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APHRODISIAC ACTIVITY OF FORMULATED TABLET OF *BOMBAX CEIBA* LINN. EXTRACT IN MALE MICE

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ABSTRACT: The present work deals with pharmacological studies of the formulated tablet of *Bombax ceiba* Linn. root extract. An aphrodisiac activity by mating behaviour test model was investigated. The dissolved tablet slurry (400 mg/kg body wt. /day) was administered orally by gavages for 28 days. Mount latency (ML), intromission latency (IL), ejaculation latency (EL), mounting frequency (MF), intromission frequency (IF), ejaculation frequency (EF) and post-ejaculatory interval (PEI) are the parameters observed before and during the sexual behaviour study at day 0, 7, 14, 21 and 28. The formulated tablet significantly reduced ML, IL, EL and PEI ($p<0.05$). The formulated tablet significantly increased MF, IF and EF ($p<0.05$). These effects were observed in sexually active and inactive male mice. *Bombax ceiba* roots extract tablets (400 mg/kg body wt.) have comparative aphrodisiac activity in inactive mice.

INTRODUCTION: Sex disorders are classified into disorders of sexual function, sexual orientation, and sexual behavior. Male sexual dysfunction (MSD) could because by various factors. These include:

- ✓ Psychological disorders (performance anxiety, strained relationship, depression, stress, guilt and fear of sexual failure).
- ✓ Androgen deficiencies (testosterone deficiency, hyperprolactinemia).
- ✓ Chronic medical conditions (diabetes, hypertension).
- ✓ Vascular insufficiency (Atherosclerosis, venous leakage).
- ✓ Penile disease (Peyronie's, priapism, phinosis, smooth muscle dysfunction).
- ✓ Pelvic surgery (to correct arterial or inflow disorder).
- ✓ Neurological disorders (Parkinson's disease, stroke, cerebral trauma Alzheimer's spinal cordornerveinjury).
- ✓ Drugs side effects (antihypertensives, central agents, psychiatric medications, antiulcer, antidepressants, and anti-androgens).
- ✓ Life style (chronic alcohol abuse, cigarette smoking).
- ✓ Aging (decrease in hormonal level with age) and.

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- ✓ Systemic diseases (cardiac, hepatic, renal pulmonary, cancer, metabolic, post-organ transplant) [1].

A man may have a sexual problem if he:

- ❖ Ejaculates before he or his partner desires.
- ❖ Does not ejaculate or experiences delayed ejaculation.
- ❖ Is able to have an erection sufficient for pleasurable intercourse.
- ❖ Feels pains during inter course.
- ❖ Lacks or loses sexual desire [2].

Aphrodisiac saresub stances that stimulate/increase sexual desire and performance. There are numerous reports of aphrodisiac activity attributed to plants' isolated constituents and synthetic compounds [3]. *Bombax ceiba* is reported to possess antihypertensive, antioxidant, antidiabetic, aphrodisiac and uterine tonicity properties [4]. The present study was undertaken to invest in male mice's aphrodisiac activity of formulated tablets from B. ceiba root extract at 400 mg/kg body wt.

Bombax ceiba Linn. or *Bombax malabaricum* D.C. or *Salmalia malabarica* (DC.) Schott and Endalbe long to family Bombacaceae. The therapeutic effect has been reported in roots, gums, stem bark, flowers and seeds, prickles young fruits. This tropical tree has a straight, tall trunk, and its leaves are deciduous in winter. Red flowers with five petals appear in the spring before the new foliage. It produces a capsule that, when ripe, contains white fibers like cotton. Its trunk bears spikes to deter attacks by animals [5-6].

Tablet is a pharmaceutical solid dosage form. A mixture of active substances and excipients is compressed to form a tablet. The excipients can include diluents, binders or granulating agents, glidants, lubricants, disintegrates to break up in the stomach, sweeteners or flavors to enhance taste, and pigments to promote visually attractiveness [7].

MATERIALS AND METHODS:

Plant Material: Roots of *Bombax ceiba* were collected from Govt. Government Vidarbha Institute of Science & Humanities localities, Amravati (Maharashtra). The plant was identified and authenticated by Dr. Vishal R. Marathe of the Department of Botany, Shri Shivaji Science College, Amravati and dried in the shade at room temperature. Dried roots were powdered in a grinder, and powdered material was suspended in a mixture of ethanol: distilled water (70:30). The suspension was stirred at 40 °C for 24 h and heated at 50 °C for 2 h. The extract was filtered and dried.

Tablet Formulation:

Preparation of Granules [8]: Driedhydro-alcoholic root sex tracts of *Bombax ceiba* were used to prepare granules by wet granulation technique with the formula shown in **Table 1.**

TABLE 1: FORMULATION FOR TABLET

S. no.	Contents	Quantity per tablet
1	Extractof *Bombax ceiba*	100mg
2	Lactose	50mg
3	Starch	25mg
4	Poly Vinyl Pyrolidone K-30	35mg
5	Sodium methyl paraben	4mg
6	Sodium propyl paraben	1mg
7	Talk	15mg
8	Magnesium stearate	10mg
9	Sodium starch glyconate	10mg
10	Isopropyl alcohol	Quantity sufficient

- ❖ The accurately weighed quantities of extracts were mixed with lactose to absorb moisture and then passed through sieve no. 60.
- ❖ Mixed with weighed quantity of excipients (Starch, PVPK-30, Sodium methylparaben, Sodium propylparaben) insufficient quantity of isopropyl alcohol to obtain dough mass.
- ❖ The wet mass was passed through sieve no. 12.
- ❖ Granules were dried in an oven at 50–55 °C for 30 min.
- ❖ Dried granules were passed from sieve no. 20.
- ❖ Then granules were lubricated by talc, magnesium stearate, and sodium starch glycolate.

Compression of Granules into Tablets: Compressed the blend after lubricating the granules

into tablets; by using eight stations mini-tablet presto prepare tablets of 250mg each.

Preformulation Studies [9]: Preformulation testing is the first step in developing dosage forms of a drug substance by any technique. It can be defined as an investigation of the physical and chemical properties of a drug substance alone and when combined with excipients. The overall objective of preformulation studies is to generate in formation use full to the formulator in developing stable and bioavailable dosage forms.

Drug Excipients Compatibility Studies: Excipient sareintegral components of almost all pharmaceutical dosage forms. The successful formulation of stable and effective solid dosage forms depends on the selection of excipients, which are added to facilitate the administration of the drug and protect it from degradation.

FT-IR Studies: FT-IR spectroscopy was employed to ascertain the compatibility between drug extract and the selected excipients. The pure drug extract, drug-excipients combinations, and formulations were subjected to FT-IR studies. Potassium bromide, pure drug extract and the excipients were heated to 105 °C for one hour to remove the moisture content in ahotairoven. Then in the presence of an IR lamp, potassium bromide was mixed with drug extract and excipients in 1: 1 ratio. Grinding in smooth mortar can affect mixing. The mixtures were then placed in the sample holder of the instrument, and the spectra were taken. The spectra were run from 4000 to 500 cm^{-1} wave numbers. FT-IR spectrum of pure drug extract was compared with FT-IR spectra of an extract with excipients. The pure drug extract and drug with excipients were scanned separately. The disappearance of extract peaks or shifting of the peak in any of the spectra was studied.

Physical Properties [10]: The powder of excipients and drug extract was characterized by the angle of repose, bulk density, tapped density, % compressibility, and weight of the tablets. It also creates the problem of hardness during the compression of tablets.

Post Formulation Studies

Evaluation of Tablets [11]: The tablets, after being compressed, were evaluated for quality control tests, *i.e.*, appearance, dimensions (diameter and thickness), weight uniformity test, hardness, friability and *in-vitro* disintegration test as per IP.

Appearance, Shape and Color of Tablets: Uncoated tablets were examined under a lens for the tablet's shape, and color was observed by keeping the tablets in light. The tablets were checked for the presence of cracks, depressions, pinholes etc if any, uniformity of the color and the polish of the tablet.

Thickness: Three tablets were picked randomly, and thickness was measured individually. It is expressed in mm, and the standard deviation was also calculated. The tablet thickness was measured using digimatic calipers (Mitutoyo Campbell Electronics, Japan).

Hardness Test: The ability of a tablet to withstand mechanical shocks in handling is hardness. The hardness of the tablets was determined using a Monsanto hardness tester. It is expressed in kg /cm2. Randomly picked three tablets were determined. The mean and standard deviation values were also calculated.

Friability Test: Ten tablets were weighed collectively and placed in the chamber of the friabilator, time a sure the friability by Roche friabilator. The tablets were exposed to rolling from 6 inches within the chamber at a rate of 25 rpm. The percent friability was determined by collectively weighing of tablets after 100 rotations (4 min) in the number of friabilator.

Weight Variation Test: Twenty tablets were weighed individually and all together. The average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variations should be within the permissible limit (±7.5%).

***In-vitro* Disintegration Test:** Place one tablet in each of the six tubes of the basket. Add a disc to each tube and run the apparatus using pH1.2 maintained at 37±2 °C as the immersion liquid.

The assembly should be raised and lowered between 30 cycles per minute in the pH 1.2 maintained at 37±2 °C. The time in the second

taken for completion is the integration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

Sexual Behavior Study: The experimental protocol to evaluate an aphrodisiac activity by mating behavior test model was approved by the institutional animal ethical committee of the Government College of Pharmacy, Amravati, as per CPCSEA guidelines.

With prior approval from the institutional animal ethical committee (Registration No.1370/ac/10/CPCSEA, Date-25/08/2010) of Government college of pharmacy, Amravati, the aphrodisiac studies were conducted on Swiss albino mice weighing 20–30 gm obtained from Shree Farm, Bhandara, Maharashtra and acclimatized for six days.

The following guidelines were followed in the study:

- Males were kept individually, but females were kept in groups.
- Training of each male for 15 min at a time was performed until sexual behavior was elicited, and when the behaviour was noticed, males were exposed to receptive females (one male with five females).
- Repeated training to overcome the lack of sexual response in the presence of observers.
- The study was conducted in a silent room under dim red light.
- During chasing each other, any jerking movement of the mating area was avoided and
- Cleaning of the mating area was performed after each trial, since it might alter the sexual behavior by urine trails left by one mice [12].

Acute Toxicity Tests: To determine acute toxicity, if any, dose of 0,0.5, 1.0 and 2 g/kg (p.o) respectively of the ethanol: water (70:30) *Bombax ceiba* roots extract were given to four groups each containing six mice. The control mice received saline in an identical manner. The mice were observed continuously for 1h for any gross behavioural changes and deaths, if any, and intermittently for the next 6h and then again at 24 h after dosing. The behaviour parameters observed were convulsion, hyperactivity, sedation, grooming, and loss of righting reflex, and increased respiration [13].

Training to Male Mice: Male mice were trained for sexual experience. To provide sexual experience, each male mouse was allowed 30 min exposure to a female mouse (used as mating stimulus). The animals were divided into active and inactive groups by testing for copulatory behavior three times over a 10 day period. The animals were considered being inactive if did not show any sexual interest during training.

Female Broughton to Estrus Phase: Female mice were artificially brought in to estrous phase as the female mice allow mating only during the theatre's phase; by the administrating suspension of estrogen benzoate at the dose of 100 µg/kg body wt. and subcutaneous administration of progesterone at the dose of 500 µg/kg body wt. 48 and 6 h respectively before the copulatory study.

The Groups and Dose of Drugs Administered: Three groups of Swiss mice were used; each group contained six animals (five females and one male). Oral administrations were done for 28 days by gavages. The dose of drugs administered peroral is shown in **Table 2.**

TABLE 2: THE GROUPS AND DOSE OF DRUGS ADMINISTERED

S. no.	Groups	Drug Administered	Dose (mg/kg body wt. p. o.)
01	Active	Control(Saline)	1ml
02	Active	Developed Tablet	400
03	Inactive	Developed Tablet	400

Mating Behavior Test [14-15]: The following parameters of the copulatory behaviour were recorded with the help of video tracking media:

- Mountlatency (ML)-time taken for the first mount following the introduction of females.

- Intromission latency (IL): time is taken for first intromission following the introduction of the female.
- Ejaculation latency (EL): time interval between first intromission and first ejaculation.
- Mount frequency (MF): no. of mounts observed in 30 min.
- Intromission frequency (IF): no. of intromission observed in 30 min.
- Ejaculation frequency (EF): no. of ejaculations observed in 30 min,
- Post-ejaculatory interval (PEI): the time between the occurrence of ejaculation and the resumption of sexual activity, as indicated by next intromission.
- The copulatory behavior study was conducted at 0, 7^{th}, 14^{th}, 21^{st} and 28^{th} days.

Statistical Analysis: All the results are expressed as the mean ± S.E.M. The data were analyzed for statistical significance by one-way analysis of variance (ANOVA) followed by Tukey test using computerized Graph Pad Prism, version 4.03 software (Graph Pad Software Inc). Values of $p<0.05$ were considered statistically significant (*$p<0.05$, **$p<0.01$, ***$p<0.001$).

RESULTS AND DISCUSSION:

Drug-Excipients Compatibility Studies: Compatibility studies were performed using IR interpretation for drug extract and for drug extract and excipients physical mixture, and it was found that there were no interactions between the drug extract and the excipients, so the further formulation was carried out.

Evaluation of Tablets:

Pre Compression Parameters: The parameters such as bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio are evaluated for prepared tablets and results are shown in **Table 3**. The angle of repose of formulations showed within 30°. Both loose bulk density (LBD) and tapped bulk density results are shown in **Table 3.** All the values obtained are within the acceptable range. This result helps in calculating the % compressibility of the powder. The formulation shows good compressibility. The granules have the required flow property and strength for compression shown by Hausner's ratio as it falls in the range.

TABLE 3: PRECOMPRESSION PARAMETERS FOR THE GRANULES

S. no.	Angle of Repose (θ)	Loose Bulk Density (gm/cm^3)	Tapped Density (gm/cm^3)	% Compressibility	Hausner's Ratio
1	26.22±0.449	0.61±0.006	0.72±0.016	17.289±1.321	1.172±0.017

* Values are mean ± SD, n=3.

Post-Compression Parameters: The results for post-compression parameters such as color, thickness, hardness, friability, weight variation, disintegration studies for formulated tablets are tabulated in **Table 4**.

Randomly picked tablets from formulated batch were examined under lens for shape and in presence flight for color. Tablets showed a flat, oval shape in brown color. Tablets mean thickness in the formulation was found to be 3.57 mm. The hardness of the formulated tablets is found to be within the limit. The friability of the formulated tablets is within limits. The weight of the tablet is 250 mg; as the permissible limits ± 7.5%, the results of the test showed that the tablet weight was within the pharmacopeial limit.

Thus formulated tablets of *Bombax ceiba* root extract complies with the IP limit. The results showed that the disintegration time of prepared tablets is in the range of 7–9 min. All the results are within the pharmacopeial limit.

TABLE 4: POST-COMPRESSION PARAMETERS FOR THE DEVELOPED FORMULATION

S. no.	Physical appearance	Thickness (mm)	Hardness (KP)	Friability %	Weight variation (mg)	*In-vitro* Disintegration Time (min.)
1	Clear, brown	3.57±0.19	7.4±0.3	0.352	250.7±1.3	7.6±0.2

* Values are mean ± SD, n=3.

Sexual Behavior Study: The observations of the sexual behavior study shows that tablet from *Bombax ceiba* root extract reduced ML, IL, EL, and PEI significantly in both active and inactive male mice. *Bombax ceiba* tablet also increased MF, IF and EF significantly in both active and inactive male mice. All these effects were observed from the 21st and 28th days of study.

Sexually active and inactive animals showed increased and improved sexual performance when *Bombax ceiba* roots extract tablet (400 mg/kg body wt.) was administered for a period of 21 to 28 days. Developed table formulation has comparative aphrodisiac activity. All the results are shown in **Table 5.**

TABLE 5: OBSERVATION OF SEXUAL BEHAVIOR STUDY

S. no.	Groups	Para	Mean± SEM				
			0day	7thday	14thday	21stday	28thday
1	Active (Control)	ML	270±2.12	275±2.48	260±2.19	285±4.02	265±4.56
		MF	31±0.91	28±0.91	35±1.29	25±1.29	33.5±1.19
		IL	333±2.38	338.75±3.25	301±2.61	370±3.85	310±4.56
		IF	10±0.91	9±0.91	12±.081	8±0.91	10±0.91
		EL	930±2.19	980±2.38	850±6.45	1020±4.56	850±6.45
		EF	1.5±0.09	1.2±0.09	1.8±0.18	1.2±0.12	1.6±0.09
		PEI	242.5±2.78	248±3.85	215±4.20	270±4.56	220±3.85
2	Active (Developed Tablet 400mg/kg body wt.)	ML	272±2.19	260±2.19	248±3.51***	210±4.20***	159±3.59***
		MF	30±0.91	35±0.91	38±0.91**	48±1.82***	57±0.91***
		IL	325±23.84	310±24.09	268±1.82	220±4.56**	190±2.38***
		IF	9±0.91	10±0.28	12±0.91	17±0.91***	22±0.81***
		EL	950±8.41	940±3.85	928±5.67	875±2.61***	802±3.65***
		EF	1.4±0.09	1.5±0.09	1.6±0.09	1.9±0.12*	2.4±0.09***
		PEI	250±4.08	239±4.39	213±2.73***	175±4.56***	110±4.56***
3	Inactive (Developed Tablet 400mg/kg Body wt.)	ML	340±9.13	328±2.58	308±2.73**	274±2.19***	205±4.56***
		MF	20±0.91	23±0.91	27±0.91***	35±0.91***	44±0.91***
		IL	385±2.38	377±2.88	351±1.68***	302±5.67***	255±4.56***
		IF	5±1.47	6±0.91	7±0.81	11±0.91**	16±0.91***
		EL	1225±10.40	1180±6.88*	1100±10.99*	990±5.49***	925±10.99**
		EF	1.1±0.09	1.2±0.09	1.3±0.09	1.7±0.08***	2.1±0.04***
		PEI	315±6.45	300±3.29	282±2.97***	249±2.58***	180±3.85***

SEM: Standard Error of Mean. Significance level: *p < 0.05, **p < 0.01, ***p < 0.001. ML– mount latency, IL –intromission latency, EL – ejaculation latency, MF – mount frequency, IF – intromission frequency, EF– ejaculation frequency and PEI–post ejaculatory interval.

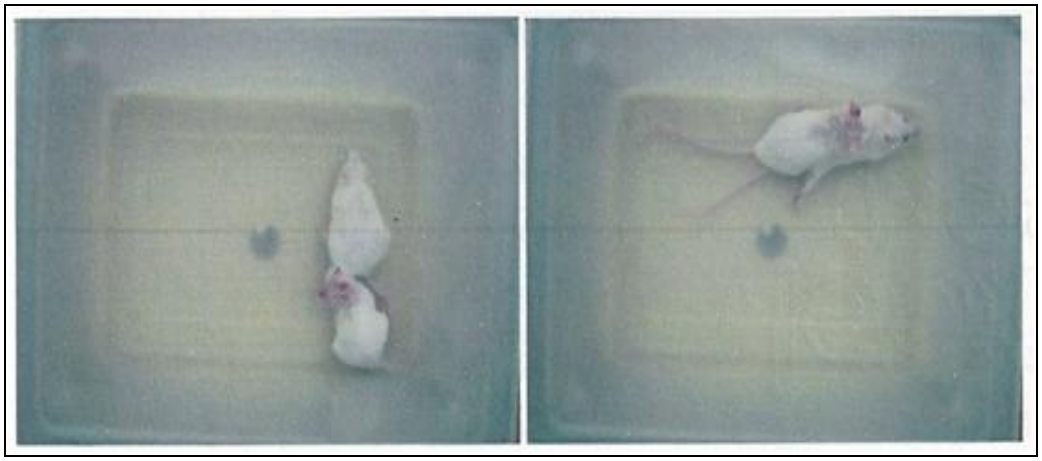

FIG. 1: GENITAL INVESTIGATION & MOUNTING OF FEMALE BY MALE MICE

The hydro-alcohol extract of this drug was found to be devoid of any general conspicuous short-term toxicity. Long-term toxicity studies, as well as systemic toxicity, remain to be studied. This plant is likely to be a safe drug as compared to synthetic drugs as this drug is used in ethnomedical practices without any recorded toxicity.

Generally: sexual behaviours are enhanced by elevated testosterone levels.

Drug-induced changes in neurotransmitter (testosterone) levels or their action in the cells could also change sexual behavior. In this connection, this herb is also considered a nervous stimulant, but active investigation is required to explore the possible mechanisms of action. The limbic system is the area of the brain most associated with sexual behavior. The research indicates the relationship between brain dopamine, 5HT, and sexual behavior by various animal and human models. Both dopamine and 5HT are implicated in depression. The relationship of dopamine to human sexual behaviour reports toper-sexuality behaviour induced by L-dopa in parkinsonian patients. CNS stimulants and antidepressants are known to affect libido, erection, ejaculation, and orgasm. It is also suspected that monoamines play a crucial role in the regulation of sexual behavior, particularly that of dopaminergic transmission in the facilitation of masculine activity. Thus, both dopaminergic and adrenergic receptors are involved in sexual behavior [16-17].

CONCLUSION: *Bombax ceiba* roots extract tablet (400 mg/kg body wt.) has comparative aphrodisiac activity in inactive mice; this suggested that *Bombax ceiba* will be the best alternative to high-cost synthetic drugs. *Bombax ceiba* is a plant with no or lesser site effect constipation [18] reported compared with synthetic drugs. So, the developed tablet will be the best alternative to tablets made from synthetic chemical moiety.

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CONFLICTS OF INTEREST: Nil

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