

FORMULATION AND EVALUATION OF IBUPROFEN FLOATING TABLET

ABSTRACT

The objective of this research work was to formulate and evaluate the gastric floating drug delivery system (GFDDS) containing Ibuprofen as a model drug. Ibuprofen is Anti-inflammatory drug. Identification of drug was done Standard calibration curve. Formulations contained HPMC, Xanthan gum, PVP K and gas generating agent such as sodium bicarbonate and citric acid were taken as independent variables. Floating systems have low bulk density so that they can float on the gastric juice in the stomach. On trial & Error basis formulation design was done. Manufacturing of tablets done on the basis of suitable batch obtained from preformulation study on lab level Tablet Press(CEMACH) by wet granulation method. Evaluations tests performed on tablets such as Hardness, Weight variation, friability along with Floating lag time & Total floating time was estimated in suitable medium. The physical parameters of the tablets were characterized and were found within the limits. On the basis of preformulation & all evaluation parameter, the formulation F1 was considered as a better formulation.

Keywords: Ibuprofen, buoyancy lag time, HPMC, Xanthine, Standard calibration curve

Introduction:-

Floating Drug Delivery System are the systems that can stay in the gastric region for several hours and thus, prolong the gastric residence time of the drugs. When the dosage form administered it contact with gastric fluid and produce effervescent and evolved CO₂ gas. This support to penetrate the fluid in tablet and float, the low density polymer HPMC various grade provide low density system so it buy out efficiently in gastric fluid. The system is as design to float and shows sustains release for better patient compliance and reduces dose. Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID).¹¹ It is a propionic acid derivative.¹² It is used for treating pain, arthritis. The bioavailability of the drug is 87-100% and the protein binding capacity is 98%. It is metabolised by liver and the biological half live is 13.3 hours. It is excreted through urine.

Aim & Objective:- The reaches investigated in present study is an attempt toward developing controlling release

oral floating tablets to increase the resident time of drug in the stomach & release for extended period of time in order to Increase the bioavailability of drug.

Providing uniform drug delivery To prepare economical preparation.

To improve patient compliance Decrease dose

Minimize side effect.

Material & Method:-

Material:-Ibuprofen obtained as a gift sample from Leben Parma, Akola. HPMC, Carbapol 940 Citric acid, lactose and Sodium bicarbonate ,Talc and MCC were obtained from Research Lab, Akola. All the chemicals and reagents required for the present experimental work are of analytical grade.

Method:-Wet Granulation Technique.

Preformulation Study:-

Physical Characterisation:- FTIR, Standard Calibration Curve

Standard Calibration Procedure Preparation of stock solution:- 10mg Ibuprofen + 100ml phosphate buffer 6.8

Preparation of different concentration: pipette out 1 ml stock solution+dilute 10ml with distilled water in 10 ml volumetric flask.

Bulk Density: It refers to packing of particles. Bulk density is used to determine the amount of drug that occupies the volume in g/ml.

Procedure: Weighed quantity of tablet blend was transferred into 100 ml measuring cylinder without tapping during transfer. The volume occupied by drug was measured. Bulk density was measured by using formula.

$$\text{Bulk Density} = m / V_i$$

Where, m = mass of the blend

V_i = untapped volume

Tapped density:

Weighed quantity of tablet blend was into a graduated cylinder. Volume occupied by the drug was noted down. Then cylinder was subjected to 100, 200 & 300 taps in tap density apparatus. According to USP,

Tapped density was calculated.

$$\text{Tapped density} = m / V_t$$

Where, V_t is tapped volume

Carr's Index (Compressibility):

The compressibility index and Hausner ratio was measures the property of powder to be compressed. The packing ability of tablet blend was evaluated from change in volume , which is due to rearrangement of packing occurring during tapping. It was indicated as Carr's compressibility index was calculated by following formula,

$$\text{Carr's index} = \left[\frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \right] \times 100$$

Hausner Ratio:

It is measurement of frictional resistance of tablet blend. The ideal range should be 1.2-1.5. It was determined by the ratio of tapped density and bulk density

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Angle of Repose (θ):

It is defined as the maximum angle that can be obtained between the free standing of powder heap and horizontal plane, which is determined by the equation:

$$\text{Angle of repose}(\theta) = \tan^{-1} h/r$$

Where, θ = Angle of repose.

h = of powder heap.

r = Radius of the powder cone.

Physical Evaluation of Ibuprofen floating tablets:-

Physical Characterisation: - FTIR, Standard Calibration Curve

Weight uniformity test:-

If the drug forms greater part of the tablet, any variation in the tablet weight obviously indicates a variation in the active ingredient this test resembles weight uniformity test. 20 tablets were selected at random and average weights were determined. Then individual tablets weighed and the individual weight was compared with the average.

$$\text{Calculate the average weight of tablets} = \frac{\text{Total weight of tablets}}{\text{Number of tablets}}$$

Number of tablets

$$\text{Average weight of tablets (X)} = \frac{(X_1 + X_2 + X_3 + \dots + X_{20})}{20}$$

Hardness test:-

The hardness of the tablets were determined using Monsanto Hardness tester. It is expressed in kg/cm². Six tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

Friability

A friability test was conducted on the tablets using an Roche friabilator. Twenty tablets were selected from each batch and any loose dust was removed with the help of a soft brush. The tablets were initially weighed (W_{initial}) and transferred into friabilator. The drum was rotated at 25 rpm for 4 minutes after which the tablets were removed. Any loose dust was removed from the tablets as before and the tablets were weighed again (W_{final}). The percentage friability was then calculated by,

$$\% \text{ Friability} = (W_i - W_f / W_i) \times 100$$

Where,

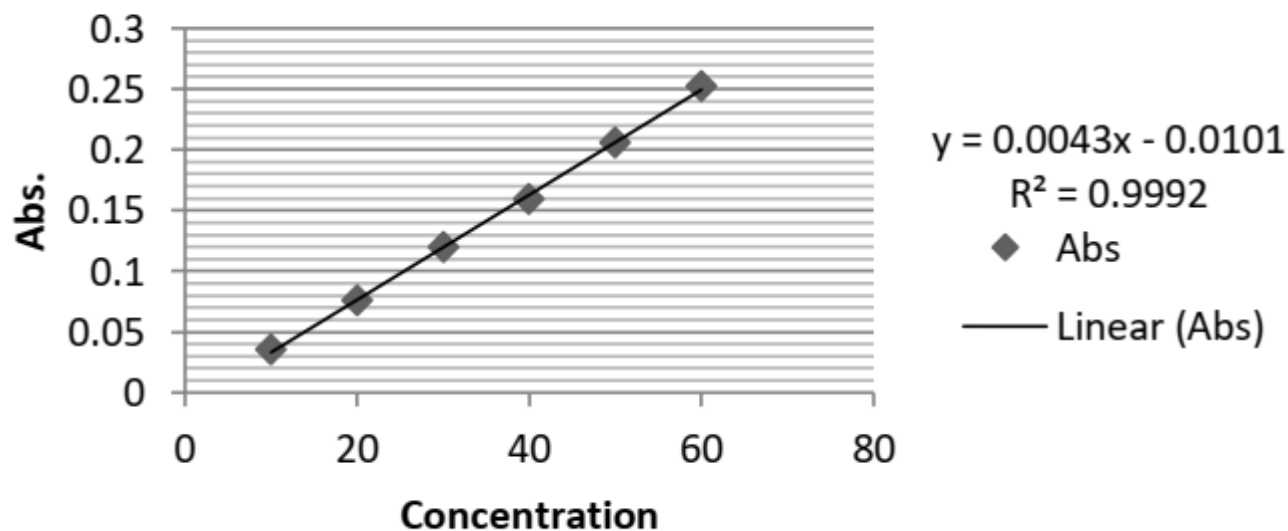
W_i – initial weight of tablets, W_f – final weight of tablets

Graphical Representation:-

Standard Curve of Ibuprofen

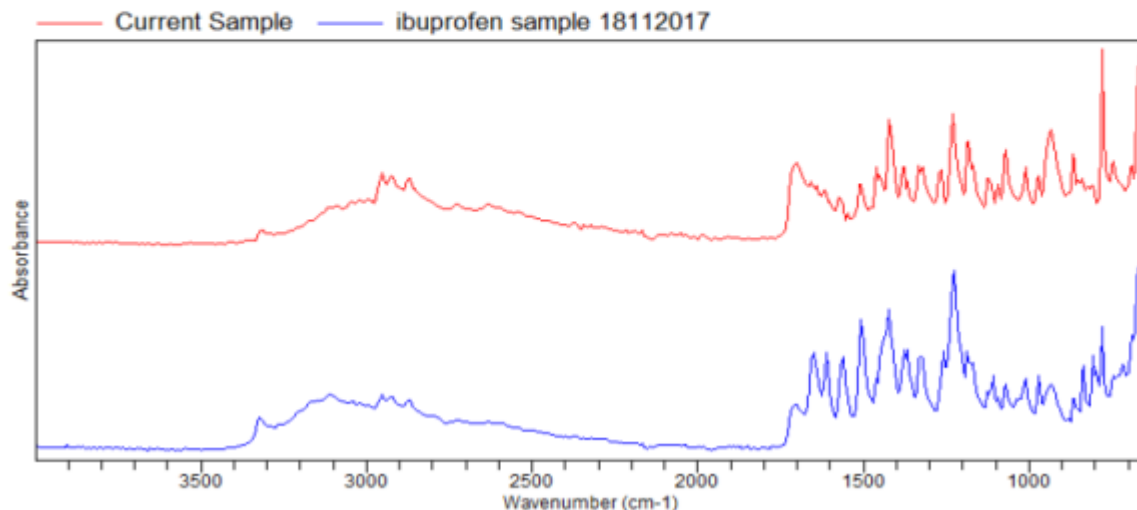
Conc	Abs
10	0.035
20	0.076
30	0.12
40	0.159
50	0.206
60	0.252

Ibuprofen Linearity Curve



Sample ID: ibuprofen sample 3 18112017
 Sample Scans: 32
 Background Scans: 32
 Resolution: 8
 System Status: Good
 File Location: C:\Users\Public\Documents\Agilent\MicroLab\Results\File Location\ibuprofen sample 3 18112017_2017-11-19T15-05-25.a2r

Method Name: Library Search Demo ATR Library
 User: RSCP@FTIR
 Date/Time: 11/19/2017 3:05:25 PM
 Range: 4000 - 650
 Apodization: Triangular



FTIR Ibuprofen Graph compared with Standard

Tabular Representation: Results of physical evaluation of Pre-compression Blend:-

Formulations	Angle of repose	Bulk Density	Tapped Density	Carr's Index	Hausner's ratio
F1	21	0.224	0.264	14.77	14.77
F2	22	0.222	0.260	14.61	14.61
F3	26	0.251	0.289	13.14	13.14
F4	25	0.229	0.260	11.92	11.92

Formulation

Table

Development of different formulations containing, varying proportions of polymers:-

Batch code	Drug (mg)	HPMC (mg)	Xanthin (mg)	NaHCO ₃ (mg)	M.C.C (mg)	Citric acid (mg)	Lactose (mg)	Mg stearate (mg)	Talc (mg)
F1	100	50	12	25	38	12	13	5	5
F2	100	37	25	25	38	12	13	5	5
F3	100	25	37	25	38	12	13	5	5
F4	100	12	50	25	38	12	13	5	5

Weight Variation, Thickness, Hardness and Friability:-

Formula	Weight variations	Hardness (kg/cm ³)	Friability (%)
F1	Comply	5.9	0.2
F2	Comply	6.3	0.3
F3	Comply	4.2	0.5
F4	Comply	3.7	0.7

Floating Lag time & Total Floating Time:-

Formulation Code	Buoyancy time (sec)	lag	Total floatation time (hrs)
F1	120		11
F2	100		09
F3	200		5.8
F4	240		8

Data showing comparative *In-Vitro* % drug release profiles for all the prepared formulations:-

Time(Hrs)	F1	F2	F3	F3	F4
30(Mins)	1.00	3.36	3.99	2.90	3.26
1	1.09	5.48	7.40	7.30	8.25
2	3.64	7.40	9.15	8.30	9.13
3	8.96	8.15	10.0	10.0	10.90
4	12.68	10.05	10.97	11.99	12.80
5	16.61	12.87	13.97	12.97	13.90
6	18.48	14.82	20.38	19.38	18.58
7	20.38	17.89	23.30	23.3	23.38
8	21.38	18.20	25.98	24.36	26.39
9	22.25	20.26	26.90	30.38	30.56
10	28.30	25.36	28.30	32.23	35.70
11	33.20	30.31	30.22	35.30	40.23
12	35.36	33.25	35.38	39.30	45.30
13	40.31	45.30	39.39	40.39	47.38

Result & Conclusion:-

From the above evaluation parameter F1 Batch shows all parameter in acceptable limits, thus Formulation F1 considered as good formulation.

Reference:-

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