

**FORMULATION AND EVALUATION OF APHRODISIAC TABLET FROM
POLYHERBAL DRUGS BY WET GRANULATION METHOD****Dr. Satendra Kumar*¹ and Dr. Anil Kumar²**¹Department of Pharmaceutics, L.N Pharmacy College, Baitalpur, Deoria, U.P.²Departments of Pharmacognosy, Pharmacy College, Itaura, Chandeshwar, Azamgarh, U.P.

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ABSTRACT

The present's research work is identified aphrodisiac plant from various ethno botanical surveys and folklore medicinal survey for aphrodisiac activity. An aphrodisiac is defined as an agent that arouses sexual desire. Erectile dysfunction or male impotence is defined as the inability of a man to achieve and maintain an erection sufficient for mutually satisfactory intercourse with his partner. Hence patients are seeking complementary and alternative medicine to treat sexual dysfunction. To overcome the problem of sexual or erectile dysfunction various natural aphrodisiac plants are potentially preferred. This study reveals that some plants and their extract have aphrodisiac activity, which are helpful for researcher to develop new herbal aphrodisiac formulations. In the recent years, interest in drugs of plant origin has been progressively increased. Aphrodisiac is the word derived from Aphrodite, the Greek goddess of sexual, love and beauty. Impotence or erectile dysfunction is said to afflict as much as 10% of the male population. Despite this staggering incidence, few cases come to light. The practice of self-medication by an increasing number of patients and the absence of real directives amplifies the potential health hazards to the community. **Conclusion-** The clients preferred to use aphrodisiacs from other systems of medicine than allopathy and majority of choice was ayurvedic aphrodisiacs.

KEYWORDS: Aphrodisiac, Erectile dysfunction, Male impotence, Herbal drugs, Prescription.**INTRODUCTION**

An aphrodisiac is defined as any food or drug that arouses the sexual instinct, induces veneral desire and increases pleasure and performance.^[1] Sound sexual and reproductive health is one of the major factors that contribute to happy family and good self- esteem among several men and women. Infertility has also played a major role in the disintegration of many families. Sexual health requires a positive approach to human sexuality and an understanding of the complex factors that shape human sexual behavior.^[2] The search for an effective aphrodisiac has been a perennial pursuit of most societies throughouthistory.^[3]

The search for an effective aphrodisiac has been a perennial pursuit of most societies throughout history.^[4] Whether the expression of sexuality leads to sexual health and well-being or to sexual behavior that put people at risk; it is determined by these factors which could also result to sexual and reproductive ill health.^[5] The drug Viagra (sildenafil) has drawn public attention to aphrodisiacs. Various substances of animal and plant origin have been used in folk medicines of different cultures.^[6]

Worldwide estimates of impotence or erectile dysfunction (ED) prevalence range from 2% in men younger than 40 year to 86% in men 80 year or older. Despite this, few numbers of cases come to light. The commercialization of new synthetic love drugs has fascinated the public interest and has led to a reassessment of classical aphrodisiacs and to the search for new ones. The practice of self-medication by an increasing number of patients, the incessant aggressive advertising of these herbal aphrodisiacs, the invasion of the medicinal market with uncontrolled dietary supplements and the absence of real directives amplifies the potential health hazards to the community.^[7,8]

The ability to procreate is enhanced through sound sexual health. Poor sexual performance is a major factor that must be overcome for lasting peace in some marriages. Sexuality is a central aspect of being human throughout life and encompasses sex, gender and roles, sexual orientation, eroticism, pleasure, intimacy and reproduction. Sexuality is experienced and expressed in thoughts, fantasies, desires, beliefs, attitudes, values, behavior, practices, roles and relationships. It is also important to note that while sexuality can include all of these dimensions, not all of them can be experienced or

expressed. Sexuality is influenced by the interaction of biological, social, economic, political, cultural, ethical, historical, and religious and spiritual factors.^[9]

Vajikaranas i.e. measures to excite lust by charms, are two kinds.

1- The external or mechanical methods as flagellation, scarification and external application on male or female genitals or extra-genital parts.

2- The medicinal or oral preparation to excite sexual passions.^[10]

The concept of sexual performance varies from one individual to another. Sexual performance is naturally important to men due to their ego and instincts to procreate. The ability to satisfy a woman, the size of a man's penis which is often though wrongly associated with sexual ability is what makes up every man. Poor sexual performance causes low self-esteem and due to natural sexual instinct, humans are able to attract suitable mates and procreate. Sexual performance in male sex is fundamental in the following areas; the ability to satisfy a woman and give her orgasms and the ability to impregnate a woman.^[11]

Folk remedies have long been advocated, with some being advertised widely since the 1930s. The introduction of the first pharmacologically approved remedy for impotence, Viagra, in the 1990s caused a wave of public attention, propelled in part by heavy advertising.^[12] In Ayurveda, poor sexual performance includes a cessation of the sexual desire owing to increased thoughts and forced intercourse, excessive use of certain substances with pungent, acid or saline taste or heat making articles which leads to loss of Saumya Dhatu (watery principle) of the organism, virile impotency resulting from inadequate semen in persons addicted to excessive sexual pleasure, diseases such as syphilis, Sahaja impotency (congenital or sexual incapacity from birth), voluntary suppression of the sexual desire by a strong man observing perfect continence and impotency due to the destruction of local Marma (spermatic cord).

Male impotence or erectile dysfunction is caused mainly by cardiovascular leakages and diabetes among other factors and the use of plants or plant based products to stimulate sexual desire and to enhance performance and enjoyment is almost as old as human race itself. Androgens play significant role in male reproductive health as it acts centrally and peripherally during initiation and sexual intercourse. Stimuli such as steroids (testosterone) are known to either up regulate or down regulate androgen response Treatment of erectile dysfunction may involve psychotherapeutic approach and pharmacotherapy using drugs such as papaverin, alprostadil, vardenafil and central stimulants like apomorphine or herbal drugs with aphrodisiac activity.^[13,14,15]

There are many herbal drugs that have been used by men with ED with varying degrees of success.

Most potent herbal aphrodisiacs are available and have little or very little side effects. Natural products are available in texts of Ayurveda for their spermatogenic and virility potential activities. Ayurvedic aphrodisiac therapeutics is grouped into vajikarana (pharmacological) and rasayana (non-pharmacological products).^[16]

History of aphrodisiac plants

Throughout history, several aphrodisiac preparations have included numbers of plants, animal organs etc. The reference to such substance has also mentioned in holy texts like Kama sutra, and the Bible to the Koran and in literature from Shakespeare and Ovid to Gilbert and Sullivan plays in the twentieth century (Sood *et al.*, 2005).

Ayurveda seers recognized the vital importance of virility and formulated "Vajikarna" therapy. Vajikarna is defining as a therapy for getting sexual urges and energy like hoarse. All important Ayurveda texts available today (Charak, Sushrta, Bhavaprakash, Nighantu etc.) have given importance to aphrodisiac (Singh and Mukherjee, 1998). In modern world a huge number of the plants, minerals, and synthetic compounds have been labeled as aphrodisiac.

Aphrodisiac plants

Sex is the one aspect of human life that has always held a position of prominence in every time and within every culture nearly without exception. It's a biological imperative of the species. Humans have always and will search for methods to induce their sexual experience and improve their performance The word 'Aphrodisiac' derived from 'Aphrodite' the Greek goddess of love and the aphrodisiac are the substances, which stimulates sexual desire (Greek- Aphrodisiacs- sexual). According to Oxford Learners Dictionary (Cowie, 1989) aphrodisiac means substance or drug arousing sexual desire, while Encyclopedia of Medicinal plants (Mnimh, 1996) explained aphrodisiac as the one which excites libido and sexual activity.

The Ayurveda define the aphrodisiac that strengthens the body by reinvigorating the related organs and holds the view that by increasing the strength of sexual organs and the overall health of the body and promote contentment psychologically. Foods itself is considered as an aphrodisiac in Ayurveda because after nourishing different tissues of the body (muscles, fat, nerves) it nourishes the reproductive fluids; and promote vigor. In general "Aphrodisiac" are the substance which are ingested, applied topically, smoked snorted or otherwise delivered in to body for improving their sex potentials.

Ayurveda realized the problem of male sexual dysfunction thousands of years ago. It realized, among

other thing, the role of nervous system, cardiovascular system, and psychological aspect of fertility and male sexual performances. The basic principle of treatment in Ayurveda is to assist the body to heal itself. The Ayurveda fundamental principle of repletion and depletion, consisting of radical and conservation treatments apply to therapy for male sexual dysfunction. Radical therapy adopts techniques to drain the waste materials of different body compartment through the nearest channel in a system – friendly manner. Radical therapy, followed by repletion and reproduction medicine therapy, can probably improve the male reproductive function by creating an optimal environment for spermatogenesis and improving intratesticular availability of nutrients. The potential of Ayurvedic and other traditional medicinal plants in the development of invaluable standardized phyto medicines and allopathic types of drug is expected to have great value, particularly in the context of male sexual problems. In Ayurvedic texts aphrodisiacs have been classified into five categories (Singh and Mukherjee, 1998).

1. Drug which increase the quantity of semen or stimulate the production of semen e.g., *Microstylis wallichii*, *Roscoea procera*, *Mucuna pruriens* and *Asparagus racemosus*.
2. Drugs, which purify and improve the quality of semen e.g., *Saussurea lapa*, *Sesamum indicum*, *Vetiveria ziznoides* and *Anthocephalus cadamba*.
3. Drugs, which help sexually and in ejaculation e.g., *Strychnos nux-vomica*, *Cannabis sativa*, *Myristica fragrance*, *Cassia occidentalis* and musk.
4. Drugs delay the time of ejaculation e.g., *Sida cordifolia*, *Asparagus racemosus*, *Cinnamomum tamala*, *Anacyclus pyrethrum*, *Mucuna pruriens*.
5. Drugs arousing sexual desire viz., *Withania somnifera*, *Datura stramonium*, *Hibiscus abelmoschus*.

The specific treatments for increase the semen and the aphrodisiac can be practiced either concurrently or in sequence. This is very clearly reflected in the various combinations of herbals and other traditional medicinal ingredients in the various Ayurveda formulations. Most of the preparation contains a few too many plant extract and many also contain some minerals. More than 60 formulations are available in the market. With reconnaissance of traditional knowledge and literature, plants with aphrodisiac potential are identified. Extensive survey of different discipline viz. taxonomy, agronomy, natural product chemistry, commerce and pharmacological studies for the aphrodisiac plants were made to understand the status of these plants in respect of characters selected in the present study. A score of zero (0) is used to indicate no further study required for the parameter in consideration, while the score of one (1) for incomplete and/or no studies reported. The sum of the individual scores is considered for knowledge gap assessment. Where in the increase in value indicate the poor status of our knowledge base.

Mechanism of action of aphrodisiac plants

Penile erection is controlled by the balance between the factors leading to the contraction and relaxation of smooth muscles of the corpus cavernosa, these effects may occur directly on the central nervous system and/or on the peripheral nervous system by the alteration of blood flow to the genitalia. Neurochemical systems such as nor epinephrine, dopamine, serotonin, acetylcholine and histamine work together for increase in sexual arousal.

There are different mechanisms of action of aphrodisiacs such as nitric oxide (NO)-based mechanism of action and androgen based mechanism of action. The neurotransmitter NO drives the relaxation of the penile vasculature and trabecular smooth muscles which play significant roles in penile erection. Relaxation of the trabecular smooth muscles of the corpus cavernous leads to decreased vascular resistance and increased blood flow to the penis. A decrease on outflow is ensured by the compression of the subtunical venules. Both increased inflow and decreased outflow results to penile engorgement and erection. Vasodilatation is mediated by NO from the vascular endothelium of the sinusoids and noradrenergic, noncholinergic and cavernosal nerves.

Androgens such as testosterone play crucial role in the development of secondary sexual characters such as epididymis, vas deferens, seminal vesicle, prostate and the penis. The conversion of testosterone to estradiol in the hypothalamus increases sexual functions. Penile erections are also caused by cyclic adenosine monophosphate pathway (cAMP) through the mediation of corporal smooth muscles and respective enzymes and proteins such as prostaglandin and the protein kinase G which causes smooth muscles relaxation and also increases the concentration of Ca²⁺ which induces a loss of the contractile tone of the penile smooth muscles and increase blood flow in the cavernous body thus yielding and erection.

Need of Aphrodisiac for men

The process of human conception is almost absurdly inefficient and completely depends on chance. There is only one sperm out of billion got the chance to encounter with egg. And if one sperm does finally complete the journey.

In general modern medicine works under three basic mechanisms:

1. Increase the blood flow to the genital organs to prolong or enhance arousal (this is the strategy of Viagra)
2. Improve the nerve ending and nerve conduction in brain.
3. Balance hormones level and increase the amount of testosterone in blood

Infertility risk factors

1. **Regional differences:** Geographical location also

- produces the affect on sperm count.
- Inhaled gets rapidly metabolized, triggering an inflammatory reaction, which could adversely affect the sperm.
 - Cigarette smoke:** Sperm count of smokers are on an average 13-17 per cent lower than non-smokers
 - Air pollution:** Men living in industrial and polluted towns have 6 times more abnormal sperm than living in clean areas.
 - Pesticides:** Exposure to pesticides results in reduced sperm count and an increase in abnormally shaped sperms
 - Chemicals:** Sperm count drops in men exposed to chemicals like DDT, PCB's (Polychlorinated biphenyls), dioxins and some petroleum by-products.
 - Anesthesia:** Animals exposed to the anesthesia enflurane show 50 percent higher sperm damage rate than those not exposed to enflurane.
 - Foods additives:** Food additive like monosodium glutamate (MSG) causes infertility in animals.
 - Occupational exposure:** Men who work in aircrafts industry, textiles, and plastic, welding, chemical solvent or even antibiotic are more at risk of having abnormal sperms.
 - Ozone affects:** As the level of ozone in ambient air increases, the sperm concentration goes down. Ozone, once

MATERIAL AND METHOD

Collection of Aphrodisiac plants

Tribullus teriistris, Pedalium murex L., Pausinystalia Yohimbe, Panax ginseng and Myristica fragrance hault were collected from near supper market Lucknow and

Evaluation Parameter of aphrodisiacs tablets

No	Ingredients	F1 batch	F2 batch	F3 batch
1	Tribullus teriistris	170 mg	170 mg	170 mg
2	Pedalium murex L	100 mg	110 mg	110 mg
3	Pausinystalia Yohimbe	50 mg	60 mg	50 mg
4	Panax ginseng	30 mg	20 mg	20 mg
5	Myristica fragrance	130 mg	110 mg	130 mg
6	Hydroxy Propyl Methyl Cellulose	15 mg	12 mg	17 mg
7	Aerosol	2.5 mg	4 mg	1.5 mg
8	Magnesium stearate	2.5 mg	4 mg	1.5 mg

Pre- Formulation Studies

Pre formulation study is the first step in potential drug development when developing a new dosage form. It is the primary investigation in drug development to obtain information on known compound properties and the proposed development schedule. As a result, this pre-formulation investigation may nearly confirm that no significant barriers to compound development exist. Angle of repose, bulk density, tapped density, compressibility indices and other pre-compression parameters.^[18]

identified by Pharmacognosy department in L.N.Pharmacy college Baitalpur Deoria U.P. Along with all other ingredients including Magnesium Stearate, HPMC, isopropyl alcohol and Aerosol, were taken from Chemistry department in L.N. Pharmacy college Baitalpur.^[17]

Collection of aphrodisiac medicinal plant for Preparation of Powder Blend

The preparation are completed in two steps.

For Granules Preparation

Initially Tribullus teriistris, Pedalium murex L, Pausinystalia Yohimbe, Panax ginseng and Myristica fragrance are cut in to pieces and pulverized into fine powder. Take the total amount of drugs in the formula, which is 480 mg. The 48 mg blend was taken and placed in another tray. In a separate beaker, combine 15 mg accurately weighted HPMC with 50 ml isopropyl alcohol and 100 ml distilled water to form a paste. Slowly add the HPMC slurry to the remaining 432 mg blend and prepare the dump mass. Finally, the dump mass is passed through sieve no. 16 to form granules before being placed in a hot air oven at 70° for 1 hour. Pass through sieve no. 20 once more. To obtain the required size of granules.

For Preparation of aphrodisiac Tablet

In a separate beaker, combine the remaining 48 mg powder blend with the lubricant (mag stearate and Isopropyl alcohol) and thoroughly mix it. Add the 48 mg powder blend to the previously prepared powder blend and mix for 15 minutes. Finally the tablet was prepared using a rotary tablet punching machine and a 10 mm punch.

Tapped Density

It is the weight of the powder divided by the minimum volume of the measuring cylinder. A graduated cylinder containing a known mass of drug or formulation is placed on a mechanical tapper apparatus, which is operated at a fixed number of taps (1000) until the powder bed reaches a minimum volume.^[19]

Angle of repose

It is the greatest possible angle between the freestanding surface of the powder heap and the horizontal plane. The fixed funnel method was used to determine it. A specific amount of powder drug was transferred to the funnel

while the orifice of the funnel was blocked with the thumb. When the powder was removed from the funnel, the angle of repose was measured and recorded in.^[20]

Angle of repose (θ) = $\tan^{-1} h/r$

Bulk Density

It is the ratio of powder bulk mass to powder bulk volume. It is represented by the letter B. To determine homogeneity, bulk density is used. $b = \text{bulk density (m/vb)}$ Where m is the sample's mass and vb is the bulk volume Tapped density (ρ_t) = Weight of powder blend/minimum volume occupied by cylinder

Hausner's Ratio

It is an indirect measure of the ease with which powder flow can be measured. Lowering the Hausner's ratio (1.25) indicates better flow properties than increasing it (>1.25).

Hausner's ratio = tapped density/ bulk density.^[21,22]

Carr's index

The percentage compressibility of the powder mixture was calculated using the following formula based on the apparent bulk density and the tapped density. Carr's index = $\frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} \times 100$

Post-formulation Studies of aphrodisiacs Tablets

To overcome faults during formulation production, the aphrodisiacs tablets were assessed for several criteria after considering preformulation. These include factors like as appearance, thickness, weight fluctuation, hardness, and friability. Table contains all of the assessment parameters for all formulations.

Physical examination

The overall look of the tablet was studied visually in terms of form, colour, texture, and odour.

Hardness

Tablet crushing strength is another name for hardness. The Monsanto Hardness Tester was used to determine the hardness of the tablet. The tablet was placed lengthwise between the upper and lower plungers, and force was applied by turning a threaded bolt until the tablet fractured, at which point the hardness of the tablet was measured in kg/cm²

Thickness

Vernier Callipers were used to determine the thickness of the tablet the tablet was placed vertically between two jaws and the thickness was measured in millimeters six tablets were used for this test.^[23]

Weight variation

The weight variation test is performed by individually weighing 20 tablets, computing the average weight, and comparing each tablet weight to the average. The weight variation test would be an acceptable way of assessing tablet medication content consistency.

Friability

It is determined by the Roche friabilator, which subjects a number of tablets to the combined effects of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance for 100 revolutions. Pre-Weighed tablets were dusted and re-weighed, and friability should be less than 1% according to established limits.

It is calculated by formula- % friability = $\frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100$

Stability study

Stability testing was performed on formulation b. 40° c/ 75% rh was studied. Tablets' physical appearance, hardness, and disintegration time were investigated.

Preparations of Methanolic samples (extract and re-crystallized)

Tribullus teriestic

Weigh correctly 247.3 mg of material and combine with 25 ml methanol in the rbf for 1 hour. Repeat for another half hour using 10 ml of methanol allow filtering through Whatman filter paper to collect the filtrate, which evaporates at 97 °C and it is re-crystallized with methanol.

Pedaliium murex L

Weigh accurately 100.3 mg of sample and mix it into the rbf with 25 ml of methanol and initially reflux for 1 hour. Repeat for another half hour using 10 ml of methanol allow filtering through Whatman filter paper to collect the filtrate, which evaporates at 97°C and it is re-crystallized with methanol.

Pausinystalia Yohimbe

Weigh an exact 200 mg sample into the rbf; mix with 25 ml of methanol, and first reflux for 1 hour. Repeat for another half hour. Using 10 ml of methanol allow filtering through Whatman filter paper to collect the filtrate, which evaporates at 97 °C and it is re-crystallized with methanol.

Panax ginseng

Weight accurately 0.06 mg sample was placed in the rbf mix with 25 ml methanol and initially refluxed for 1 hour. Repeat for another half hour. Using 10 ml of methanol allow filtering through whatman filter paper to collect the filtrate, which evaporates at 97°C and it is re-crystallized with methanol.

Punarnava

Weight accurately 0.260 mg sample, mixed with 25 ml methanol in the rbf, and initially refluxed for 1 hour. Repeat for another half hour. Using 10 ml of methanol allow filtering through whatman filter paper to collect the filtrate, which evaporate at 97°C and it is re-crystallized with methanol.

Myristica fragrance

Weigh accurately 200 mg sample into the rbf; mix with 25 ml of methanol, and first reflux for 1 hour. Repeat for another half hour. Using 10 ml of methanol allow filtering through whatman filter paper to collect the filtrate, which evaporates at 97 °C and it is re-crystallized with methanol

RESULT

Aphrodisiacs tablets were made by using the wet granulation process. This process was used to make standard aphrodisiacs tablets with minimum processing steps. The physiochemical properties of aphrodisiacs

tablets show satisfactory results that are within the range of prescribed standards range.

Pre- Compression Studies of Powder Blend

Pre-compression studies of blend powder shows the results of the powder mix in various range like. Angle of repose, bulk density, tapped density, Carr's index, and Hauser's ratio were determined to be adequate assessment metrics. The study of pre formulation characteristics revealed that there is no moisture in power. The flow rate analysis concluded that the powder mix has an optimal percentage that results in the highest flow rate. The powder shows an excellent flowing quality that does not interfere with the tablet punching process.

Evaluation parameter

Sr.no	Evaluation test	F1 Batch	F2 Batch	F3 Batch
A	Tapped density	0.3235 gm./cc	0.3135 gm./cc	0.3250 gm./cc
B	Bulk density	0.3035 gm./cc	0.2859 gm./cc	0.2654gm/cc
C	Angle of repose	16.96 °c	22 °c	23 °c
D	Carr's index	6.05 %	8.7 %	16.89 %

Stability studies

Sr.no	Evaluation test	Formulation (F2 Batch)	
		Zero Month	One month
a	Odor	Odorless	Odorless
b	Colour	Light brownish	no change
c	Hardness	3 kg/cm ²	3 kg/cm ²
d	Texture	Smoothness	Smoothness
e	Disintegration Time	3 (minutes)	4 (minutes)

Post-Compression Study

Sr. no	Evaluation test	F1 Batch	F2 Batch	F3 Batch
1	Hardness	3.6 kg/cm ²	3 kg/cm ²	5.2 kg/cm ²
2	Weight Variation Test	0.510 mg	0.502 mg	0.480 mg
3	Friability	0.095 %	0.65%	0.0765%
4	Diameter	11.2 mm	11.2 mm	11.2 mm
6	Disintegration Time	4 min	4 min	8 min
7	Thickness	3.62 mm	3.61 mm	3.74 mm

DISCUSSION

On the present study we found that the aphrodisiacs tablets were made using the wet granulation method and produced adequate and acceptable results. It was concluded that herbal aphrodisiacs tablet prepared in the form of cost effective tablet to minimize patients compliance in terms of suppressing side effects and enhancing positive effects on the body. Along with we determined that the aphrodisiacs tablets which are high efficacy can be used to treat and prevent a variety of ailments containing sexual problem because they are indigenous aphrodisiacs, they can also be cost effective.

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