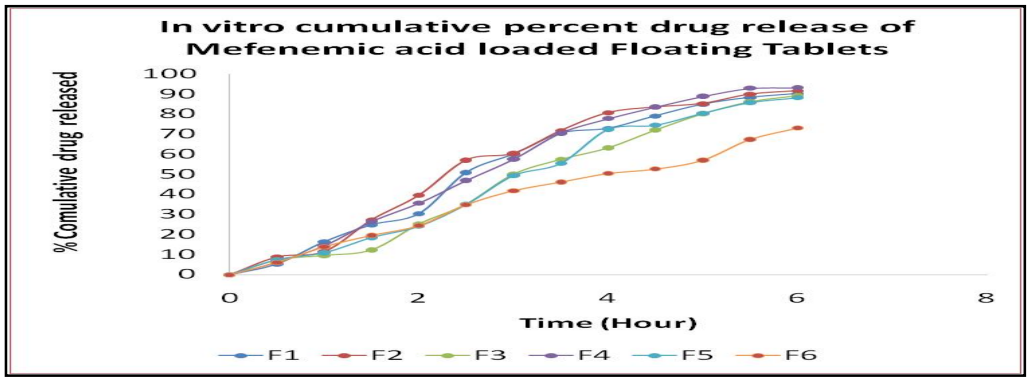

Fig. 1: *In-vitro* drug release profile of Mefenamic acid Tablets

Dissolution was carried out in USP apparatus 2, paddle type, six bucket dissolution apparatus. Formulated (F1, F2, F3, F4, F5, F6.) tablets were fixed with sinkers and put in the buckets of the dissolution apparatus filled with 0.1 N Hydrochloric acid up to 900 ml maintained at a temperature of 37 ± 0.5 ° C and paddle rotation speed at 50 rpm. Samples were withdrawn at time

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points of 30, 60, 90, 120, 150, 180, 210, 240, 270, 300, 330 and 360. Min and analyzed in UV-spectrophotometer (Shimadzu UV-1800) at lambda max of 285 nm. The values of absorbance obtained were used to calculate the amount of drug release.

Table 18: Release kinetics study of F6 formulation

TIME (Min)	Log Time	Square root of Time	Cumulative % Drug Released	Log Cumulative % Drug Released	Cumulative % Drug Remained	Log Cumulative % Drug Remained
0	0	0	0	0	0	0
30	0.30	1	6.14	0.79	93.86	1.97
60	0.48	1.41	13.98	1.14	86.02	1.93
90	0.60	1.73	19.66	1.29	80.34	1.90
120	0.70	2	24.52	1.38	75.48	1.87
150	0.78	2.23	34.94	1.54	65.06	1.81
180	0.85	2.45	41.95	1.62	58.05	1.76
210	0.90	2.64	46.27	1.66	53.73	1.73
240	0.95	2.82	50.53	1.70	49.47	1.69
270	1	3	52.74	1.72	47.26	1.67
300	1.04	3.16	57.17	1.75	42.83	1.63
330	1.08	3.31	67.5	1.82	32.5	1.51
360	1.28	3.46	73.2	1.86	26.8	1.42

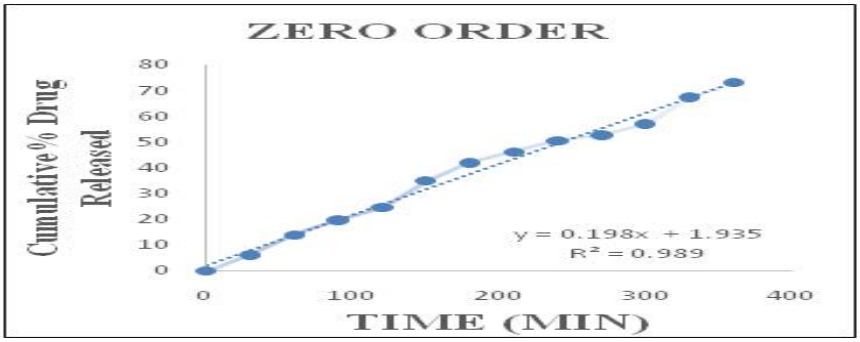

Fig. 2: zero order release kinetic graph.

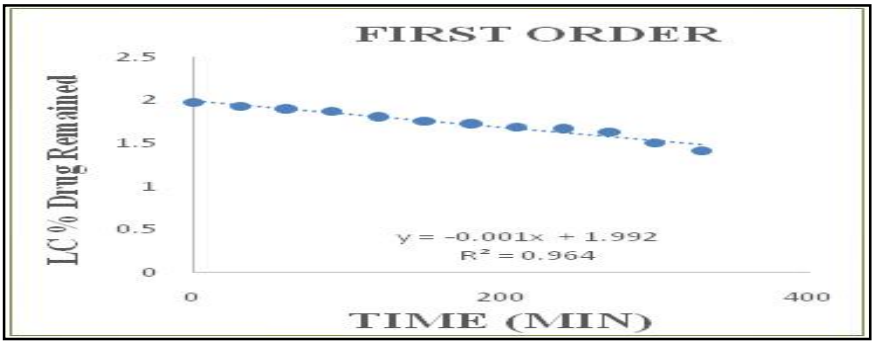

Fig. 3: first order release kinetic graph.

Further kinetics study was done for optimized formulation F6 using zero order, first order. This shows r2 values varies from 0.989-0.964, which concludes this formulation is best fitted in zero order model with r2 value 0.989.

Conclusion

The Chemical compatibility was determined using TLC. The study reveals that the drug and the Excipients were chemically compatible with each other as there was no significant change in the Rf values. The Excipients are compatible with the drug selected for the formulation.

The parameters such tapped density, bulk density, Carr's index, Hausner's ratio and angle of repose, were determined and the results were reported, as shown in Table.05 The bulk density and tapped density were tabulated and was found to be 0.52±0.18 to 0.57±0.05 and 0.62±0.05 to 0.71±0.04 respectively. Carr's index or compressibility index and Hausner's ratio was found to be in between 11.11% to 23.94% and 1.12±0.05 to 1.27±0.18. The angle of repose for different formulations was less than 30, which indicates good flow properties of the powder. The values were found to be in between 26.0±0.05 to 29.7±0.02. All these results indicate that the powder possessed satisfactory flow properties. The results were found to be within the limits and satisfactory. The pre-compression parameters of the powder blend (F1-F6) were shown in **Table 05**

The thickness of the tablets was found to be in the range of 3.91±0.19 mm to 3.96±0.06. According to the weight variation test in U.S.P, the percentage deviation of the tablets weighing in the range of >324 mg is ±10%. The weight of all tablet formulations was as per the official requirements. Good uniformity in drug content was found among different formulations and the drug content was more than 97%. The hardness of the tablets was found to be in the range of 6.5-7.3 kg/cm^2.Tablet hardness isn't an absolute indicator of strength. Another measure of tablet's strength is friability. Conventional compressed tablets that lose less than 1% of their weight are generally considered accepted. In the present study, the friability for all the formulations was below 1% indicating that the friability was within the prescribed limit.

Tablets containing higher amount of Xanthan gum and guar gum generally showed longer total floating time. It ranged from 6.0 to 6.5 h. F6 had Total Floating Time 6.5 h due to the synergistic effect of Xanthan and guar gum, higher amount of polymer that made dosage form excellently buoyant due to maximum swelling.

Dissolution was carried out in USP apparatus 2, paddle type, six bucket dissolution apparatus. Formulated (F1, F2, F3, F4, F5, F6.) tablets were fixed with sinkers and put in the buckets of the dissolution apparatus filled with 0.1 N Hydrochloric acid up to 900 ml maintained at a temperature of 37 ± 0.5 º C and paddle rotation speed at 50 rpm. Samples were withdrawn at time points of 60, 120, 180, 240, 300, 360, 420, 480, 540, 600, 660, and 720. Min and analyzed in UV-spectrophotometer (Shimadzu UV-1800) at lambda max of 285 nm. The values of absorbance obtained were used to calculate the amount of drug release. Further kinetics study was done for optimized formulation F6 using zero order, first order. This shows r2 values varies from 0.989-0.964, which concludes this formulation is best fitted in zero order model with r2 value 0.989.On the basis of present study it was concluded that floating tablets of Mefenamic acid can increase the bioavailability as well as gastric residence time and thus batter patient compliance may be achieved.

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