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Original Research Article

Preparation and Characterization of Atenolol Gastro-Retentive Tablet Using Bajari Stem Pith Powder as A New Polymer.

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Abstract: ***Background***: Natural polymers are currently being employed in place of synthetic gastro-retentive polymers. These ecofriendly plant-based materials are inexpensive, biocompatible, and biodegradable with no harmful effects. ***Purpose***: The main goal of the current study was to create gastro-retentive Atenolol tablets using Bajari Stem Pith (BSP) powder as a new polymer and to extend the drug release for eight to twelve hours. ***Methods***: BSP powder was used in the current study to develop gastro-retentive Atenolol tablets. The wet granulation method was selected for the making of gastro-retentive tablets based on the unique features of the constituents in the tablet formulation. The tablets were subjected to general tests of tablet including floating lag time, floating time, swelling index and drug release. ***Results***: The prepared gastro-retentive tablets passed every tablet evaluation test. The produced tablet's floating behavior and dissolution pattern demonstrated that it is a good gastro-retentive tablet that maintains drug release for up to eight hours. Dissolution profile data were integrated into different release kinetic models to examine the mechanism of drug release and analyze the release behavior of each formulation. M6 was found to be the most effective gastro-retentive tablet. ***Conclusions***: This study concludes that as the concentration of BSP powder rises, there is an increase in floating time and a commensurate decrease in tablet dissolution rate. The best formulation, M6, has demonstrated superior floating behavior and is composed of 15% BSP powder and 12% HPMC (K-100M). The produced gastro-retentive tablet formulation exhibits a swelling-controlled and diffusion-controlled drug release mechanism, as indicated by the release kinetics investigations, which point to an anomalous (non-fickian) diffusion pattern.

Keywords: Atenolol; Bajari Stem Pith; Floating behavior; HPMC; Sustained release:

INTRODUCTION

Due to its affordability, ease of self-medication, and ease of intake, the oral route is the most popular and practical of all. Because tablets are more stable in storage than other dosage forms and are suitable for production, they are the most popular form of dose for oral formulations on the market. [1]

However, the oral route has several disadvantages, such as inconsistent drug absorption due to varying gastrointestinal transit, insufficient drug release from medication, and shorter stomach residence time. These disadvantages result in decreased stomach bioavailability for several drugs. [2] The scope of gastro-retentive systems has improved as a result of efforts to improve stomach retention in order to address these problems. Gastric retention duration is increased by these systems. [3] In situations when drugs must act locally in the stomach, like when treating an H. pylori infection, the Gastro-retentive Drug Delivery System (GRDDS) also enhances the outcome of treatment. [4] GRDDS is also advantageous for drugs that are well absorbed via the stomach and are especially stable in the stomach's acidic environment. For drugs that are unstable in the alkaline intestinal environment, GRDDS is also beneficial. Since atenolol is unstable in the intestines and mostly absorbed from the upper gastrointestinal tract, numerous researchers have created gastro-retentive floating tablets to improve bioavailability. [5]

Floating, swellable, expandable, mucoadhesive, and other systems are all included in GRDDS. The floating system was shown to be the most effective of these gastroretentive systems in delaying the stomach transit time. Floating systems are designed to keep the dosage form floating on stomach fluid for extended periods of time. To create the floating drug delivery method, several researchers use effervescent substances including sodium bicarbonate, tartaric acid, and citric acid. [6, 7, 8]

The design of a gastroretentive system has shown promise in the field of pharmaceutical technology. With the exception of complex production processes like coating and palletization, the kind and quantity of polymer in the preparations mostly determine the drug's release from the dosage form. [9]

ACE-inhibitors like atenolol are used to treat a variety of heart problems. Atenolol is a water-soluble compound that is quite stable in the stomach's acidic environment. Additionally, the stomach absorbs it to a greater degree. However, atenolol becomes unstable and cannot be absorbed from the colon as the pH rises due to the alkaline environment of the intestine. [10, 11, 12, 13]

The use of natural polymers in the manufacturing of innovative formulations with enhanced unique properties has increased in demand. Natural plant-based materials are more patient-friendly, affordable, biocompatible, biodegradable, renewable, and may be processed in an environmentally benign way. [14] As low density excipients, only a small number of polymers could be used in the formulation of GRDDS. In this study, we used powdered Bajari stem pith as a low density polymer. The most widely grown grain in the world in Central America is bajari (Zea mays L.), a member of the Poaceae family. Due to its widespread cultivation and excellent yield output in the global market, bajari is known as the "Queen of Cereals" worldwide. Every season of the year is suitable for growing bajari crops. There are several different types of bajari, such as popcorn, sweet corn, baby corn, white grain, and yellow grain. In addition, bajari is an essential industrial raw material that is used to make a variety of chemical excipients, including sorbitol, glucose, dextrose, and starch. Bajari stem pith may therefore be utilized in place of the low density excipients that are currently on the market. 35.7% cellulose, 18.7% hemicelluloses, and 30.2% lignin make up bajari pith, which is abundantly available, biodegradable, biocompatible, nontoxic, and reasonably priced. [15]

In this investigation, the natural polymer Bajari Stem Pith powder is used in varying amounts to formulate a gastro-retentive Atenolol tablet using the wet granulation process. The purpose of the study was to use Bajari Stem Pith powder with a desired dissolution profile to make an Atenolol gastro-retentive sustained release matrix tablet.

MATERIAL AND METHOD

2.1 MATERIAL

The fresh stems of Bajari plant were collected from

the home farm of Jamner, Tal. Jamner, Dist. Jalgaon (Maharashtra) in the month of December. Atenolol was purchased from Surgical Home, Ambala cantt, (Hariyana). Labware Chemicals, Latur, Maharashtra, provided HPMC (K100M), PVP (K90), Microcrystalline cellulose, Talc, Magnesium stearate, Isopropyl alcohol (99.90 %) AR grade, and Hydrochloric acid (37 %) AR grade. During entire research distilled water was utilized.

2.2 METHOD

I. Preformulation studies on Atenolol

Preformulation is the study of physicochemical characteristics of drug molecule alone or in combination with excipients.

A. Melting point determination of Atenolol

Atenolol melting point was determined by digital melting point apparatus. [16]

B. Determination of maximum wavelength (λmax)

Exactly weighed 100 mg of Atenolol was placed to the volumetric flask (100 mL capacity) half filled with 0.1N HCl (simulated gastric fluid). The flask was shaken vigorously until the drug dissolves completely. Then volume was then adjusted with 0.1 N HCl (Stock solution-I). 2 mL of drug solution was withdrawn from stock solution-I and poured in volumetric flask (100 mL capacity) and again the volume was compensated with 0.1 N HCl (Stock solution-II). The resultant solution (Stock solution-II) was then analyzed with UV visible spectrophotometer by scanning between 200-400 nm to identify the wavelength (λmax) at which maximum absorbance is obtained. [17]

C. Preparation of calibration curve of Atenolol

In the similar way to that of the λmax determination, Atenolol standard solution series was prepared with concentrations of 04, 08, 12, 16, and 20 µg/mL by using 0.1N HCl. The resultant solutions were then analyzed with UV visible spectrophotometer at 219.7 nm. [17]

D. Compatibility between drug and excipients

a. IR (Infra-red) study

IR spectra of Atenolol (ATL), Bajari Stem Pith powder (BSP) and physical mixture of ATL and Bajari Stem Pith powder (BSP) were performed on Fourier Transform Infrared Spectrophotometer (MIRacle 10). Small quantity of sample was taken and directly put on IR platform. Then the spectrum was studied in the 4000 to 400 cm-1 wavelength region. [18]

b. DSC (Differential Scanning Calorimetry) study

Thermogram of Atenolol (ATL) alone, Bajra Stem Pith powder (BSP), and physical mixture of ATL, BSP powder were performed on a Shimadzu DSC 60. This instrument is calibrated for temperature and enthalpy by using pure indium. 3-5 mg of Atenolol was placed on non-fermetic Aluminum pans and crimped and finally covered with lid. It was then scanned at 50-300 ºC. Meanwhile the heating rate is maintained at 10 ºC/min under a continuous nitrogen gas purging (rate of flow 20 mL/min). The instrument uses a refrigerated cooling system. [19]

E. Solubility of Atenolol

Methanol and distilled water was used to check the solubility of Atenolol.

II. Preparation of Bajari Stem Pith powder (BSP)

Bajari is a tropical plant which is sowed in between last week of May to 2nd week of June (Kharif season) and harvested in late September or October. After the harvesting of Bajari from the plant, the remaining stem part was allowed to dry completely. Then dried stem was used for the further use. The outer covering of the stem was removed and inside spongy pith portion was separated. The obtained pith portion was then separated for any other impurities. The crude pith was then subjected to size reduction using cutter mill to obtain Bajari Stem Pith powder (BSP).

III. Formulation of gastroretentive tablets

To check the floating lag time, floating time and dissolution behavior of tablet formulation, tablets were prepared by using BSP powder. Following table shows the concentration of BSP powder.

Table 1: Formula for gastroretentive tablets using BSP powder

Sr. No.	Ingredients	M1	M2	M3	M4	M5	M6
1	Atenolol	50	50	50	50	50	50
2	BSP powder	-	-	-	15	30	45
3	HPMC (K100M)	18	36	54	36	36	36
4	Sodium bicarbonate	30	30	30	30	30	30
5	PVP-K90	10	10	10	10	10	10
6	Microcrystalline cellulose	184.5	166.5	148.5	151.5	136.5	121.5
7	Talc	4.5	4.5	4.5	4.5	4.5	4.5

8	Magnesium stearate	3	3	3	3	3	3
9	Isopropyl alcohol	Q. S. (Applicable to all batches)					
Total tablet weight		300 (Applicable to all batches)					

*All values in the table are in mg.

Ingredients in the formula were accurately weighed. The PVP-K90 was then slowly dissolved in Isopropyl alcohol. The solution was agitated to dissolve PVP-K90 and create a homogeneous transparent binder solution. Atenolol, BSP powder, and microcrystalline cellulose were thoroughly blended for 25 minutes in a mortar with a pestle. With the proper amount of binder, the resultant blend was granulated. During granulation, no lump development was detected. The granules were obtained by passing the cohesive material through a 20# sieve. The resulting granules were dried in an oven at 50 °C. Sifting the dry granules through a 16# sieve, the remaining materials, such as magnesium stearate and talc, were screened through a 30# sieve and uniformly combined with the produced granules for lubrication. To make the tablet, 300 mg of granules were weighed and compressed using a KBR press.

IV. Evaluation of granules

The granules were evaluated by angle of repose and compressibility index as per the previously established method. [21] Further granules were also tested for their bulk and tap densities.

V. Evaluation of gastroretentive tablets

Gastroretentive tablets were evaluated by thickness, diameter, hardness, weight variation test, and friability. [22]

A. Estimation of drug content

Randomly twenty tablets were selected and weighed. Triturate all 20 tablets to obtain the powder. The powder was weighed in such a manner that it should contain 25 mg of the Atenolol. The powder was placed in volumetric flask (capacity- 100 ml) and dissolved in 0.1N HCl. The final volume was compensated using the same medium. Further dilutions were made using the same medium to get the resultant solution of 10 µg/ml of Atenolol. This solution was then filtered and filtrate was subjected to UV visible spectrophotometric analysis at 205 nm and finally the absorbance was measured.

It is possible to assess drug content by using the formula:

$$\text{Drug content (\%)} = \frac{\text{Practical concentration}}{\text{Theoretical concentration}} \times 100$$

B. Floating lag time

To calculate the floating lag time, a tablet was immersed in a beaker containing 900 ml of 0.1N HCl, and the time it took for the tablet to reach the surface of the medium was recorded using a stop watch. [23, 24]

C. Floating time

The amount of time that tablets float on medium is called floating time. A tablet was incorporated in 900 ml of 0.1N HCl in dissolution type II apparatus, which was then rotated at 100 rpm at 37 °C to simulate a stomach environment. A stopwatch was used to keep track of time. [24, 25]

D. Swelling index

Placing the tablet in a basket containing the dissolution medium 0.1N HCl at 37 °C 0.5 °C was used to measure the swelling index. The tablet was removed after a certain time interval, blotted using tissue paper to remove excess water, and weighed on an electronic balance. The following formula was used to determine the swelling index. [26]

$$\text{Swelling index (\%)} = \frac{\text{Swollen tablet weight} - \text{Dry tablet weight}}{\text{Dry tablet weight}} \times 100$$

E. In vitro dissolution studies

For all formulations, release study was carried out in triplicate using type II dissolution apparatus under sink conditions. The selected medium for dissolution was 900 ml 0.1N HCl maintained at 37 °C ± 0.5 °C with the rotational speed of paddle 50 RPM. 5 ml aliquot was sampled, filtered, and 2 ml of which was diluted to 10 ml by 0.1N HCl after predetermined time intervals. The resultant solutions were subjected to absorbance estimation by using UV visible spectrophotometer at 205 nm. [27]

a. Estimation of t75 of % CDR

“t75 is the time required to release 75 % of drug from the formulation." This information can be used to assess the drug release pattern of a gastroretentive sustained release tablet that has been manufactured. [28]

b. Drug release kinetic studies

The data were fitted into the Zero order, First order, Higuchi model, and Korsmeyer-Peppas models to examine the mechanism of release and release kinetics of the dosage form. The best-fit model was chosen based on the R2 values obtained. [30]

c. Mean dissolution time (MDT)

MDT is the time taken by a medicine to dissolve. MDT stands for the polymer's drug release retarding efficiency. A greater MDT shows a polymer's potential to delay drug release, and vice versa. Following equation is used to calculate MDT. [31]

$$MDT = \frac{\sum_{j=1}^{n} t_j^{*} \Delta M_j}{\sum_{j=1}^{n} \Delta M_j}$$

Where j, n, tj, tj and Mj indicates sample number, number of time increments, the time between tj and tj-1, and an extra amount of drug dissolved respectively.

VI. Stability study

Tablets (M6) were subjected to six month accelerated stability study at 40 °C, 2 °C, and 75 % RH. To assess the influence of accelerated storage conditions on these parameters, samples were collected and tested at the beginning, after 3 months, and after 6 months for description, floating time, swelling index, and t75 of % CDR. (FDA: guidelines for stability studies, www.ich.org/ stabilitytesting-for-new-dosage-forms.html). [32]

RESULT AND DISCUSSION

I. Preformulation studies on Atenolol

A. Melting point determination of Atenolol

Atenolol has a melting point of 153-154 °C, according to melting point apparatus.

B. Determination of maximum wavelength (λmax)

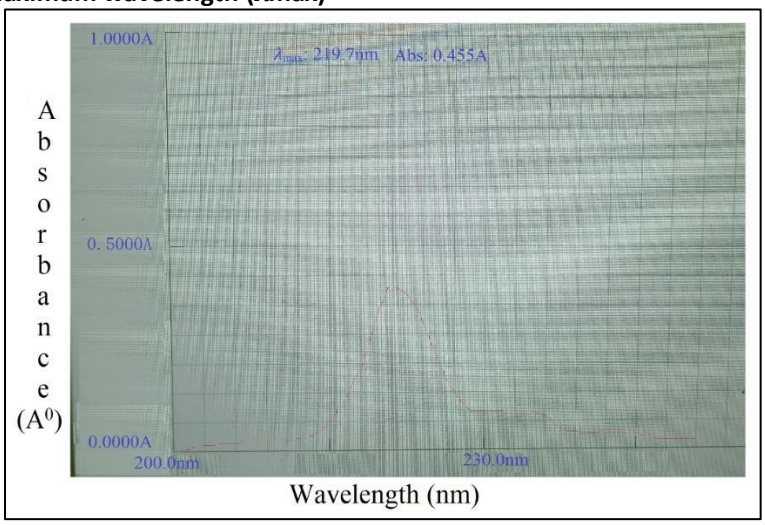

Figure 1: λmax of Atenolol in 0.1N HCl

The λmax of Atenolol solution having concentration 20 µg/ml in 0.1 N HCl was found to be 219.7 nm.

C. Preparation of calibration curve of Atenolol

The absorbances obtained for the prepared solutions of various concentrations of Atenolol are given in table 2 and graph is shown in figure 2.

Table 2: Calibration curve of Atenolol in 0.1N HCl

Sr. No.	Concentration	Absorbance

	(µg/mL)	(A°)
1	4	0.076
2	8	0.152
3	12	0.228
4	16	0.304
5	20	0.388

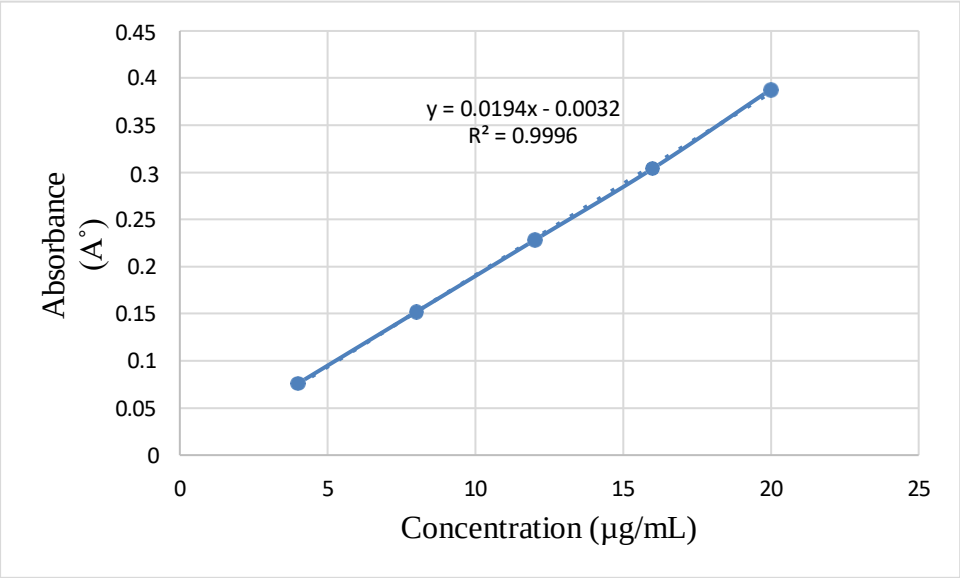

Figure 2: Calibration curve of Atenolol in 0.1 N HCl

Slope	0.0194
Intercept	0.0032
R2	0.9996

D. Compatibility between drug and excipients

a. IR (Infra-red) study

FTIR spectra of Atenolol (ATL) and physical mixtures of ATL + BSP (Bajari Stem Pith powder) as shown in fig. 3 and 4 respectively were taken to check the compatibility of drug with excipient used in the tablet formulation. Various prominent peaks with their corresponding functional groups are given in table 3.

Table 3: Interpretation of Atenolol by IR

Sr. No.	Observed peak (cm-1)	Functional group
1	3346.50	-OH
2	2970.38	H-N
3	2920.24	C-CH3
4	2852.72	-CH2
6	1641.42	C=O
7	1562.34	O=C-NH2
8	1514.12	Aromatic conjugated C=C
9	798.53	C=CH2

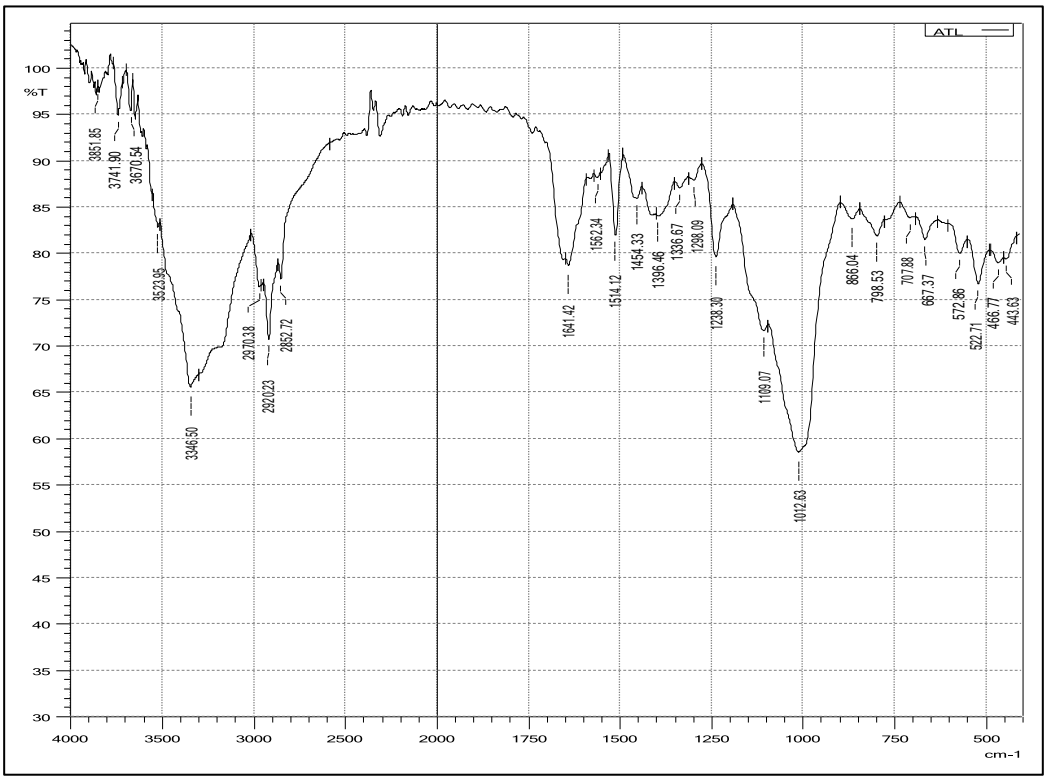

Fig. 3: IR spectra of ATL

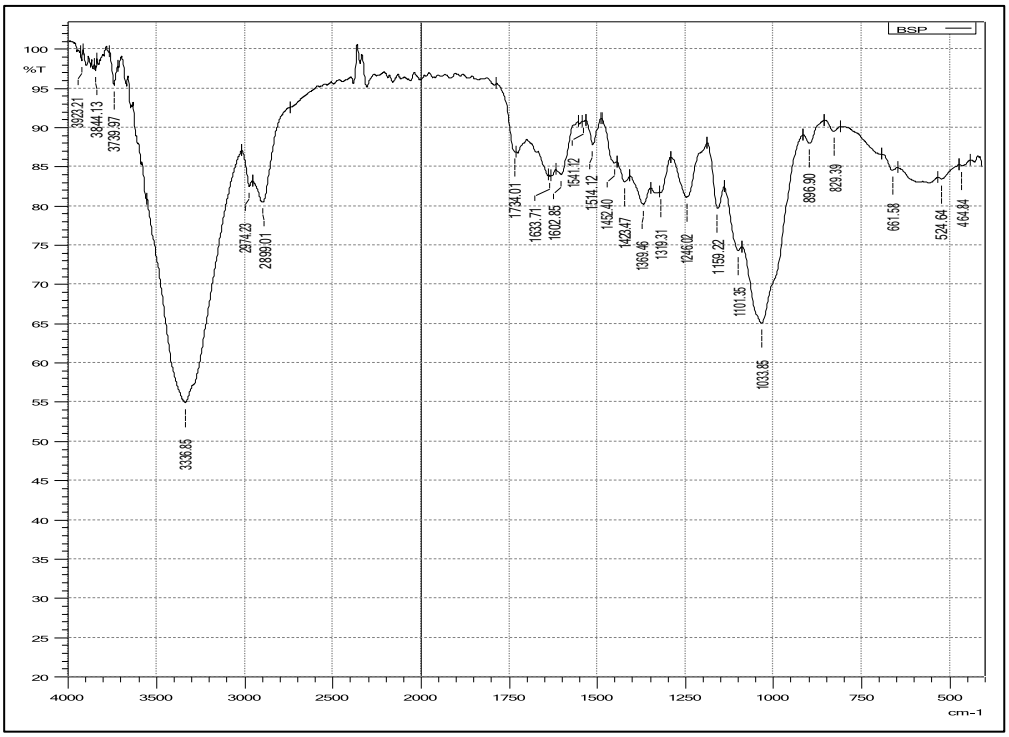

Figure 4: IR spectra of BSP

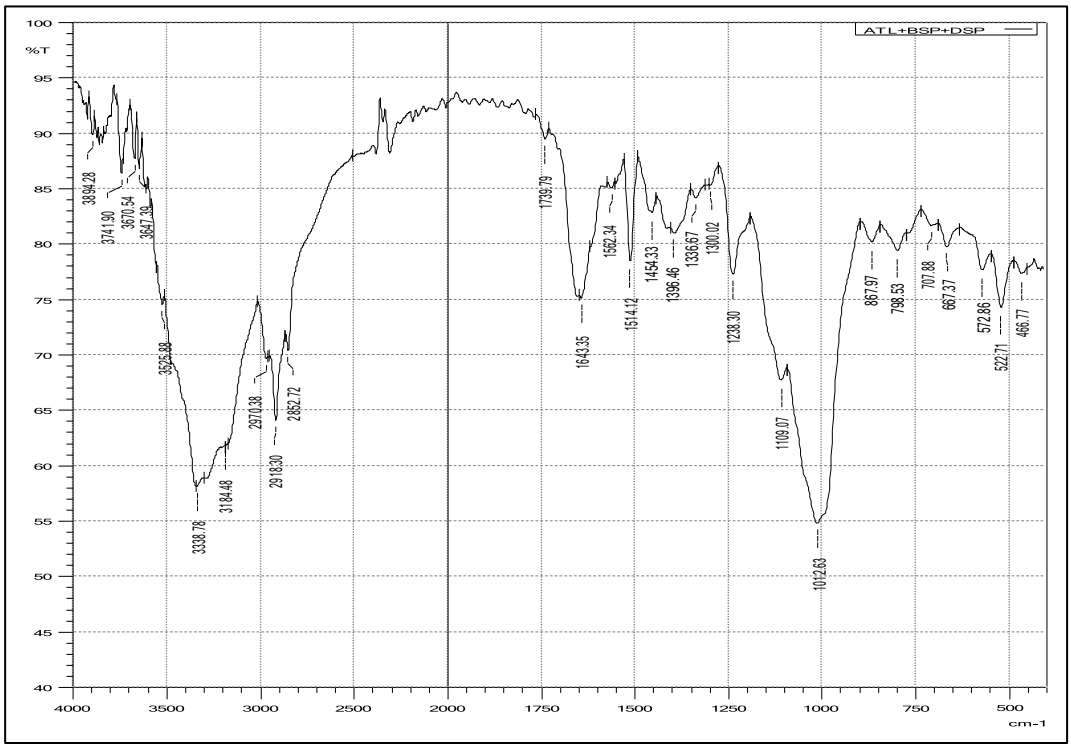

Fig. 5: IR spectra of ATL and physical mixture of ATL and BSP

By cross checking the prominent peaks of some characteristic functional groups in ATL, BSP and IR spectra of physical mixtures of ATL + BSP, it can be revealed that there is no significant shifting of peaks observed. As a result, there appears to be no chemical interaction between the ATL and BSP powders.

b. DSC (Differential Scanning Calorimetry) study

DSC spectra of ATL, BSP and physical mixtures of ATL and BSP as shown in fig. 6, 7 and 8 respectively were recorded to see the thermal behavior of drug and also to check drug-excipients compatibility.

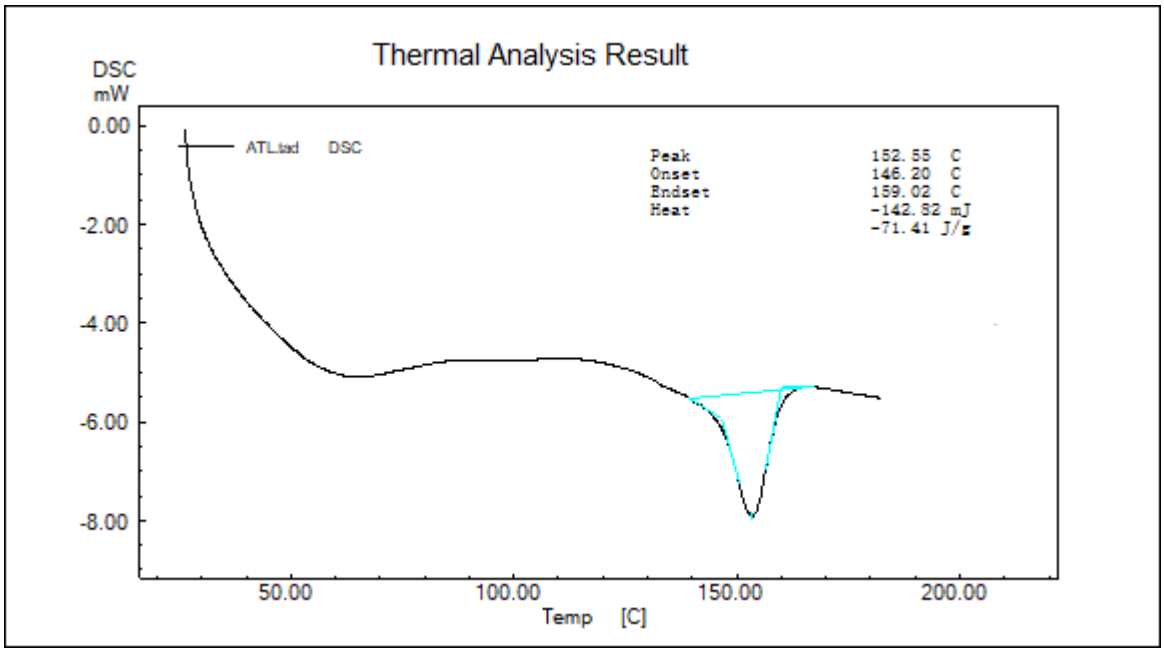

Figure 6: DSC spectrum of ATL

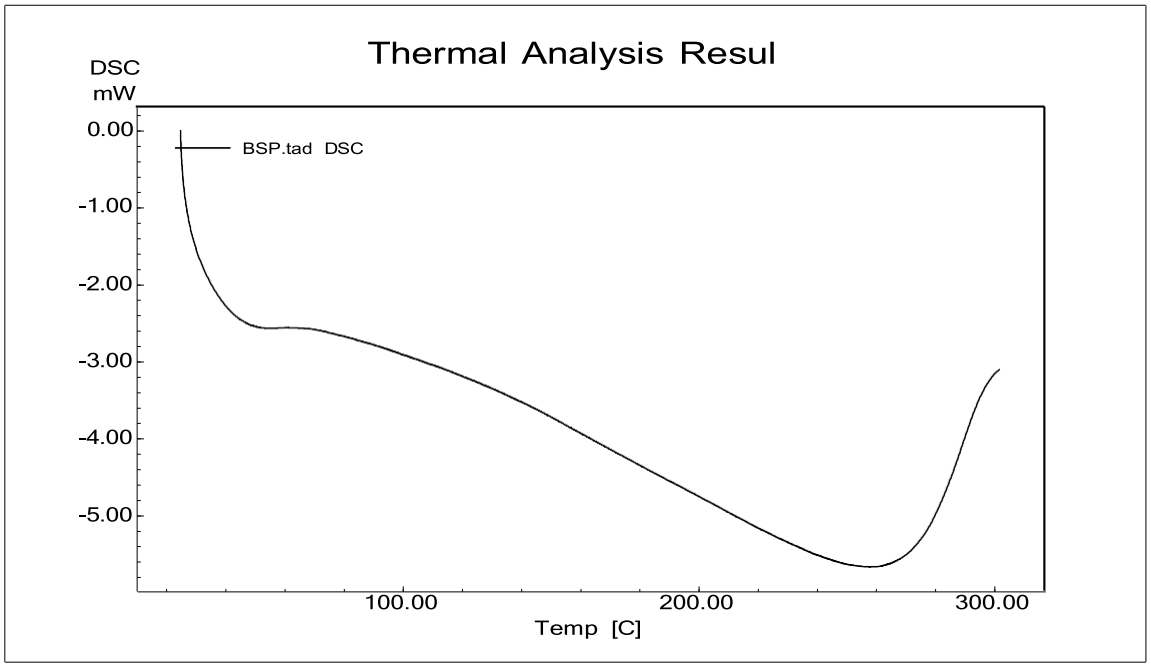

Figure 7: DSC of physical mixture of BSP

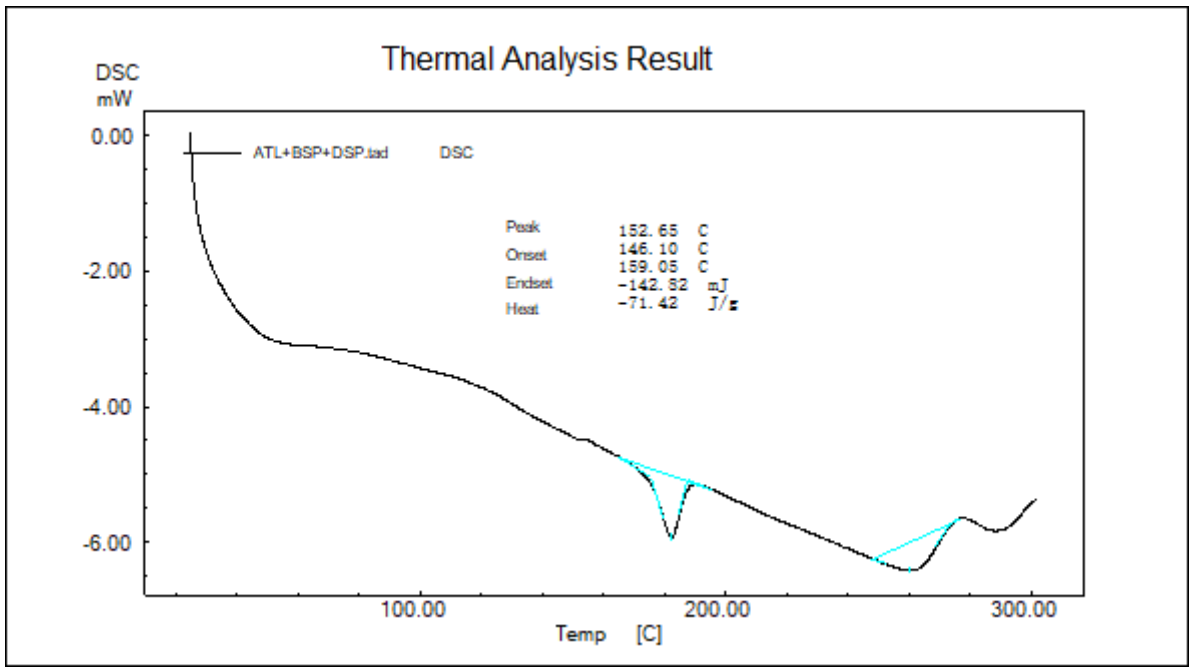

Figure 8: DSC spectrum of physical mixture of ATL and BSP

The DSC thermogram of Atenolol indicated a characteristic endothermic peak at 107.55 °C which suggests the melting point of Atenolol. The DSC thermogram of physical mixture of ATL and BSP indicated a prominent peak at 152.65 °C. When DSC spectrum of ATL was compared with physical mixture of ATL and BSP, no shifting of the endothermic peak of drug was found. Thus it can be revealed that, there is no interaction between Atenolol and BSP powder.

E. Solubility of Atenolol

Atenolol solubility was tested in distilled water and methanol. Atenolol was found to be freely soluble in both distilled water and methanol. So Atenolol could be used as ideal candidate for the designing of gastroretentive sustained release tablet.

II. Preparation of Bajari Stem Pith powder (BSP)

The BSP powders obtained after preparation was used for formulation of gastroretentive tablet of Atenolol. The photograph of BSP powder captured after preparation is given in figure 9.

Fig. 9: BSP powder

III. Formulation of gastroretentive tablets

The gastroretentive tablets were prepared as per the process mentioned in method. These tablets were further subjected to various evaluation parameters.

IV. Evaluation of granules

The flow characteristics of granules from manufactured tablet formulations were assessed using a variety of measures. Table 4 shows the results of granule evaluation parameters.

Table 4: Evaluation of granules

Batch	Bulk density (gm/ml)	Tapped density (gm/ml)	Angle of repose (0)	Compressibility index (%)	Hausner's ratio
M1	0.457	0.542	25.3	14.6	1.3
M2	0.511	0.473	27.2	18.3	1.2
M3	0.429	0.488	24.2	16.9	1.1
M4	0.361	0.659	26.4	10.1	1.2
M5	0.416	0.470	25.1	13.2	1.1
M6	0.372	0.565	28.3	14.3	1.3

From table 4, it can be said that the granules of the all 6 batches possess acceptable flow properties.

V. Evaluation of gastroretentive tablets

The physical properties of the gastroretentive tablet formulations prepared are mentioned in table 5.

Table 5: Physical properties of gastroretentive tablets

Batch	Thickness (mm)	Diameter (mm)	Hardness (Kg/Cm2)	Weight variation (mg)	Friability (%)
M1	1.82±0.104	7.95±0.004	4.87±0.119	303±0.12	0.12±0.135
M2	1.90±0.092	8.10±0.006	4.68±0.045	296±0.19	0.16±0.110
M3	1.86±0.149	7.90±0.005	5.13±0.082	301±0.05	0.14±0.085
M4	1.80±0.092	8.00±0.009	5.05±0.065	298±0.10	0.13±0.133
M5	1.89±0.052	7.95±0.003	4.82±0.054	295±0.14	0.15±0.140

M6	1.92±0.124	8.00±0.005	5.13±0.114	297±0.15	0.12±0.115

* n=3; values are expressed as mean ± SD

All the physical properties of gastroretentive tablets as mentioned in table 5 are in the acceptable range of their specifications.

A. Estimation of drug content

UV spectrophotometric analysis was used to determine the drug content of the various formulations. The percentage drug release from the amount of drug available in the tablet is critical. The drug content ranged from 99.35 to 103.09 %. Table 6 shows the drug content of various formulations.

B. Floating lag time

Floating lag time for all the batches of gastroretentive tablet formulations was found in the range from 7 to 23 Sec. Details are given in table 6.

C. Floating time

Floating time of all batches obtained is shown in table 6. Batch B1, B2 and B3 contains HPMC (K100M) at 6, 12 and 18 % respectively without use of BSP powder. On the other hand further batches B4, B5 and M6 contain BSP powder at 5, 10 and 15 % respectively along with 12 % of HPMC (K100M) in constant concentration in all batches. By looking towards the table 6, it could be said that when HPMC (K100M) concentration increases in formulation batches B1, B2 and B3, the floating time increases from 3 to 3.9 hrs. But when BSP powder (at 5, 10 and 15 %) is combined with HPMC (K100M) at constant concentration 12 % common to all batches, floating time increases from 4.8 to 9 hrs. This suggests that the use of BSP powder in gastroretentive tablet formulation helps to ameliorate the floating time.

Table 6: Drug content with floating behavior of gastroretentive tablets

Batch	Drug Content (%)	Floating lag time (Sec.)	Floating time (Hrs.)
M1	97.25±0.03	9±0.9	3±0.1
M2	102.20±0.04	16±0.4	3.2±0.2
M3	99.06±0.01	7.1±0.7	3.9±0.3
M4	103.35±0.02	17.1±0.5	4.8±0.6
M5	97.01±0.03	23±0.2	6.8±0.1
M6	98.51±0.04	13±0.4	9±0.6

* n=3; values are expressed as mean ± SD

D. Swelling index

Swelling index of the various gastroretentive tablet formulations is shown in table 7. Due to fluid imbibition by the polymer matrix, the tablet absorbs the surrounding liquids and expands in weight. Table 7 and figure 8 suggests that swelling index of tablet containing BSP powder is better than that of the HPMC (K100M). The swelling ability of BSP powder in tablet form was good, which may be beneficial to provide sustained release of drug from the gastroretentive tablet. Gastroretentive tablet formulation of batch M6 provided best swelling index 208.23 % up to 10 hrs.

Table 7: Swelling index of gastroretentive tablets

Time (h)	Swelling index (%)					
	M1	M2	M3	M4	M5	M6
0	0	0	0	0	0	0

1	24.74 ±0.6	17.80 ±0.4	27.22 ±0.7	46.63 ±0.8	66.89 ±0.3	75.89 ±0.1
2	47.66 ±0.5	52.24 ±0.3	43.44 ±0.6	87.10 ±0.4	121.67 ±08	128.83 ±0.6
3	44.58 ±0.3	72.66 ±0.5	58.94 ±0.5	121.94 ±0.6	148.65 ±0.7	154.85 ±0.5
4	-	69.72 ±0.7	71.65 ±0.5	155.69 ±0.6	169.68 ±0.5	173.31 ±0.4
6	-	-	72.53 ±0.6	175.56 ±0.4	185.53 ±0.7	198.17 ±0.5
8	-	-	-	176.64 ±0.7	197.66 ±0.3	206.44 ±0.2
10	-	-	-	-	199.11 ±0.8	208.23 ±0.7

*n=3; values are expressed as mean ± SD

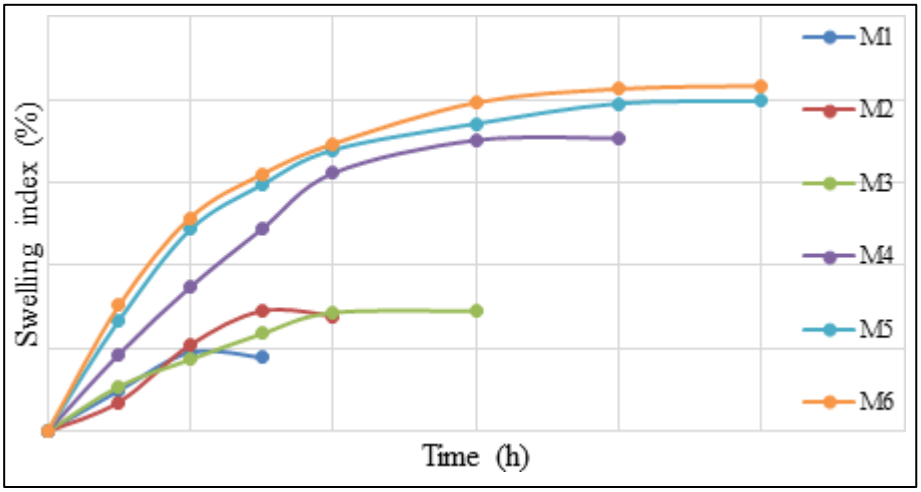

Figure 8: Comparison of swelling index of M1 to M6

E. In vitro dissolution studies

From table 8 and figure 9, the % cumulative drug release study can be well explained. Here BSP powder used to prepare the gastroretentive tablet, showed good floating ability. On the other hand HPMC (K100M) provides excellent sustained release pattern. When HPMC (K100M) alone is used without BSP powder, the formulations (formulation M1, M2, and M3) showed floating only up to 4 hours. So further sustained release effect even if getting, is not of much significance as per as the gastroretentive tablet is considered. Hence further drug release has not been taken in to dissolution data. From the graph it can be revealed that the formulation M6 has given the best floating as well as sustained release profile. If formulation M4, M5, and M6 are compared, the study says that as the concentration of BSP powder increases, floating time increases. On the other hand synthetic polymer HPMC (K-100M) serves to provide sustained release effect to the gastroretentive tablet. Formulation M6 showed 91.8 % drug release up to 8 hours.

Table 8: % Cumulative drug release of gastroretentive tablets

Time (h)	% Cumulative drug release (%)					
	M1	M2	M3	M4	M5	M6
0	0	0	0	0	0	0
0.5	9.8±0.2	13.5±0.5	10.13±0.3	18.9±0.5	17.5±0.6	12.5±0.7
1	22.9±0.5	20.8±0.6	16.7±0.6	36.5±0.6	24.8±0.4	22.8±0.8
1.5	35.0±0.6	31.8±0.7	25.6±0.2	55.1±0.5	38.3±0.6	36.0±0.2
2	45.6±0.6	39.6±0.7	38.5±0.7	64.2±0.3	53.1±0.2	48.8±0.8
3	-	52.1±0.6	44.2±0.6	77.2±0.5	59.5±0.5	55.1±0.6
4	-	-	56.0±0.2	82.5±0.5	67.9±0.6	66.8±0.4
5	-	-	-	85.6±0.4	79.4±0.3	77.4±0.6
6	-	-	-	88.5±0.7	89.6±0.6	78.6±0.8

7	-	-	-	-	95.2±0.6	83.2±0.4
8	-	-	-	-	-	91.8±0.6

*n=3; values are expressed as mean ± SD

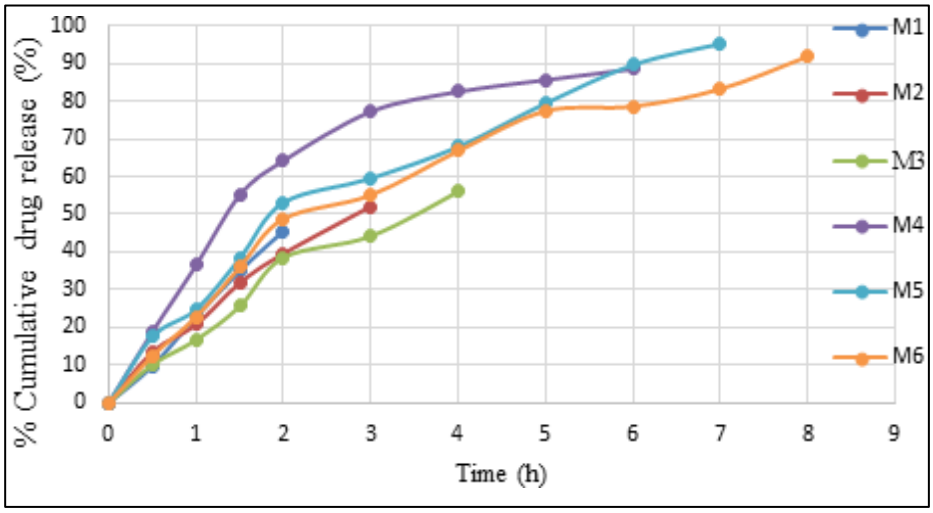

Figure 9: Comparison of % Cumulative drug release of gastroretentive tablets

a. Estimation of t75 of % CDR

"t75 is the time required to release 75 % of drug from the formulation." This information is helpful in determining the drug release pattern of tablets. Table 9 shows the time necessary to release 75% of the medication from gastroretentive tablets.

Table 9: t75 of % Cumulative drug release of gastroretentive tablets

Formulation	M1	M2	M3	M4	M5	M6
t75 (h)	3.2	4.3	5.2	4.1	4.7	6.0

Table 9 showed that formulation M6 has given highest t75 of % CDR i.e. 6 hours among all prepared gastroretentive tablets.

c. Drug release kinetic studies

The data obtained from the dissolution study was subjected to release kinetic studies to know the drug release mechanism. R2 values shown in table 11 suggest the best-fit model of gastroretentive tablet.

Table 11: Curve fitting of drug release of gastroretentive tablets

Formulation	R2				Release exponent (n)
	Zero order	First order	Higuchi	Korsmeyer Peppas	
M1	0.987	0.936	0.928	0.998	0.898
M2	0.974	0.943	0.946	0.996	0.811
M3	0.969	0.860	0.961	0.971	0.816
M4	0.790	0.698	0.967	0.918	0.451
M5	0.951	0.842	0.988	0.976	0.599
M6	0.931	0.762	0.987	0.980	0.608

The curve fitting results of drug release data indicated that release of Atenolol from gastroretentive tablet follows Higuchi model (M4, M5, M6) and Korsmeyer Peppas model (M1, M2, M3). The formulation which follows Higuchi model describes the release of Atenolol from insoluble matrix of BSP powder. And the formulation which follows Korsmeyer Peppas model describes the release of Atenolol from HPMC (K100M) a polymer matrix. The values of release exponent (n) determined from drug release data ranges from 0.451 - 0.898, indicating mostly the anomalous (non-fickian) diffusion mechanism of drug release. From this it can be concluded that the prepared gastroretentive tablet follows both diffusion controlled and swelling controlled mechanisms of drug release.

d. Mean dissolution time (MDT)

MDT indicates the drug release retarding efficiency of polymer. A higher MDT indicates a higher drug release retarding ability of the polymer and vice versa. Values of MDT of all the formulations are mentioned in table 12.

Table 12: MDT of gastroretentive tablets

Formulation	M1	M2	M3	M4	M5	M6
MDT (h)	0.99	1.31	1.73	1.61	2.45	2.37

Table 12 shows that gastroretentive tablets containing BSP powder along with HPMC (K100M) showed better MDT than formulations containing HPMC (K100M) alone. Hence it can be concluded that HPMC (K100M) in combination with BSP powder used in gastroretentive tablet showed excellent release retardant ability.

VI. Stability study

The best selected formulation M6 was then subjected to accelerated stability study at 40 ˚C ±2 ˚C temperature and 75 % ±5 % relative humidity (RH) are mentioned in table 13.

Table 13: Accelerated stability study

Stability study period	Description	Floating time (Hrs.)	Drug content (%)	Swelling index (%)	t75 of % CDR (Hrs.)
Initial	Yellowish tablet	8.5	102.22	212.36	6.0
After 3 months	Yellowish tablet	9	100.95	207.33	5.6
After 6 months	Yellowish tablet	8	99.77	210.67	5.4

The accelerated stability study was carried out for the best selected formulation M6. The stability study results obtained revealed that floating time, swelling index, t75 of % CDR and drug content are within acceptable limits. No change in the results observed after 3 and 6 months of stability study. Thus, the formulation M6 can be said to be stable.

CONCLUSION

According to the research's findings, the formulation batch M6 of the gastroretentive Atenolol tablet, which contained 15% BSP powder and 12% HPMC (K100M), demonstrated an excellent dissolving profile. Floating behavior indicated that when the concentration of BSP powder increases, so does the gastro-retentive tablet's floating time. The usage of low density unique natural polymer BSP powder is the primary cause of the gastro-retentive of batch M6's floating behavior, which prolonged up to nine hours. It is evident from a number of evaluation criteria that BSP powder is a very effective natural polymer for making gastro-retentive Atenolol tablets that also provide a sustained release effect when mixed with HPMC (K100M) for eight hours.

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