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Chewable Tablets of Syzygium Cumini

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Abstract: Jamun is a popular indigenous fruit Of India. It has got very valuable place in Ayurvedic medicines. It is believed to be a boon for diabetic patients. But in India, its organized orcharding is still lacking mainly because of lack of proper information on cultivation practices and non-availability of dwarf and high yielding varieties. In this booklet all the information on jamun cultivation has been collected and presented in a simple and interesting form.

This research highlights the chemical composition and antioxidant potential of leaf gall extracts (aqueous and methanol) of Syzygium cumini (S. cumini), which have been extensively used in traditional medications to treat various metabolic diseases.

Keywords: Syzygium cumini, Medicinal uses, Myrtaceae, Phytochemistry, Traditional uses, Jambolan, Common plum, Java plum, Eugenia jambolana commonly known as jambolan, black plum, jamun, java plum, Indian blackberry, Portuguese plum, Malabar plum, purple plum, Jamaica and damsonplum.

I. INTRODUCTION

A. Material and Methods

Seeds from the domestically grown Syzygium cumini plant were collected, shade dried, powdered and sieved. The authentication of the plant was obtained from Botanical Survey of India (BSI), Deccan Regional Centre, Hyderabad, India. Stevia powder was purchased from The Herbs N Spices, Neemuch, Madhya Pradesh, India. Lactose, acacia, glucose, talc, magnesium stearate, Hydroxy Propyl Methyl Cellulose (HPMC), sodium alginate, guar gum, polyethylene glycol (PEG) 400, dichloromethane and ethanol were purchased from S.D Fine Chem Ltd. Mumbai, Maharashtra, India. Methods Phytochemical Screening: The seed powder was subjected to phytochemical analysis by performing tests for alkaloids, cardiac glycosides, flavonoids, steroids/triterpenoids, tannins and phenols and saponins as reported previously. Formulation of chewable tablets of Syzygium cumini

1) **Seed Powder:** Tablets were formulated by direct compression method. Seven formulations were formulated with constant amount of seed powder and varied concentrations of excipients as shown in table 3. The excipients and the seed powder were added into a mortar-and-pestle in the decreasing order of their weights, mixed thoroughly and the powder was evaluated for angle of repose, bulk density, tapped density and Carr's index which are tabulated in table 2. Chewable tablets were formulated using R & D scale tablet punching machine (Karpatavastatinvati Engineering Ltd.).

B. Pre-Compression evaluation

Angle of repose: The angle of repose of the powder blend was calculated using funnel method. A known amount of the powder blend was placed in a glass funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the powder blend. The powder blend could flow through the funnel



Calculated using the following equation.

$$\tan\theta = h/r$$

Where,

$\tan\theta$ is the angle of repose

h is the height

r is the radius of the powder mass.

Determination of Bulk density and Tapped density: A 20 mg of the powder was placed into a 100 mL measuring cylinder and the initial volume was observed. The cylinder could fall onto a hard surface from the height of 2.5 cm with a time interval of 2 sec. Tapping was continued until no further change in volume was noted. The bulk density and tapped density were calculated using the following formula :

$$\text{Bulk density} = W/V_o$$

$$\text{Tapped density} = W/VF$$

Where W = weight of the powder;

V_o = initial volume of powder;

VF = Final volume of powder

The ratio of the tapped density to the bulk density is called Hausner's ratio. Hausner's ratio >1.25 indicates good flowability of the powder.

Compressibility Index: Compressibility index or Carr's index is an important measure that can be obtained from the bulk and tapped density. It is calculated by the equation,

$$\text{Carr's index} = (\text{Tapped density} - \text{Bulk density}) / \text{Tapped density}.$$

For a material to be more flowable it needs to be less compressible. A material having value of less than 20% has good flow properties.

II. DIABETES

Diabetes is a condition that happens when your blood sugar (glucose) is too high. It develops when your pancreas doesn't make enough insulin or any at all, or when your body isn't responding to the effects of insulin properly. Diabetes affects people of all ages. Most forms of diabetes are chronic (lifelong), and all forms are manageable with medications and/or lifestyle changes.

The technical name for diabetes is diabetes mellitus. Another condition shares the term "diabetes" — diabetes insipidus — but they're distinct. They share the name "diabetes" because they both cause increased thirst and frequent urination. Diabetes insipidus is much rarer than diabetes mellitus.

A. Types of Diabetes

There are several types of diabetes. The most common forms include:

- 1) *Type 2 diabetes*: With this type, your body doesn't make enough insulin and/or your body's cells don't respond normally to the insulin (insulin resistance). This is the most common type of diabetes. It mainly affects adults, but children can have it as well.
- 2) *Prediabetes*: This type is the stage before Type 2 diabetes. Your blood glucose levels are higher than normal but not high enough to be officially diagnosed with Type 2 diabetes.
- 3) *Type 1 diabetes*: This type is an autoimmune disease in which your immune system attacks and destroys insulin-producing cells in your pancreas for unknown reasons. Up to 10% of people who have diabetes have Type 1. It's usually diagnosed in children and young adults, but it can develop at any age.
- 4) *Gestational diabetes*: This type develops in some people during pregnancy. Gestational diabetes usually goes away after pregnancy. However, if you have gestational diabetes, you're at a higher risk of developing Type 2 diabetes later in life.





III. SYMPTOMS

A. Symptoms of Diabetes Include

Increased thirst (polydipsia) and dry mouth. Frequent urination.

Fatigue.

Blurred vision.

Unexplained weight loss.

Numbness or tingling in your hands or feet. Slow-healing sores or cuts.

Frequent skin and/or vaginal yeast infections.

IV. COMPLICATION

Nerve damage (neuropathy), which can cause numbness, tingling and/or pain. Nephropathy, which can lead to kidney failure or the need for dialysis or transplant. Retinopathy, which can lead to blindness.

Diabetes-related foot conditions.

Skin infections.

Amputations.

Sexual dysfunction due to nerve and blood vessel damage, such as erectile dysfunction or vaginal dryness.

Gastroparesis.

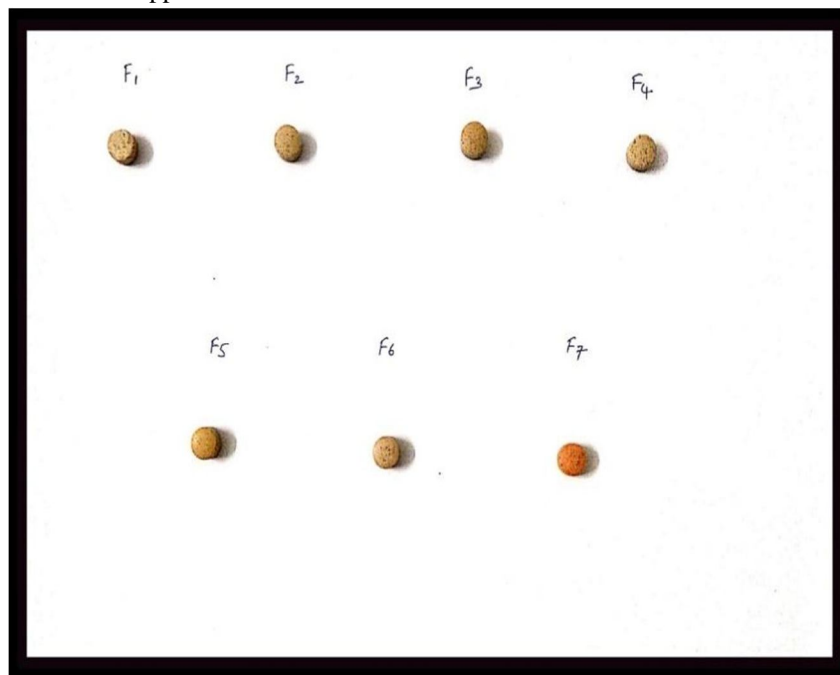
Hearing loss.

Oral health issues, such as gum (periodontal) disease.

V. PREPARATION AND EVALUATION OF CHEWABLE TABLETS

Chewable tablets of *Syzygium cumini* seed powder have been prepared by direct compression method, depicted in figure 1. The composition of these chewable tablets is shown in table 3. Lactose was used as a diluent to increase the bulk of the powder mixture. Acacia acts as a binding agent which holds the powder material together by adhesion or cohesion. To mask the taste of the seed powder, glucose was used as a sweetening agent. Talc was incorporated as a glidant and magnesium stearate was used as a lubricant. While the powder mixture was compressible directly without adding the binder, the tablets were unstable separating into layers (also called lamination of the tablet). When 50 mg (10%) of the binding agent was incorporated, the hardness of the resulting tablets was poor ($<1 \text{ kg/Cm}^2$), which might be due to insufficient binder. To improve the stability of the tablets, the binder concentration was further increased to 17% keeping the quantity of other excipients constant. A total of seven formulations were made using R & D scale tablet punching machine (Karpatavastatinvati Engineering Ltd.). Color, weight variation, hardness, friability, thickness and disintegration time were evaluated and the data are presented in table 4. All the evaluations tests have been performed from F3 through F7 as F1 and F2 failed in the pre-formulation stage itself. The physical appearance of the tablets was smooth and uniform with no cracks and with a diameter of 1 cm. To ensure each tablet contains desired amount of seed powder, weight variation test was conducted. The tablets met the USP specifications that not more than 2 tablets are outside the percentage limit which is $\pm 5\%$. All the tablets were within $\pm 10\%$ variation from the average weight of the formulation. Friability is generally referred to loss in weight of tablet in the containers due to removal of fines from the tablets surface. Friability generally reflects poor cohesion of tablets ingredients. Friability test was performed with 10 tablets of each formulation. The average weight loss of the tablets following friability testing was with 1% of the average weight of the formulation indicating the physical stability of the tablets when exposed to mechanical shock and attrition.

Hardness test was performed to provide a measure of the tablet's strength as the tablets need to be hard enough for packing and moving, but not so hard creating difficulty during chewing. The hardness ranged from 2.5 to 3.0 kg/cm². Thickness of the tablets was found to be from 0.76 to 0.78 cm from F3 to F7 which might affect disintegration. Disintegration time of chewable tablets should be short enough to prevent choking in case the patient does not completely chew it. Six tablets were tested for disintegration from each formulation. The disintegration time of the tablets ranged from 22 to 25 min. All the formulations F3 to F7 have been shown to be stable and meet the United States Pharmacopoeia (USP) quality control standards for chewable tablets. It should be noted, however, that in F6 stevia was used to replace glucose, which makes it suitable for diabetic patients. The formulation F7 has a coloring agent to improve its aesthetic appeal. The results of all the evaluation tests have been tabulated in table 5.



S. No	Evaluation test	Test values
1	Bulk density	0.107gm/ml
2	Tapped density	0.110gm/ml
3	Angle of repose	26.5
4	Husner's ratio	1.1
5	Car's index	7.69

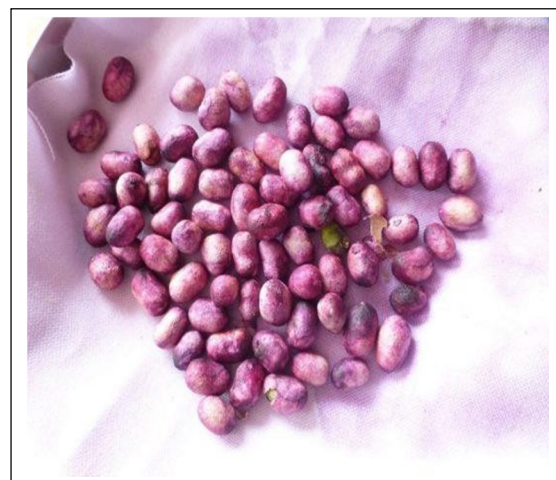
Table 3 : Flow properties of formulation for chewable tablets

Ingredients	F1 (mg)	F2 (mg)	F3 (mg)	F4 (mg)	F5 (mg)	F6 (mg)	F7 (mg)
Seed powder	200	200	200	200	200	200	200
Lactose	200	200	250	250	250	250	250
Acacia	-	50	100	100	100	100	100
Glucose	10	10	-	10	10	-	-
Talc	05	05	05	05	05	05	05
Stevia	-	-	-	-	-	10	10
Magnesium stearate	05	05	05	05	05	05	05
Colorant	-	-	-	-	q.s(turmeric)	-	q.s(orange)
Total weight(mg)	420	470	560	570	570	570	570

Table 4 : Formulation of Chewable Tablets

VI. EVALUATION

Parameter	F1	F2	F3	F4	F5	F6	F7
Color	Lamination was observed. This may be due to lack of binder	Poor hardness due to insufficient binder	Buff	Buff	Pale yellow	Buff	Orange
Weight variation			P	P	P	P	P
Hardness			2.5±0.1	3.0±0.1	2.8±0.2	3.0±0.1	3.0±0.2
Friability			P	P	P	P	P
Thickness (cm)			0.76±0.01	0.77±0.01	0.78±0.01	0.77±0.01	0.77±0.01
Disintegration time(min)			25±0.5	23±0.5	22±0.5	22±0.3	23±0.5
Diameter (cm)			1	1	1	1	1



VII. RESULTS AND DISCUSSION

Phytochemical Screening: Phyto constituents like alkaloids, cardiac glycosides, flavonoids, steroids, tannins and phenols were found to be present whereas saponins tested to be absent. The results are depicted in table 2.

VIII. CONCLUSION

Chewable tablets of *Syzygium cumini* seed powder were formulated and evaluated. Preformulation studies were done to optimize the composition of the tablet powder blend. The FTIR studies showed that there is no interaction between the seed powder and the tablet excipients. The antimicrobial studies revealed that the formulation is having antimicrobial activity against *E. coli* and *B. Subtilis*. The chewable tablet formulation has the potential to be used as a nutraceutical.

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1) *Conflict of interest*: The authors declare no conflict of interest.

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