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Formulation Develoment And Evaluation Herbal Effervescent Floating Tablet By Using Syzygium Cumini Seed Extract Used In Treatment Of Diabetes

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Abstract

Background: Floating tablets prolong the gastric residence time of drugs, improves bioavailability, and facilitate local drug delivery to the stomach. With this objective, floating tablets containing extract of *Syzgium cumini seed extract* as active ingredient was prepared for the treatment of antidiabetic.

Material and method: Floating tablets of *Syzgium cumini seed extract* were prepared by direct compression method using Magnesium stearate, Microcrystalline cellulose, Citric acid and Sucrose. The formulations were evaluated for various physical parameters, floating lagtime.

Result: The thickness was in the range 4.02-4.086 mm. The hardness ranged from 3.1-3.3 kg/cm^2, All formulations passed the USP requirements for friability and uniformity of weight. The buoyancy time of all tablet formulations was less than 5min and tablet remained in floating condition throughout the study.

Conclusion: The optimized formulation was found to be F5 batch which released 98.13% of drug in 8hr *invitro*, while the floating lag time was 92 seconds.

Keywords: Syzygium cumini, floating tablet, Antidiabetic, Xanthum gum, Buoyancy time.

INTRODUCTION:

According to World Health Organization, about 80% of the world population maintain their primary health care by using herbal medicine. Nowadays herbal drugs have gain wide spread acceptability. Floating drug delivery is a type of controlled drug delivery system which is capable of controlling the rate of drug delivery, prolong the duration of therapeutic activity and target the delivery of the drug to a specific site. Floating drug

delivery system of tablet have bulk density less than gastric fluid and so remain buoyant in the stomach where the drug is release slowly in the upper GIT for local and systemic effect without affecting the gastric emptying rate for a prolonged period. In the effervescent tablet there is a use of swellable and effervescent components which upon arrival in the stomach, carbon dioxide is released and the formulation to float in the stomach. Floating tablets prolong the gastric residence time of drugs, improve bioavailability, and facilitate local drug delivery to the stomach. Ulcer results due to unbalance between formation of gastric acid and maintenance of the protective mucosal barrier that depends on secretion of bicarbonate, prostaglandins and mucosal growth factors. Gastric ulcers are caused due to insufficient mucosal protection, whereas duodenal ulcers are caused due to excessive acid secretion. Syzygium cumini seed and syzygium cumini extract was as shown in fig. 1 & 2.

Fig. 1: *Syzygium cumini seed*

Fig. 2: *Syzygium cumini extract*

Materials:

The *Syzygium cumini* seed powder were purchased from shree dhanvanatari herabals (Pune), Sodium bicarbonate and Surcrose was purchased by saurav scientific (Pune), Gaur gum and Magnesium sterate pallave chemicals solvent Pvt. Ltd. (Mumbai), Microcrystalline cellulose was purchase by Loba chemi Pvt. Ltd. (Mumbai), Citric acid purchased by BHARAT MAHAL , Marine drive (Mumbai) 400 002 (India), Xanthum gum Vishal-Chem (Mumbai) 400 002 (India)

Methodolody:

Analytical method development:

a) Determination of absorption maxima:

A solution containing the concentration 10 µg/ml drug was prepared in 0.1N HCL UV spectrum wastakenbyusingUVspectrophotometer.Thesolutionwasscannedintherangeof 200-400nm.

b) Preparation calibration curve:

10mg *Syzygium cumini seed* extract was dissolved in10mlof 0.1N HCL (stock solution1) from stock solution1 1ml of solution was taken and made upwith10mlof 0.1NHCL(100µg/ml). From this1ml was taken and made up with 10 ml of 0. 1N HCL (10µg/ml). The above solution was subsequently diluted with 0. 1N HCL to obtain the series of dilutions containing 2, 4, 6, 8, 10 µg /ml of per ml of solution. The absorbance of above dilutions was measured at 236nm by using the UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking the concentration on X-Axis and absorbance on Y-Axis which gives a straight-line linearity of standard curve was assessed from the square of the correlation coefficient (R^2) which determined by the least-square linear regression analysis.

Drug- Excipient compatibility studies:

Fourier-Transform Infrared Spectroscopy (FT-IR):

The compatibility between the pure drug and the excipients was detected by the FT-IR spectra obtained on Bruker FT-IR Germany . The solid powder sample directly place on yellow crystal which was made up of ZnSe. The spectra were recorded over the wave number of 4000cm^{-1} to 550cm^{-1}.

Pre-formulation parameters:

Preformulation is defined as the phase of research and development in which preformulation studies characterize physical and chemical properties of a drug molecule in order to develope safe, effective and stable dosage form[2]. Flow properties of powder (before compression) are characterized in the terms of Angle of repose, Carr's index and Hausner's ratio.

Bulk density:

Bulk density of powder is a ratio of them as of powder sample to its volume.

Bulk density=Mass/Bulk volume

Tapped density:

Tapped density of powder is a ratio of the mass of powder sample to its volume occupied by the powder after it has been tapped for the definite period of time.

Tapped density=Mass/Volume

Angle of repose:

The powder are poured through the walls of the funnel, which was fixed at position such that it slower tip was at height of exactly 2 cm above the surface of the graph paper. The powder were poured till the time when the lower tip of the channel. The formula for angle of repose is as below:

$\Theta = \tan^{-1} (h/r)$

Where,

Θ = Angle of repose

h=Height of the pile

r=Average radius of the base of piles

Carr's index:

Carr's index determine the compressibility of a powder which is based on tapped density and bulk density. The formula for carr's index is as below:

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

Hausner's ratio:

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Lower Hausner's ratio Better flow ability Higher Hausner's ratio Poor flowability.

Table no.1. Formulation of effervescent floating tablets of *Syzygium cumini seed* extract

Sr. No.	Ingredints (Mg)	F1	F2	F3	F4	F5	F6
1	Extract *(Syzygium cumini seeds)*	350	350	350	350	350	350
2	Gaur Gum	-	-	23	35	23	35
3	Xanthum Gum	10	15	-	-	10	15
4	Sodium Alginate	5	5	5	5	5	5
5	Sodium Bicarbonate	50	50	50	50	50	20
6	Citric Acid	2	2	2	2	2	2
7	Microcrystalline Cellulose	68	63	55	43	5	28
8	Magensium Sterate	5	5	5	5	5	5
9	Sucrose	10	10	10	10	10	10
Total Weight 500 Mg							

Evaluation of post-compression parameters of prepared tablets:

1) Diameter and Thickness:

The diameter and thickness of the tablets was determined by using Vernier caliper. The thickness of tablet is depends upon the diameter of the die. Ten tablets were selected at random from each batch and average value were calculated.

2) Hardness test:

Hardness of the ten tablets was determined using the Monsanto hardness tester and the average values were calculated.

3) Friability:

The friability of the tablets carried out in a Roche friabilator. Friability done with the 20 tablets adjust the time at 4min. and speed at 25 rpm.

$$\text{Friability (\%)} = \frac{W1 - W2}{W1} \times 100$$

Where, W_1=Initial Weight of Tablets, W_2=Final Weight of Tablets

4) Weight variation test:

As per Indian pharmacopoeia, weight variation can be done by using 20 tablets and their weight was determined individually and correctly on a digital weighing balance the average weights of tablet was determined from the collective weight.

5) Content uniformity:

Percentage drug content of herbal floating tablets develop to ensure content consistency of active drug substance

6) *In-vitro* disintegration time:

In-vitro disintegration test was carried out with the 6 tablet using 0.1NHCL at 37ºC±2°C was used as disintegration media and the time in a second taken for a complete disintegration of the tablet with no palatable mass remaining in the apparatus measuring in the seconds.

7) Determination of swelling index:

The drug release from any tablet depends upon percentage of intake of medium, the medium used as 0.1 N HCl. The medium of temperature was maintained at 37±0.5ºC throughout the study. The swelling index was determined by the following equation:

Swelling index = $(W_t - W_0) \times 100/W_0$

Where,

W_0=Initial weight of tablet

W_t=Weight of the tablet at time

8) Floating lag time (Buoyancy time):

The time intervals between the tablets took to emerge on the surface of 0.1 N HCl (floating lag time) and the time the tablets constantly float on the surface of 0.1 N HCl (duration of floating) were evaluated in 100ml beaker.

9) *In vitro* drug release study:

The release rate of herbal floating tablet of *Syzygium cumini seed* extract was determined as per United State Pharmacopoeia (USP) using dissolution testing apparatus 2 (Paddle method). The dissolution test was performed by using 900 ml of 0.1NHCl (pH=1.2), at 37±0.5ºC at 50rpm. 10ml samples were drawn with every one hour upto a period of 20-24 hrs .the samples were diluted suitably and filtered. The required dilutions were made with and the solution was analyzed for the drug content by using UV detector. From this %drug release was calculated and this was plotted against function of to the pattern of drug release[5].

RESULTS AND DISCUSSION:

1) Calibration curve:

Graph of *Syzygium cumini seed* extract was taken in 0.1N HCL (pH 1.2). Standard graph of *Syzygium cumini seed* extract was plotted as per the procedure in experimental method and its linearity is shown in Table No.2 and Fig no.2. The standard graph of *Syzygium cumini seed* extract show good linearity with R2 of 0.99992, which indicates that it obeys "Beer- Lamberts" law

Table no.2. Observation of graph of *Syzygium cumini seed* extract in 0.1NHCl

Conc(µg/mL)	Absorbance
2	0.182
4	0.384
6	0.564
8	0.754
10	0.965

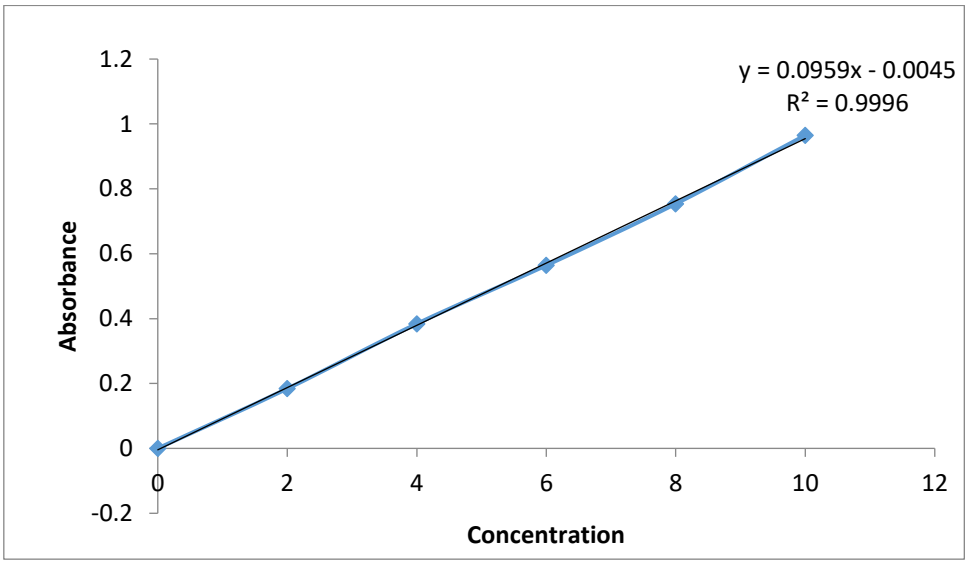


Fig. no.2. Calibration curve of *Syzygium cumini seed extract* extract in 0.1 N HCL

2) FT-IR:

There was no disappearance of any characteristics peak in the FT-IR spectrum of drug used. This indicates that there is no chemical interaction between the drug used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions.

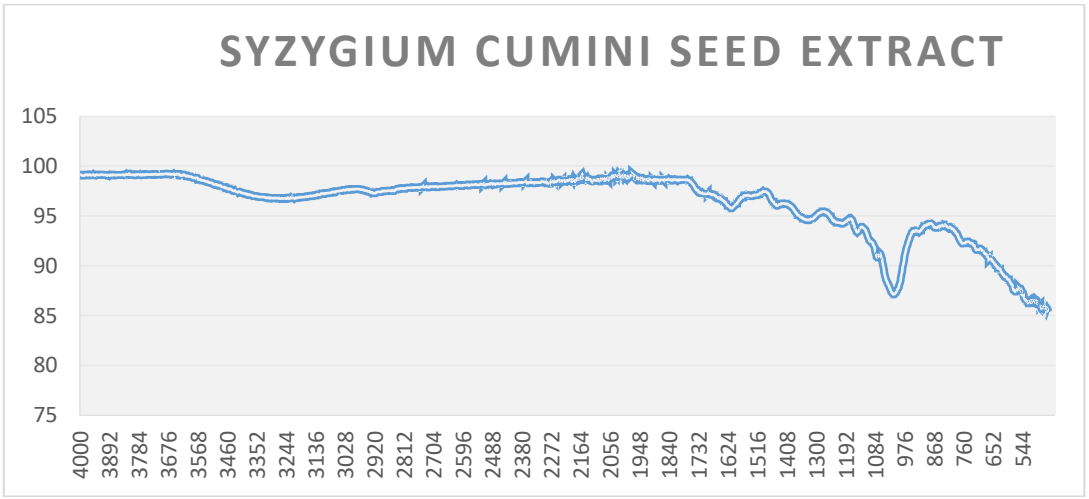


Fig.no.3. FT-IR *Syzygium cumini seed* extract

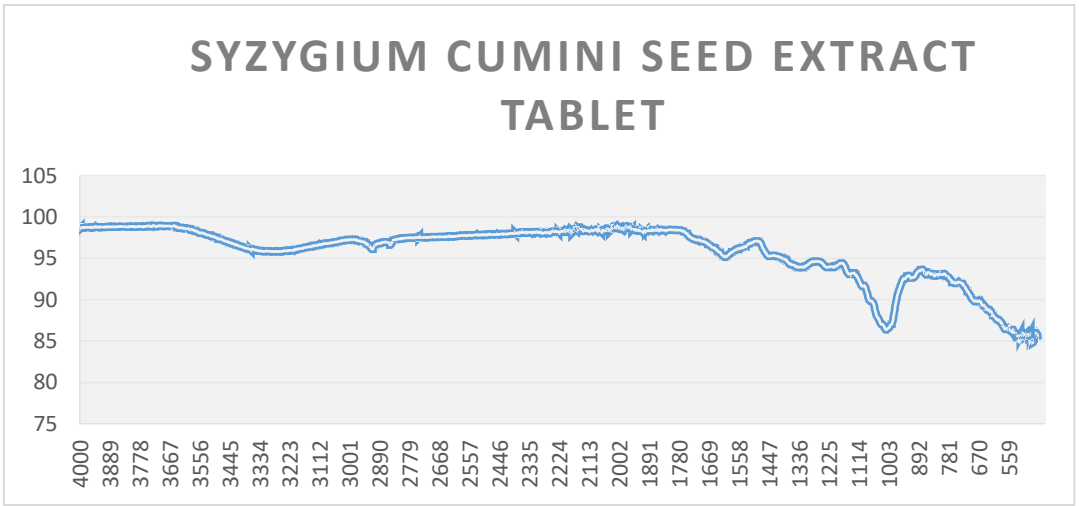


Fig.no.4. FT-IR*Syzygium cumini seed* extract tablet

3) Preformulation parameters:

From the above result of pre-compression parameter of tablet it was observed that the bulk density ranged between 0.16 to 1.18g/ml and tapped density ranged between 0.89 to 1.20 g/ml, which make them float able in the gastric fluid. The other micromeritic properties such as Carr's index, Hausner's ratio revealed no significant differences. Angle of repose was obtained between 37.91 to 50.12 indicating good flow properties. Hardness, friability, weight variation, thickness, disintegration time of tablet formulation were within acceptable limits and the drug content in all the batches of *Syzygium cumini seed* extract ensured that the uniformity of the drug content in the tablets.

Table no.3. Evaluation of mixed blend of drug and excipients.

Batches	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio	Angle of repose (º)
F1	1.18	1.20	2	0.97	50.12
F2	0.86	0.89	3.7	0.96	43.71
F3	0.83	0.91	9.4	0.91	40.99
F4	0.16	0.89	3.6	0.96	46.26
F5	0.83	0.90	8	0.92	37.91
F6	0.94	0.98	4	0.96	42.89

4) Evaluation of post-compression parameters of prepared tablets:

Weight variation data of the tablets shows no significant difference in the weight of individual tablet from the average value. The thickness was in the range 5.02-5.08 mm. The hardness rangedfrom4.18-4.35kg/cm^2, All formulations passed the USP requirements for friability and uniformity of weight Swelling index was found in the range 33.78-39.29%. The buoyancy time of all tablet formulations was less than 5min. and tablet remained in floating condition throughout the study.

Table no.4. Evaluation of Herbal Floating Tablet of *Syzygium cumini seed* extract

Formulation code	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Weight variation	Swelling index(%)	Floating Lag time	Total Floating Time (Hrs)
F1	4.2±0.056	5.02±0.12	0.8 ±0.01	498±0.012	36.23±0.11	2.25min	12
F2	4.22±0.22	5.04±0.52	0.8 ±0.06	502±0.02	38.29±0.12	3.03min	11
F3	4.23±0.09	5.02±0.11	0.4 ±0.23	510±0.053	37.02±0.13	3.15min	10
F4	4.18±0.124	5.08±1.01	0.8 ±0.02	505±0.012	39.29±0.17	3.10 min	10
F5	4.3 ±0.12	5.02±0.47	0.6±0.27	495±0.012	36.52±0.12	2.15min	12
F6	4.35±0.15	5.03±0.32	0.53±0.24	512 ± 0.02	33.78±0.19	2.25min	11

Floating lag time:

Fig.no.5. At initial time

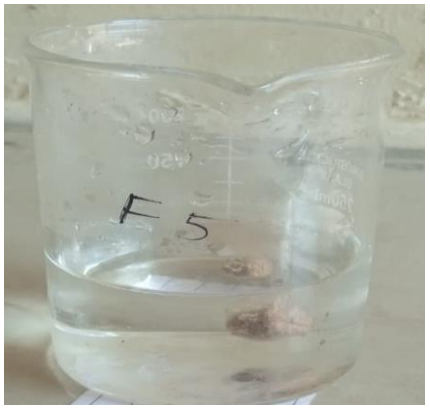


Fig.no.6. After 58 sec

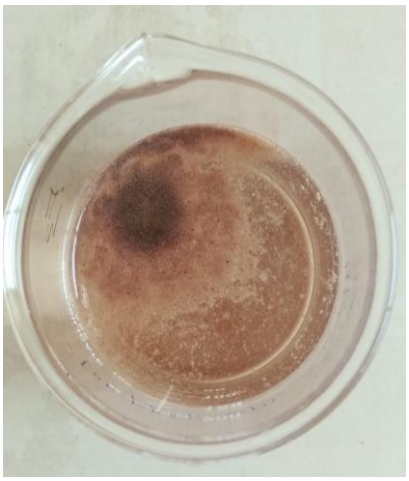
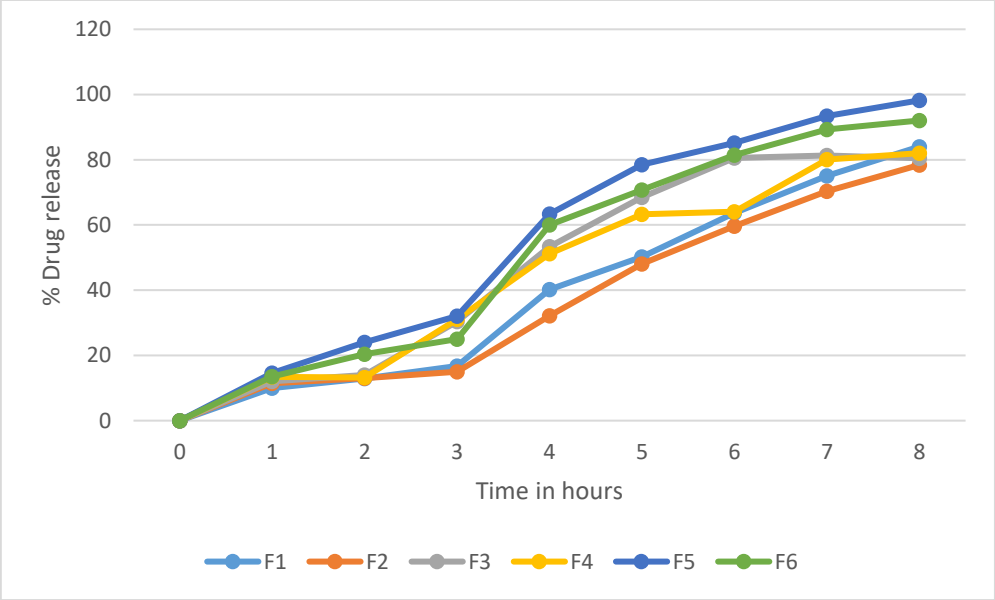


Fig.no.7. After 92 sec

Fig.no.8. After 12 hr

***Invitro* drug release study:**

The release of *Syzygium cumini* from different formulations were determined using USP Paddle apparatus 2 under sink conditions. The dissolution medium was 900 ml of a 0.1 N HCl solution (pH=1.2), at 37 ± 0.2ºC at 50 rpm. 10 ml samples were drawn with every one hour upto a period of 20-24hrs. samples were diluted suitably and filtered. The required dilutions were made with and the solution was analyzed for the drug content by using UVdetector. From this % drug release was calculated and this was plotted against function of to the pattern of drug release. The percentage cumulative drug release of all formulation from F1to F6 were within the range of 78.40 – 98.20% for8 hrs (Fig.no.9). from the results of *in vitro* drug release studies, it concludes that F5 had better controlled release than the other formulation.



Figno.9. Percent age of Drug Release

CONCLUSION :

In this study, gastro-retentive herbal floating tablet of *Syzygium cumini* seed extract can be successfully prepared by using direct compression techniques. The prepared herbal floating tablet were evaluated for various parameter like drug content, floating lag time (buoyancy time), *in vitro* drug release study, etc. and shows the satisfactory result. The formulation was prepared to reduce the side effects and increase the clinical effects. The optimized formulation was found to be F5 which released 98.20% of drug in 8hr *in vitro*, while the floating lag time was 92 seconds. From this results obtained, it was concluded that formulation F5 desirable Sustained effect for 8 hrs having 98.20% release at the end of 8hours.

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