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Formulation And Evaluation Of Antipyretic, Analgesic Capsule From *Ficus Benghalensis Linn* And *Acacia Nilotica Linn* Bark

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Abstract

Ficus benghalensis also known as banyan tree is a large, evergreen tree native to the Indian subconstituent and southeast asia. It belongs to the family *moraceae*. *Acacia nilotica* also called as Babool or gum arabic, is a tropical tree native to africa, Asia and Australia, belong to family *fabaceae*. The ***ficus benghalensis*** and ***Acacia nilotica linn*** bark powder was converted into batches on the basis of their particle size. It has observed that, batch A (sieve no.44) passes all the preformulation parameter. This batch was finally used to prepare the antipyretic & analgesic capsule with different concentration. After that F_2 batch was checked for weight variation, disintegration test, moisture content, pH. It has been observed that disintegration test F1, F2, F3 and F4 was 9.58 sec, 8.12 sec, 8.48 sec, 9.40 sec respectively. Also, batch f1 passes the weight variation test. The antimicrobial test against *E.coli, C.albicans and S.aureus* was performed that, it shows zone of inhibition around -ve, 21mm, 19mm after 24 hrs.

Keywords: *ficus benghalensis*, *Acacia nilotica*, antipyretic and analgesic capsule, *moraceae*, *fabaceae*.

1. INTRODUCTION :-

A. ***Banyan tree*** *(Ficus benghalensis*) commonly known as the indian banyan or simply the banyan tree, is large & evergreen tree belonging to *moraceae* family. It is also called as bargal, East india fig. It is the tree characterized by its aerial roots, which grow from the branches down to its ground forming new trunk that to spread over a vast area. The mature trees can reach 20 to 25 meter (65 to 80 feets) height, main trunk diameter range from 5 meters (16 meters) or more and grayish-brown bark. Different parts of the banyan tree, such as used as traditional medicines. The *ficus benghalensis* linn occurs naturally in tropical and subtropical region of southeast asia, india(bangladesh, Nepal, Srilanka)East africa, northern Australia. The *ficus benghalensis* linn are rich in flavenoids, phenols, terpenoids, fatty acids, terpenes, tannis, sterols of the leaves & bark.

The *ficus benghalensis* linn commonly used to treat diabetics, oxidants, inflammatory, wound healing, pain, fever, stress, cancer, tumor, skin disease and digestive condition. Pharmacological studies conducted on the methanolic extract of *ficus benghalensis* linn root found to stimulate cell mediated and antibody mediate immune responses in rats(1). The aqueous and ethanolic extract of *ficus benghalensis* linn shows wound healing activity(2). The leaf extract of *ficus benghalensis linn* shows antioxidant activity(3).

The methanolic extract *ficus benghalensis linn* of dried leaves shows anti-inflammatory and analgesic activity

in rats(4). The ethanolic and aqueous extract of *ficus benghalensis* linn shows analgesic & anti-pyretic activity(5). The methanolic extract of *ficus benghalensis* linn fruit has significant anti-stress activity(6).

B. Babool/Babul (*Acacia nilotica*) commonly known as gum arabic tree, Egyptian thom, indian gum Arabic, belonging to family *fabaceae*. It is known for its bright yellow, fragrant flowers and hard, durable wood. *Acacia nilotica* is medium sized tree grow upto 15-20 meters in height. The fruit is a long, flat and curved pod containing seeds with often dark brown and black. The *Acacia nilotica* mainly grows in tropical and subtropical region of Africa, Middle East, India, Nepal, Bangladesh. The tree has been used in traditional medicine. *Acacia nilotica* Different parts of the tree, includes the bark, gum, leaves and pods are used in traditional medicinal purpose. *Acacia nilotica* to be rich in phenolics consisting condensed tannin, gallic acid, catechin, phlobatannins, epigallocatechin-s, flavonoids, alkaloids and other compounds.

Acacia nilotica are commonly used to treat cancer, diabetic, asthamatic, vasoconstrictor, mutagenic, cough, diarrhea, dysentry, wounds. Pharmacological studies the methanolic extract of leaves of *Acacia nilotica* shows wound healing activity(8). Antibacterial (skin diseases) shows the extract of Seed of *Acacia nilotica(7)*. The extracts of *Acacia nilotica* leaves, pod, bark shows antioxidant and antimaterial activity(9). The aqueous bark extract of *Acacia nilotica* shows antipyretic, antiinflammatory and antinociceptive activity in albino mice(10). The aqueous extract of *Acacia nilotica* root shoes analgesic and antipyretic activity using acetic acid induced writing model and brewers yeast model(11). The methanolic extract of root of *Acacia nilotica* shows antimalaerial activity(12).

1.1 Antipyretic

An antipyretic is a medication or substance that helps to reduce or eliminate fever (pyrexia) by lowering the body temperature. Antipyretics work by :

1. Inhibiting prostaglandin synthesis
2. Blocking cyclooxygenase (COX) enzymes
3. Acting on the hypothalamus to regulate body temperature
4. Reducing cytokine production

Example of antipyretics:- Acetaminophen, Ibuprofen, Aspirin, Naproxen.

1.2 Analgesic

Analgesics are medicines that selectively relieves pain by acting in the central nervous system (CNS) or on the peripheral pain mechanism, without significantly altering consciousness. Analgesics work by:

1. Blocking pain signals to the brain
2. Reducing prostaglandin production (which sensitizes nerve endings to pain)
3. Binding to opioid receptors (in the case of opioids)
4. Interfering with pain pathways in the brain and spinal cord

Example of analgesic :- Ibuprofen, Naproxen, Aspirin, celecoxib.

1.3 Benefits of antipyretic and analgesic :-

- Reduce risk complication
- Reduce fever
- Pain relief
- Relive discomfort
- Prevent febrile seizures
- Relieves menstrual cramp
- Improve sleep
- Reduce inflammation

1.4 MODE OF ACTION

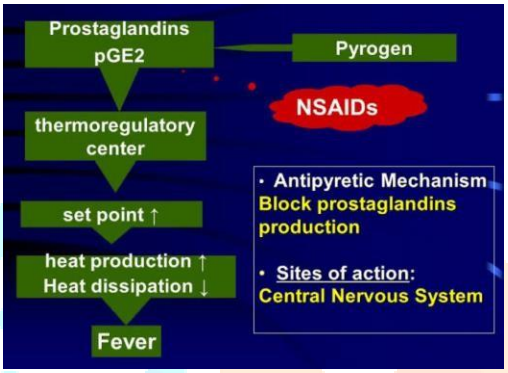

Fig.1: MOA OF ANTIPYRETIC

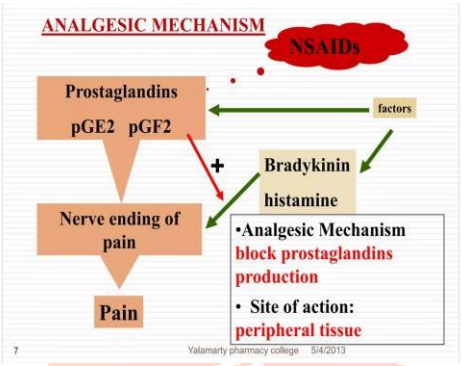

Fig.2: MOA OF ANALGESIC

2. PLANT PROFILE:

A. Banyan tree :

Banyan tree (*Ficus benghalensis*) commonly known as the indian banyan or simply the banyan tree, is large & evergreen tree belonging to moraceae family. It is also called as bargal, East india fig.

➢ **Scientific classification**:-

- Name of The Plant :- Banyan Tree
- Scientific name: *Ficus benghalensis* .
- Kingdom: Plantae
- Division:- Magnolia
- Class: magnoliophyte
- Family: Moraceae
- Genus: *Ficus*
- Species: *Fecus benghalensis*
- Common name of The Plant: Bargad, wad, Bhupade, vati
- Synonym: banian, Pig Tree, *ficus benghalensis*, Indian banyan

Fig.3 : Plant *ficus benghalensis*

- **Chemical Constituents :-**
  Flavonoids, Terpenoids, Phenols and Texpenes, sterols, amino acids, Fatty acids.

- **Uses :-**
  Antioxidant, anti inflammatory, Antipyretics, toothache, Antimicrobial, Antidiabetic, wound healing, anticancer, digestive condition.

B. Babool :

Babool/Babul (*Acacia nilotica*) commonly known as gum arabic tree, Egyptian thom, indian gum Arabic, belonging to family fabaceae. It is known for its bright yellow, fragrant flowers and hard, durable wood.

- **<u>Scientific classification</u>**:-
  - Name of The Plant:- babool or babul
  - Scientific name: *Acacia nilotica*
  - Kingdom: Plantae
  - Division:- mangnoliophyta
  - Class: mangnoliopsida
  - Family: fabaceae
  - Genus: *Acacia*
  - Species: *nilotica*
  - Common name of The Plant: *Acacia nilotica*
  - Synonym: babul, babool

Fig.4: Plant *Acacia nilotica*

- **Chemical Constituents :-**

Gallic acid, dicatechin, quercetin, robidandiol, B-amyrin,betulin, sitosterol and glucoside, isoquercetin

- **Uses :-**

antiinflammatory, analgesic, antibacterial, anti-cancerous, antidiabetic, antihypertensive, antioxidant, antistress, antimalerial.

3. CAPSULE:

A capsule is a type of container that is commonly used in the medical and pharmaceutical industries. It is usually made of two parts: a shell and a cap. Capsules are used to hold medications, supplements, or other substances in a convenient and easy-to-swallow form. They come in different sizes and can be made from various materials, such as gelatin or vegetarian alternatives. Capsules are designed to dissolve or break down in the body, releasing the contents for absorption.

Fig. 5: Capsules

❖ **Types of capsules :**

1) Hard gelatin capsule
2) Soft gelatin capsule

1. Hard Gelatin Capsules:

A hard gelatin capsule is a type of capsule that is usually used to contain medicine in the form of dry powder or very small pellets. Oral medications include tablets and hard gelatin capsules that are filled with powder. Hard gelatin capsules are usually filled with powders, granules, or tiny pellets.

Fig. 6: Hard Gelatin Capsule

2. Soft Gelatin Capsule:

A soft gelatin capsule is a type of capsule that is usually used to contain medicine in the form of liquid or powder, and which dissolves more quickly than a hard gelatin capsule.Soft gelatin capsules dissolve readily in the gastric juices of the stomach, and may work faster than other capsules.

Fig. 7: Soft Gelatin Capsule

❖ **Advantage**

1. Capsules are tasteless, odorless and can easily be administered.
2. Combination of powders we can use.
3. There are attractive in appearance.
4. The drugs having un-pleasant odor and taste are enclosed in a tasteless shell.
5. They can be filled quickly and conveniently.
6. Physician can change the dose and combination of drug according to patient requirement.
7. They are economical.

❖ **Disadvantages :**

1. Hygroscopic drugs are not suitable for filling into capsules, because they absorb water present in capsule shell makes shell very brittle and ultimately lead to crumble into pieces.
2. The concentrated solutions which require previous dilution are unsuitable for capsules because if administered as such lead to irritation into stomach.

4. SIZES OF CAPSULES

DIFFERENT SIZES OF CAPSULE

SIZE	AVERAGE CAPACITY (mg)	VOLUME CAPACITY
000	800 ~ 1600	1.37 ml
00	600 ~ 1100	1.00 ml
0	400 ~ 800	0.68 ml
1	300 ~ 600	0.48 ml
2	200 ~ 400	0.36 ml
3	162 ~ 324	0.27 ml
4	120 ~ 240	0.20 ml

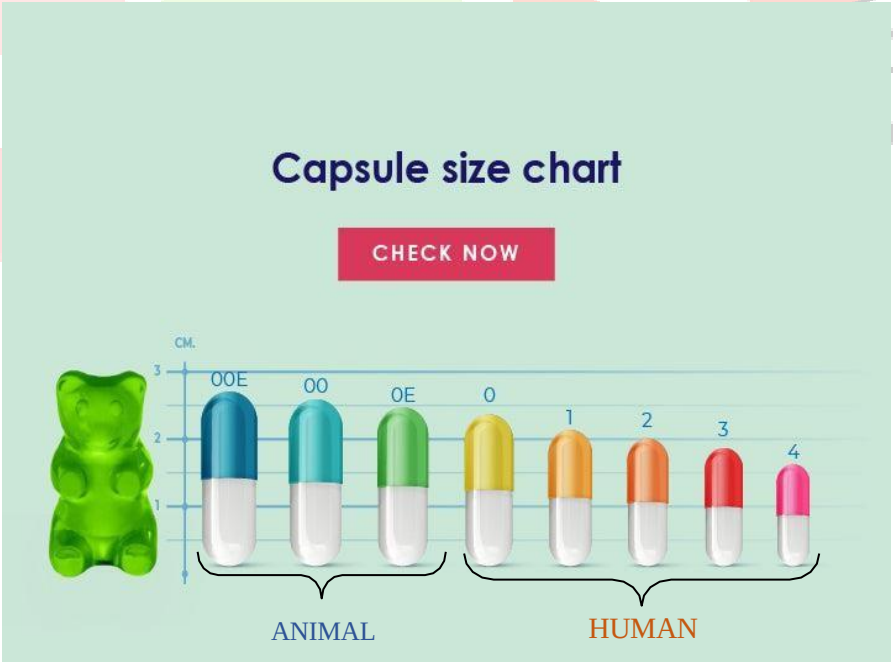

Fig. 8: Different size of capsule

5. MATERIALS AND METHODS :-

a) MATERIALS :

1. Banyan tree bark powder
2. Babul tree bark powder
3. Empty Capsule shell

b) APPARATUS :

1. Tray dryer
2. Weighing balance
3. Capsule filling machine
4. pH meter
5. Hot air oven
6. Disintegrater

- **Preparation method of capsule**

- **The process typically involves the following steps:**

1. **Selection of ingredients**: Choose the active ingredient(s) and any necessary excipients or fillers
2. **Mixing**: The ingredients are carefully blended together to ensure uniform distribution.
3. **Encapsulation**: The mixture is then filled into empty capsule shells using specialized equipment.
4. **Capsule sealing**: The two halves of the capsule shells are joined together, usually by mechanical or heat-sealing methods.
5. **Quality control**: The finished capsules undergo quality testing to ensure they meet the required standards for potency, purity, and uniformity

1. PREFORMULATION STUDY :-

1. Bulk density
2. Tapped density
3. Porosity
4. Carr's index
5. Hausner's ratio
6. Angle of repose
7. % Ash Value
8. Solubility ¸
9. Antimicrobial study

- **BULK DENSITY :**

The bulk density of a powder is the ratio of the mass of an untapped powder sample and its volume including the contribution of the inter-particulate void volume.

FORMULA:

$$\textbf{BULK DENSITY} = \frac{\textbf{MASS}}{\textbf{BULK VOLUME}}$$

- **TAPPED DENSITY**

The tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample.

FORMULA:

$$\textbf{TAPPED DENSITY} = \frac{\textbf{MASS}}{\textbf{TAPPED VOLUME}}$$

- **POROSITY**

Porosity or void fraction is a measure of the void (ie. "empty") spaces in a material, and is a fraction of the volume of voids over the total volume, between 0 and 1, or as a percentage between 0% and 100%.

FORMULA:

$$\textbf{POROSITY} = \frac{\textbf{VOLUME OF VOIDS}}{\textbf{TOTAL VOLUME}} \times \textbf{100}$$

- **CARR'S INDEX**

Carr's Index of any solid is calculated for compressibility of a powder which is based on true density and bulk density.

FORMULA:

$$\textbf{CARR'S INDEX} = \frac{\textbf{TAPPED DENSITY} - \textbf{BULK DENSITY}}{\textbf{TAPPED DENSITY}} \times \textbf{100}$$

- **HAUSNER'S RATIO**

Hausner ratio is defined as the ratio of a powder's tapped bulk density to its poured (loose) bulk density

FORMULA:

$$\textbf{HAUSNER'S RATIO} = \frac{\textbf{Tapped density}}{\textbf{Bulk density}}$$

- **ANGLE OF REPOSE**

Angle of repose powder poured from a vessel forms a cone-like pile. The angle of repose- the angle between the slope of the pile and the horizontal correlates with the strength of particle- particle interactions and, therefore, is measured to infer flowability.

FORMULA:

$$\emptyset = \tan^{-1}\frac{h}{r}$$

Where,

h : the height in cm

r : the radius in cm

∅: the angle of repose

- **% ASH VALUE**

The ash values usually represent the inorganic residues such as phosphates, carbonates and silicates present in herbal drugs

FORMULA

$$\%\ \mathbf{ASH} = \frac{W_2 - W_0}{W_1} \times 100$$

W_2: weight of crucible + ash

W_O: weight of crucible

W_1: weight of sample

- **SOLUBILITY**

Solubility is the ability of a solid, liquid, or gaseous chemical substance (referred to as the solute) to dissolve in solvent (usually a liquid) and form a solution. We are going to check solubility of our sample in water, acidic and alkaline solution.

➢ **ANTIMICROBIAL STUDY**

We have to check the antimicrobial property of our sample by suing different antimicrobial agents like *E. Coli, S. Aureus* & *Candida albicans.*

Procedure :

The antibacterial activity was measured by agar cup method. Nutrient agar (Himedia) was prepared and sterilized at 15 Psi for 15 minutes in the autoclave. It was allowed to cool below 45°C and seeded with turbid suspension of test bacteria separately, prepared from 24 hours old slant cultures. 5% inocula were used every time.

The bacterial cultures selected were, two Gram negative cultures *viz. Escherichia coli, Salmonella typhi* and two Gram positive cultures *viz. Staphylococcus aureus, Bacillus subtilis*. This seeded preparation was then poured in sterile petri plate under aseptic condition and allowed to solidify.

Cups of 10mm diameter were borered in the agar plate with sterile cork borer.

100 ul of compound solution prepared in Dimethyl Sulphoxide (1%) was added in the cup under aseptic condition with the help of micropipette. 100ul of DMSO was also placed in one of the cup as blank (negative control). A standard antibiotic disk impregnated with 10 units of Penicillin was also placed on the seeded nutrient agar surface as standard reference antibiotic (positive control).

The plates were kept in refrigerator for 15 minutes to allow diffusion of the compound from agar cup into the medium. Then the plates were shifted to incubator at 37°C and incubated for 24 hours.

After incubation plates were observed for the zone of inhibition of bacterial growth around the agar cup. Results were recorded by measuring the zone of inhibition in millimeter (mm) using zone reader.

2. EVALUATION PARAMETERS OF CAPSULE:

a. OFFICIAL TEST

1. Weight variation test
2. Disintegration test
3. Moisture content
4. pH test

b. UNOFFICIAL TEST

1. General appearance
2. Size
3. Shape
4. Colour
5. Odour

Fig. 11: Batches of Capsule

3. RESULT AND DISCUSSION

A. PROCUREMENT:

Procurement of Sample: The banyan tree and babul tree bark has been collected from Loha and empty capsule shell collected from Nanded, Dist-Nanded.

B. AUTHENTIFICATION:

The sample was authentified by Dr. V.R.Marathe, HOD (Botany dept.) of NES Science College , Nanded.

C. PRE-FORMULATION STUDY

a) Banyan:

b) Table no. 1: Preformulation of banyan sample

BATCH	**A (Sieve no.44)**	B (Sieve no.60)	C (Sieve no.80)	D (Sieve no.100)
1. Bulk density	**0.36g/ml**	0.34g/ml	0.33g/ml	0.36g/ml
2. Tapped density	**0.42g/ml**	0.4g/ml	0.42g/ml	0.44g/ml
3. Carr's index	**14.28 %**	14.28 %	21.42 %	18.18 %
4. Hausner's ratio	**1.16**	1.17	1.27	1.18
5. Angle of repose	**27'47ºc**	30'54ºc	30'96ºc	35'36ºc
6. % Ash value	**15 %**	15 %	15 %	15 %

In this preformulation study of Banyan sample we observed that, the **Batch A (sieve # 44)** has good flow Property and other parameter then can be utilized have final preparation of capsule.

c) Babul:

Table no. 2: Preformulation of babul sample

BATCH	**A (Sieve no.44)**	B (Sieve no.60)	C (Sieve no.80)	D (Sieve no.100)
1. Bulk density	**0.39g/ml**	0.38g/ml	0.40g/ml	0.45g/ml
2. Tapped density	**0.46g/ml**	0.46g/ml	0.5g/ml	0.6g/ml
3. Carr's index	**17.94 %**	17.39 %	20 %	25 %
4. Hausner's ratio	**1.17**	1.21	1.25	1.33
5. Angle of repose	**28'36ºc**	30'96ºc	33'02ºc	34'60ºc
6. % Ash value	**12 %**	12 %	12 %	12 %

In this pre−formulation study of Babul sample we observed that, the **Batch A (sieve # 44)** has good flow Property and other parameter then can be utilized have final preparation of capsule.

- **SOLUBILITY:**

A) Banyan sample

Table no. 3: Solubility of Banyan Sample

BATCH	Solubility in water	Solubility in NaOH (0.1N)	Solubility in HCl (0.1N)
A	**Sparingly soluble**	**Sparingly soluble**	**Slightly soluble**
B	Slightly soluble	Sparingly soluble	Very slightly soluble
C	Insoluble	Poorly soluble	Slightly soluble
D	Insoluble	Poorly soluble	Poorly soluble

In this study of Banyan sample we observed that Batch A Sample was Sparingly soluble in water, 0.1N NaOH and 0.1N HCl. While other batches are insoluble or poorly soluble

B) Babul sample

Table no. 4: Solubility of Babul Sample

BATCH	Solubility in water	Solubility in NaOH (0.1N)	Solubility in HCl (0.1N)
A	**Sparingly soluble**	**Sparingly soluble**	**Slightly soluble**
B	Slightly soluble	Sparingly soluble	Poorly soluble
C	Slightly soluble	Sparingly soluble	Insoluble
D	Insoluble	Sparingly soluble	Insoluble

In this study of Babul Sample we observed that Batch A Sample was Sparingly soluble in water, 0.1N NAOH and 0.1N HCl. While other batches are insoluble or Slightly soluble

- **ANTIMICROBIAL STUDY :**

Medium: Nutrient agar (*E.coli, S. aureus*), **Method:** Agar cup method Sabouraud agar (*candida albicans*)

Cup size: 10mm

Dose of compound: 10%

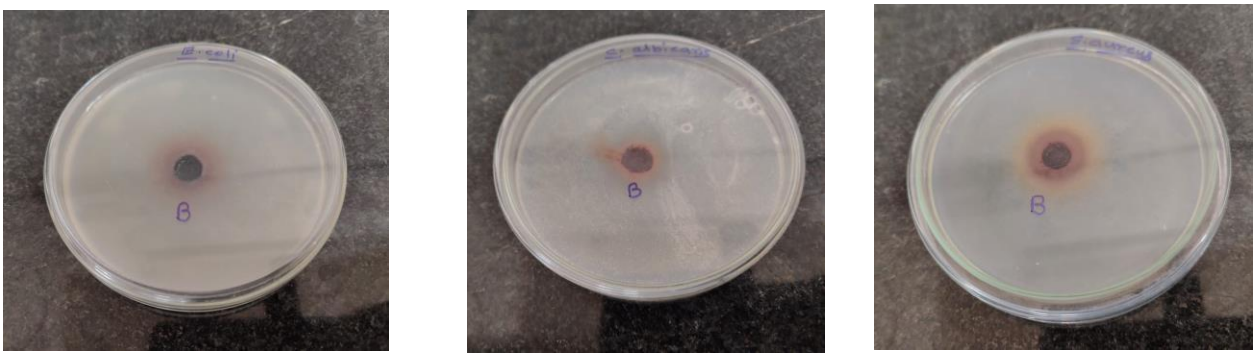

fig.no: 12 A} E. Coli inoculation B} Candida albicans inoculation C} S. aureus inoculation

OBSERVATION

Sr. No.	Compound	E. coli	S. aureus	Candida Albicans
1	Sample	-ve	19mm	21mm

We have performed the antimicrobial study against *E. coli, C. albicans* and *S. aureus* found that our sample shows -ve, 21mm, 19mm zone of inhibition after 24 hrs.

A. FORMULATION TABLE

Table no. 5: Formulation of capsule

INGREDIANTS	F1	F2	F3	F4
Banyan bark powder (API)	**250gm**	200gm	300gm	175gm
Babul bark powder (API)	**250gm**	300gm	200gm	325gm
TOTAL	**500gm**	500gm	500gm	500gm

We have prepared all batches having 500 mg wt., and concentration were changed to prepare F1, F2, F3, and F4 batches.

B. ORGANOLEPTIC CHARACTER

Table no.6: Organoleptic Characteristics of capsule

PARAMETER	OBSERVATION
Size	0
Shape	Cylindrical
Colour	Light brown powder
Odour	Characteristic odour

C. EVALUATION TABLE

Table no. 7: Evaluation of capsule

TEST	F1	F2	F3	F4
Disintegration test	**9.58 sec**	8.12 sec	8.48 sec	9.40 sec
Weight variation test	**Pass**	Fail	Fail	Fail
Moisture content	**20.90 %**	17.32 %	18.74 %	17.57 %
pH test	**6.5**	7.0	5.5	5.5

From above evaluation study we observed that batch F1 qualified all the evaluation test.

4. CONCLUSION

From current research work we come to know that the *ficus benghalensis linn* and *Acacia nilotica linn*. can be converted to antipyretic and analgesic capsule having good organoleptic properties.We also identify that batch A(sieve # 44) has good flow property, bulk density, tapped density, porosity, carr's index, hausner's ratio, angle of repose, % ash value, antimicrobial study, weight variation, disintegration test was performed. We also performed antimicrobial study of the *ficus benghalensis linn* and *Acacia Nilotica linn* bark powder and we gate zone of inhibition against *E.coli* is (negative), *S. aureus* (19mm) and *Candida albicans* (21mm) to prepare its solid unit dosage form (capsule) which will be more stable. After that, we have used this batch A (sieve # 44) for final preparation. We have again prepared 4 batch by using batch A. Then, we come to the conclusion that, batch f1 qualify all the evaluation test like weight variation test, disintegration test, moisture content, etc.

5. FUTURE PROSPECTIVES

We can continue this project by changing it's dosage form and performing animal study.

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