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A Newsletter By : ASSOCIATION OF MANUFACTURERS OF AYURVEDIC MEDICINES

President's Message

Dear Readers,

Ministry of AYUSH has urged AYUSH Drugs Manufacturers Associations take notice of the MoU with the Advertising Standards Council of India (ASCI) to curtail malpractices in the advertisement of Ayurvedic, Siddha, Unani and Homoeopathic drugs and various therapies, and abstain from making such advertisements and exaggerated claims in the print and electronic media that may mislead the public and tantamount to violation of legal provisions and guidelines of advertising. In this regard, cooperation of all concerned is solicited with immediate effect to achieve the objective of curbing the veracity of misleading/improper advertisements of ASU&H produces across print and electronic media.

Best Wishes!!

Vaidya Devender Triguna

Honoured with Padma Shri and Padma Bhushan

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From the Editor's desk

Dear Readers,

The year has started on a good note. To curtail malpractices in the advertisement of ASU drugs and various therapies, Ministry of AYUSH has signed a MoU in January, 2017 with the Advertising Standards Council of India (ASCI). AYUSH has also decided to celebrate Hakim Ajmal Khan's birthday (February 11) as World Unani Medicine Day. To mark the occasion, award in various categories will be presented. The recent Nutraceuticals Regulations has listed some 400 ingredients of plant or botanical origin which can be used as ingredients in the foods covered under these regulations. Excerpts from the same are reproduced for information to our readers.

Heavy metal contents in cosmetics have been a matter of concern since long. The recent GSR (56) E on regulations on import of cosmetics containing mercury is reproduced for our readers. The section on clinical studies presents an article on the efficacy of Stimulex capsules in sexual dysfunctions in diabetic subjects. Honey has been used for food and medicinal purpose since time immemorial and apiculture is one of the most widespread agricultural activities practiced all over the world. In the section on special reports is presented an article on the Global Trends in Bee Keeping Practices.

We invite suggestions and feedback from our readers, as also some articles they wish to contribute. We also call for manufacturers of ASU Drugs and allied herbal industry to join our association and make it stronger, as in unity we stand and in unity we shall succeed. Wishing our readers happiness & prosperity!!

Warm Regards,
Dr. J.L.N. Sastry
On behalf of Editorial Board.

A Publication of:

Association of Manufacturers of Ayurvedic Medicines

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th January, 2017

G.S.R. 56(E).— Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 1017, dated the 28th October, 2016, in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), dated the 28th October, 2016, for inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And Whereas copies of the said Official Gazette were made available to the public on 28th October, 2016; And, Whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government; Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (2nd Amendment) Rules, 2017.

   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), for rule 135A, the following rule shall be substituted, namely,-

   "135A. Regulation of import of cosmetics containing mercury. Cosmetics imported into India shall contain mercury in the following proportion, namely;

   (a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative;

   (b) in other finished cosmetic products, unintentional mercury shall not exceed one part per million (1 ppm).".

3. In the said rules, for rule 145D, the following rule shall be substituted, namely,-

   "145D: Regulation of use of mercury compounds in cosmetics. Cosmetics manufactured in the country shall contain mercury in the following proportions, namely,-

   (a) in cosmetics intended for use only in the area of eye, the level of mercury not exceeding seventy parts per million (0.007 per cent.) of mercury, calculated as the metal, as a preservative; (b) in other finished cosmetic products, unintentional mercury shall not exceed one part per million (1 ppm).".

[F.No. X 11035 / 276 /2015-DFQC]

K. L. SHARMA, Jt. Secy.

Foot-note.- The principal rules were published in the Gazette of India vide notification Number F.28-10/45- H (1) dated the 21st December, 1945 and lastly amended vide notification number G.S.R. 41(E) dated the 17th January, 2017.

K.11024/ 3/ 2013-DCC (AYUSH) Government of India

Ministry of Ayurva Yoga & Natropathy.Unani .Stdha and Homoepathy (AYUSH)

AYUSH Bhawan

B.Block, CGO Comptex.

INA, New Dethi-110023.

Dated: 31st January, 2017.

Subject: Ministry of Ayush signs Memorandum of Understanding with the Advertising Standards Council of India (ASCI) for monitoring of Ayush Advertisements in print and Electronic media-reg

The undersigned is directed to refer the subject cited above and inform that with the objective to curtai l malpractices in the advertisements of Ayurvedic, Siddha, Unani and Homoeopathic drugs and various therapies, Ministry of AYUSH has signed a MoU on 20th January,2017 partnering with the Advertising Standards Council of India (ASCI) and it available in the Minislry's websile www.avush.gov.in for public information and compliance by the stakeholders.

AYUSH Drugs Manufacturers Associations are hereby urged to take notice of the MoU and inform their member manufacturers to abstain from making such adverlisements and exaggerated claims in the prinit and electronic media that may mislead the public and tantamount to violition of legal provisions and guidelines of advertising. Concerned advertiser/manufacturer , as and when informed by ASCI and brought to the notice of State Authority about the inappropriate advertisement, should comply for rectifiying or withdrawing that adverlisement wiihin the given timelines. Otherwise action shall be initiated by the State Authority agoinst the defaulter occuring in controvenion of there legal provisions of the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954, Drugs & Cosmetics Act, 1940 and rules thereunder and other prescribed guidelines and code of advertising. With this aim-specific caution cooperation of all concerned is soliciled with immediate effect to achieve the objective of curbing the veracity of misleading/ improper advertisements of ASU&H producit across print ond electronic media.

(R. P. Shukla)

Under Secrelory to the Govt. of India

To

All AYUSH Drugs Manufacturers Associotions

Global Trends in Bee Keeping Practices

Gaura Verma, Ashish Kumar Dixit,
Dabur Research & Development Centre, Sahibabad, Gzb.U.P

Global Trends in Bee Keeping Practices

The raising & caring of bees for commercial or agricultural purpose is called Apiculture. It is one of the most widespread agricultural activities that are practiced all over the world. Today, 56 million beehives exist in the world and 1.2 million tons of honey is produced from these hives. ¼ of the produced honey is subject to trade and 90% of the exports come from nearly 20 honey producing countries.[1]

'*The preservation and promotion of bee populations is a public purpose that supports the environment, aesthetics, welfare and public health. Bees are critical part of flowering plant pollination and reproduction.*'[2]

Apiculture is not all about honey production. Across the globe, bees find major commercial utilization as pollinators. Bees pollinate plants so that plants can reproduce. Because of their pollinating abilities, honey-bees are the most economically important insects on earth, and certainly the most studied. Use of bees as pollinators has shown significant improvement in crop yield in all commercial crops including, cereals, pulses, fruits & vegetable. The average range of yield enhancement has been recorded between 35%-50%. Talking of the utility(s) of bees, honey production is essentially a secondary issue. Pollination can be achieved only by using large numbers of honey-bees. In this way, our crops and wildflowers are pollinated, and the beekeeper also obtains a pollination fee and honey for sale. This article throws light/ enlightens the various aspects of bee-keeping viz., the history, trends, global statistics, modern bee-keeping practices & current challenges in bee-keeping.

Bee-keeping: Global History & Origin

In ancient Egypt, honey bees were kept in pottery jars. Egyptians used honey in various foods as well as to keep their skin beautiful. Archaeologists even found honey in King Tutankhamen's tomb that was roughly 2,000 years old In ancient times, honey and beeswax were used to pay taxes, rent, and other fees. It was so highly valued that many people accepted it in place of money.[1]

The earliest records of beekeeping date back approximately 10,000 years to cave drawings in Spain depicting two beekeepers high in the air collecting honey from an aerial nest. Rock drawings of Paleolithic age are shown in Figure1. At some later time, beekeepers started to keep bees in hollow logs lying on the ground or wedged into the crook of a tree. Figure 2 shows rock painting of Neolithic age from India. The **"top bar hive"** was first recorded in print in the 17th century but was likely used long before that.

In the 18th century the **"woven skep"** was introduced allowing beekeepers to easily move their bees from one location to another. It was in 1806 when the **"moveable frame hive"** was invented by a Ukrainian beekeeper then remodeled by an American, Lorenzo Langstroth in 1851. The **"Langstroth hive"** is the standard for modern hive design used in most commercial beekeeping applications around the world.[3]

Bee-keeping trends across the globe

Traditional hives are inexpensive to manufacture but difficult to move and the design prevents the beekeeper from easily checking colony health. Transitional hives (top bar hives) are relatively inexpensive to manufacture and allows the beekeeper to check colony health, however the hive is difficult to move and the design prevents high honey yields. The modern hive is more expensive to build but allows for easy management, movement, and high honey yields.

In Asia, beekeepers use different types of bee hives. Log and box hives are two types used by beekeepers in most of Asia. A log hive is a log that can be opened on either end and has a hollow center that is large enough for a bee hive. Many beekeepers prefer this type of hive because it is inexpensive and can be kept almost anywhere. Box hives are also relatively inexpensive, but the main advantage of box hives is that beekeepers can open them to inspect their bees. This is important to make sure that bees are healthy and that the queen is laying eggs.[1]

In Europe, urban beekeeping, is a rapidly growing hobby for people who want fresh, local honey. In Paris, the honey production per hive has been recorded as hgh as 110 Kg

Fig. 1: Paleolithic age drawing [3]

Fig. 2: Rock Painting from Neolithic Period from India[3]

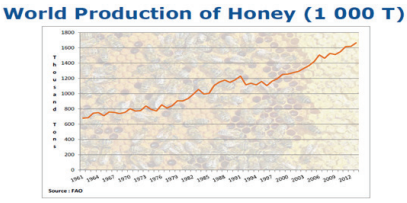

Fig. 3: Trends in World's Production of Honey

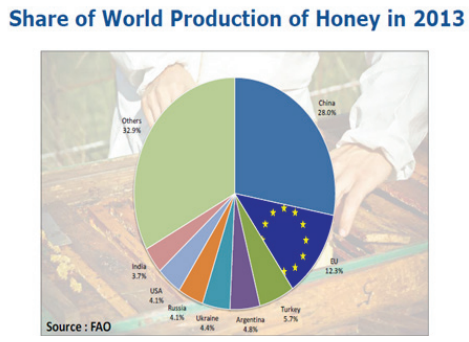

Fig. 4: Share of World's Production of Honey

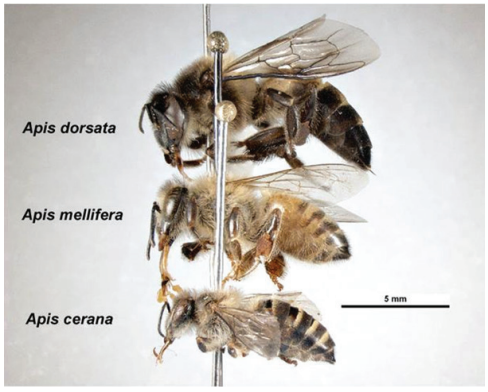

Fig. 5: Types of Honeybees[20]

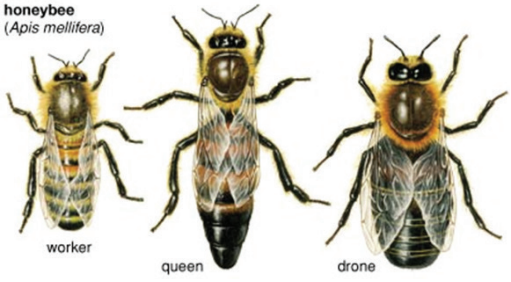

Fig. 6: The Members of a Bee Hive[2]

Fig. 7: Colony Collapse Disorder[12]

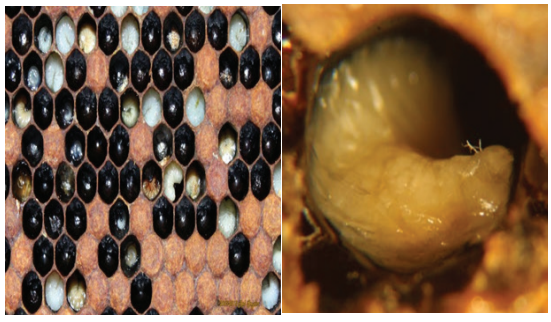

Fig.8: Foulbrood[12]

per hive. The hives in the rural areas produce an average of 15 Kg of honey per harvest. In other cities also, such as London, urban beekeeping is growing.

In Africa, many beekeepers use top bar hives. Top bar hives are a long hive with a removable top and frames. This type of hive is great for beekeepers producing comb honey. Com honey is the honey within the bee wax combs of the hive . For this purpose specialized hives are prepared. These hives are primarily used in small villages where logs for preparing log hives are not available.

In the United States, there are many different types of beekeepers, such as urban beekeepers and commercial beekeepers that truck their bees across the country for pollination. Besides, no matter what country the beekeepers live in, honey bees are used for pollination.

Global statistics

According to FAO, the honey production across the world was close to 1.8 million metric tons in the year 2013. The global market statistics show that China currently produces half the world's honey with the average beekeeping operation consisting of about 50 colonies. Canada is about ninth in the world in terms of honey production yet the typical beekeeper in Canada has over 1,000 colonies and produces the highest average yield in the world, at 150kg of honey per colony, i.e. by & large the highest productivity recorded in the world. India stands at eighth position contributing 3.7% of the total world honey production but the average productivity of honey per colony is as low as 20-30 kg. World honey production statistics recorded in the year 2013, is shown in Figure 3 and the overall contribution of individual countries in the global market with respect to honey production for the year 2013 is given in Figure 4.

The entire continent of Africa produces only about 10% of the honey in the world but has the potential to equal or surpass China due to its ideal weather conditions and lush vegetation. Unfortunately, deforestation for charcoal appears to be hurting Africa's progress in honey production for the time being.7

Bees of the World[1]

Three main types of bees are found across the world. These are shown in Figure 5. Besides honey bees, few other types of bees are also used as pollinators in some parts of the world.

1. African Honeybees (*Apis mellifera* scutellata)

The African honeybee, *Apis mellifera scutellata*, is found in east, central and south Africa. It is also found in virtually every country in South America, and is well established in the southern USA. Although it is an aggressive bee, it is a good honey producer and is immune to the Varroa mite and almost every disease known due to its short gestation period and propensity to abscond at the first sign of stress.

2. **Asian Honeybees (*Apis cerana*)**

The Asian honeybee, *Apis cerana*, is found in India, China and south Asia. It is a gentle bee with average to low honey production. The maintenance & bee-keeping of *Apis cerana* is less resource intensive. Therefore, these bees are traditionally kept by local tribes in India. They are known to build their hives naturally, in the forest areas. And hence, are also source of livelihood for forest based honey hunters

3. European Honeybees (Apis *mellifera)*

The European bee, Apis Mellifera, is found throughout Europe, Russia, Canada, and most of the United States. It is a gentle bee and a prolific honey producer, preferred by virtually all commercial beekeepers when it is available. At present, *Apis mellifera* is the most common species of honey bees used for commercial bee-keeping across the world.

4. Other pollinators found in Asia

The close relatives of modern honey bees are bumblebees and stingless bees . These bees are also social to some degree, and social behavior seems a plesiomorphic trait that predates the origin of the genus. Despite of their poor honey production capabilities, these bees are very potential pollinators & hence are reared in many parts of the continent. Keeping of bumblebees & stingless bees is less intensive/ demanding in terms of space & resources. Among the extant members of *Apis*, the more basal species make single, exposed combs, while the more recently evolved species nest in cavities and have multiple combs, which has greatly facilitated their domestication.[9]

Basics of Bee-keeping

Honey bee is a social insect. It survives a close interactive unit called colony. The members of the colony are interdependent with roles and responsibilities specified for each member. Therefore, to know the crux of bee-keeping, it is mandatory to understand the social structure

of a typical bee-hive/ colony. [1,10,11]

Social Structure of a Bee Colony

Picture of different members of a bee-hive is given ion Figure 6. Honey bees live in a very organized way with a well defined organogram. In a hive, only the sterile female workers do all the in-hive work (cleaning, drying nectar into honey, feeding young) and outside work (foraging for water, pollen, nectar and propolis, and colony defense). The only job of the queen is to lay about 2,000 eggs per day and to release queen mandibular pheromone to let the workers know that she is present and healthy. The male (Drones are assigned with the task of mating with the queens. The drones are produced only during June to August (Monsoons/ rainy season). A typical colony of bees has about 30,000 – 60,000 workers, one queen and a few to hundreds of drones. The workers that repair, clean & construct the hive and also guard the queen, are called nursing bees. The workers that fly out of the hive in search of nectar are called foragers. About 1/3 of the workers are foragers. Foragers show flower constancy so they tend to focus on flowers of a single species, resulting in more efficient pollination.

Internal Factors Affecting Foraging Behavior: To provide adequate pollination,Honey bee colonies must be of sufficient strength with respect to numbers. The colonies are maintained free of diseases and parasites. Vital features of a healthy colony are a laying queen, and adequate "brood" (immature stages which include eggs,larvae and pupae).[1] A newly installed package bee colony, with 1 Kg of bees is started with about ~9,000-11,000 workers and is not considered ready for pollination work. Major focus of members of a new colony is brood rearing & development. Therefore only 10% of the workers are sent for foraging.. Stronger colonies send out about 30% of bees as foragers. A typical median strength over-wintered colony would have about 30,000 workers and can send out 10,000 foragers[11]. With adequate resources, colonies can develop a work force of 60,000 or more workers at the peak of the season. Brood frames are checked for the presence of chalkbrood, foulbrood, parasitic mites and symptoms of virus or other pathogens of honeybees. In general, 3-5 frames of solid brood are required to confirm fertility of the queen and a healthy colony[1]

External Factors Affecting Foraging Behavior: Environmental factors affect honey bee foraging. Bees do not work in the rainy and cloudy days. Foraging activity is positively related to temperature, with a linear relationship from 15-35°C. Foraging activity slows when it gets too hot (over 35°C). High winds (above 20 mph) alter or inhibit flying activity, with bees choosing flight paths that are less affected by wind. As an example, honey bees placed for pollination of orchards will concentrate their efforts near the orchard floor under windy conditions, leaving the orchard crop poorly pollinated. In the contrary, bumble bees can forage at lower temperature and lower light conditions.[11]**Hive Density Recommendations:**

As new fruit and vegetable varieties are released, recommendations made by the developer shall be reviewed & adopted. Further, the pollination activity should be monitored regularly. The perception of human-bee interactions among the local community(s) proves to be a potential obstacle in adoption of bee-keeping. To overcome this problem, a hive density limit should be maintained. This shall minimize conflicts between people and honeybees.

Hive Placement:

Correct placement of hives is an important consideration for beekeeping. Hives are located in a quiet area of the lot. Hives are kept away from roads, sidewalks, and rights of way. The entrance of the hive is placed in the bee flight direction. On an average bees can explore distance up to 1.5 Km for foraging whereas in the current age, this range has decreased to 0.8 Km. Due to satellite signals & mobile wavelengths, the bees forget their way back to the hive beyond 0.8 Km distance. Therefore, in case of discrepancies, from the suggested placement patterns, barriers (hedges, shrubs, or fencing six to twelve feet high) are used to redirect the bees' flight pattern.[6]

Swarming:

"*Swarming is the process by which a new honey bee colony is formed when the queen* ***bee*** *leaves the colony with a large group of worker bees. In the prime swarm, about 60% of the worker bees leave the original hive location with the old queen."*[19] Swarming is a natural instinct of honeybees that occurs chiefly from spring to early summer. In certain cases, swarming may end up becoming a nuisance. Honeybee colonies are managed to prevent or minimize swarming by (1) brood chamber

manipulation, (2) colony division, (3) adding supers for brood rearing and honey storage, and (4) replacing old or failing queens.

Provision of Water:
A good quantity & quality of fresh water is required for bee-keeping throughout the active flight season of the bees. Bees are sun-loving insects & prefer areas rich in sunlight for moisture accumulation, for example wet sand or gravel or the edge of a birdbath. In very hot weather, bees use a large amount of water to maintain temperature and humidity within the hive.

Queen Replacement or Substitution:
Generally, *Apis mellifera* is a gentle bee. In case of abnormal behavior of the bees of a colony, like unusual defensive characteristic (stinging or attempting to sting without provocation) or swarming attempts, new queen is introduced to the hive. Queens is allowed to sustain in the hive only, so far it is capable to lay eggs to maintain the brood population & has not grown old.

Robbing Behavior:
When nectar is scarce, honeybees may rob honey from other hives. In these circumstances, working on hives is avoided as spilled honey encourage robbing. To prevent robbing, buildings and trailers used for honey extraction must be made bee-proof, as far as is practicable.

Migratory Movement of Honeybees and use of Consolidation Yards:
Migratory beekeeping practices include the use of temporary consolidation yards. The practice demands utmost care & attracts significant logistic expenditure, therefore large number of colonies are temporarily unloaded upon return from migratory movement. There are likely to be some negative impacts of congregating a number of colonies at a single place like competition, hive robbing, high logistics & increased chances of bee-human interactions. Considering the facts, excess colonies are dispersed from the consolidation yard/ place. While dispersing excess colonies, factors like weather, time of pollination are also taken into account. During winters, honeybees cluster in the colony and little or no activity is observed. On sunny or mild days, honeybees leave the colony for cleansing flights, but they quickly return to their colony.[11] Over-wintering the colonies can also be ventured at one place. It is vital to estimate the period for which the respective colonies shall require migration. Adequate food & water is provided to address the foraging needs of the colonies.[10]

Considerate Hive Management:
Weather conditions highly influence bee behavior and plans for bee-keeping. Extended hive manipulations, particularly removing honey, is planned in accordance with the prevalent weather conditions. Using smoke to restrict the bee activity during honey extraction and/or hive inspection is a common practice adopted worldwide.

Disease Control:
Honey bees are susceptible to a number of diseases and pests. Brood diseases, including Foulbrood, Chalkbrood,, Nosema, and Viruses. Precautions about mixing hive equipments & hive purchasing are natural measures to control/ prevent brood diseases. Management of parasitic mites and other pests is also equally important for successful bee-keeping. Foulbrood infested hive is shown in Figure 8.

Crisis Alarm : **Colony Collapse Disorder (CCD)**
Honey bees and other pollinators are dying off at unprecedented rates around the world. First reported in France followed by US and other countries, colonies have been collapsing with adult bees abandoning their hives. In 2006, this phenomenon was named colony collapse disorder (CCD).[1] For most of the past decade, the world has been losing about 30% of its bee population due to pests, pesticides, and changing weather patterns. The beekeeping community is able to make up the losses using bee livestock from survivor colonies, but the cost to do so is borne by the beekeeper in lost productivity from the survivor plus the additional feed and labor costs incurred to replenish the apiary[12]. If this loss goes beyond 60% the beekeeping would become economically non-viable for the commercial beekeepers. There is no single cause of CCD rather it is caused by a combination of factors acting in concert to weaken bee colonies to the point of collapse. Lead suspects in this context are, nutritional stress, pathogens and pesticides. Figure 7 provides a visual of CCD.

During the recent years, the frequency of incidences of CCD has increased exponentially. Researches have been

conducted to understand the impact of various factors on bees. Radio frequency devices were attached to honey bees to test impact of sub-lethal doses of Thiamethoxam (a neonicotinoid) on foraging, homing & survival. The study confirmed the hypothesis that sub-lethal, field-realist doses of the chemical undermine bee foraging & homing abilities.[13] Whereas in a study to analyze the effects of sub-chronic exposure to sub-lethal doses of pesticides on honeybee, it was shown that repeated exposure to certain doses of Thiamethoxam has no behavioral effect whereas, when applied in acute conditions, it results in appearance of few behavioral deficits.[1]

The behaviors of adult forager bees was monitored under highly controlled conditions to observe effect of imidacloprid fed at sub-lethal doses in sugar solution. All doses given caused significant reduction in mobility that lasted for one to several hours. The bees lost their communicative ability at all doses failing to coordinate their activities with other bees.[1] While studying harmful effects of Imidacloprid & Fipronil on honey bees, it was observed that convulsions & paralysis in bees feeding on fipronil. Both insecticides disturbed the primary activities, of the hive. They also concluded that their protocol provided an indispensable interface between controlled conditions in the laboratory & field.[1] Further, few researchers ventured into finding out combined effect of these factors on honey bees. They proved that, these factors have adverse impact on vital activities of the bees whether in solo or in synergy. Bees are exposed to fatal pesticides not only while foraging but also by disproportionate or excessive application of these, to the brood in order to maintain brood & the queen in a healthy condition.

Natural Bee-keeping

Considering the harmful impact of existing agricultural & beekeeping practices on the honeybees, a new concept is trending now a days, i.e. Natural Bee-keeping. Rather in other words we are back to basics. It is virtually not possible to avoid exposure of bees to agriculture pesticides. Instead, by adopting natural beekeeping practices, Hive level exposure may be avoided.

'Natural beekeeping' is a term that has come to be applied to a style of beekeeping that puts the emphasis on the honeybees themselves, rather than their products. It could be characterized as beekeeping for the sake of the bees, not the honey.[1] In natural beekeeping Interference in the natural lives of the bees is kept to a minimum. Nothing is put into the hive that is known to be, or likely to be harmful either to the bees, to humans or to the wider environment and nothing is taken out that the bees cannot afford to lose. The bees know what they are doing: our job is to listen to them and provide the optimum conditions for their well-being, both inside and outside the hive.[1] It is highly sustainable & carbon neutral method whereas to a certain extent, this concept appears to be more theoretical and commercially non-viable.

To avoid honeybee exposure to agricultural pesticides, judicious & wise application of pesticide is highly recommended. Broad spectrum & systemic pesticides should be avoided. As far as possible, pesticide application in the field should be done during evening hours. And, most importantly, excess application should be strictly/ critically controlled.

Conclusion

Beekeeping is a lucrative trade even using simple management techniques. 'Beekeeping as an enterprise fits in very well with small scale farmers' livelihoods. Bees work along the natural patterns of local agro-ecological zones and provide positive impacts to the fauna and flora found within. It is an enterprise that can provide for employment, income and economic security for the farm family and others in rural areas.'[1] Bees provide for a wide range of products, viz. honey, wax, pollen, royal jelly, propolis, venom, etc. and hence diverse income opportunities. Therefore, by and large, honeybee is the most useful insect for the mankind.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA)

Nutraceuticals Regulations

New Delhi, the 23'd December, 2016

The Food Authority has notified the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 in the Gazette oflndia on 23rd December 2016.

These regulations cover eight categories of foods, namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty Food containing plant or botanicals, Foods containing Probiotics, Foods ontaining Prebotics and Novel Foods. Requirements for such foods as detailed in these reguations pertain to essenital composition; claims and labellingv etc. The regulations do not allow the use of hormons or steroids or psychotropoic ingrediets in any of articles of food.

These regulations include various Schedules detailing provisions relating to vitamins, minerals and amino acids; botanical ingredients; nutraceutical ingredients; food additives; probiotics and prebiotics.One of the schedules lists 400 ingredients of plant or botanical origin which can be used as ingredients in the foods covered under these regulations.

These regulations not only open the window for such food products in the domestic market, as as the demand of various stakeholders for over a years now, but also strenghtens the food safety authorities to effectively regulate such products (both domestically produced and imported while ensuring their food safety and efficacy. The above regulation will come into force on the date of their publication in Official Gazette. However, the obligation of Food Business pr~riltor to comply with the provisions of the said regulation will be effective from 1st January, 2018.

Excerpts from these regulations are being reproduced for information to readers.

No. 1-4/ Nutraceutical/ FSSAI-2013.-Whereas the draft of the Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods, and Novel Food) Regulations, 2015, was published as required by sub-section(!) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India No. 1-4/

Nutraceutical/ FSSAI-2013, dated the 30111 July, 2015, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of a period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 11111 September, 2015;

And whereas objections and suggestions received from

the public within the specified period on the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92, read with sub section (1) of section 22 of the Food Safety and Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India hereby makes the following regulations, namely:-

Regulations

l. Short title and commencement. - (1) These regulations may be called the Food Safety and Standards (Health Supplements, Nutraccuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st January, 2018.

2, Definitions.- In these regulations, unless the context otherwise requircs,.

(a) "Act" means the Food Safety and Standards Act, 2006 (34 of 2006);

(b) "Food Authority" means the Food Safety and Standards Authority of India established under section 4 of the Act;

(c) "food for special dietary use" shall have the meaning assigned to it in section 22 of the Act; (d) "food for special medical purpose" means food intended for-

(i) particular dietary usc specially processed or formulated;

(ii) the dietary management of persons and used only under medical advice;

(iii) the exclusive or partial feeding of persons with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites; or

(iv) other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by food for specific nutritional usc, or a combination of them;

(e) "food with added prebiotic ingredients" means food that contains added prebiotic ingredients which are non

viable food components that confer health benefits to the consumer by modulation of gut microbiota;

(f) "food with added probiotic ingredients" means food with live micro-organisms beneficial to human health, which when ingested in adequate numbers as a single strain or as a combination of cultures, confer one or more specified or demonstrated health benefits in human beings;

(g) "functional food" shall have the meaning assigned to it in section 22 of the Act;

(h) "health supplements" shall have the meaning assigned to it in section 22 of the Act;

(i) "non-food" means an ingredient or a substance which is not a 'food' as referred to in clause U) of section 3 of the Act;

(j) "novel food" shall have the meaning assigned to it in section 22 of the Act;

(k) "nutraceuticals" shall have the meaning assigned to it in section 22 of the Act;

(l) "nutritional ingredients" means the ingredients specified in Schedules other than the food additives specified in Schedule VA to Schedule VF, packed and made available in a form not for retail-consumer usc, but meant for use in formulating a product falling under various categories of these regulations or other categories specified in the Food Safety and Standards (Food Products Standards and Food Additves) Regulations, 2011;

(m) "nutrient ingredients" means vitamins, minerals, and amino acids as specified in Schedule I and Schedule II;. (n) "pre-mixes" means a combination of two or more ingredients specified in the Schedules in a specific proportion with or without additives, packed and meant for use in formulating a product falling under any category of these regulations or under the categories specified

in the Food Safety and Standards (Food Products Standards and Food Additves) Regulations, 2011;

(o) "specialty food containing plant or botanical ingredients" means food which is shown to be containing plant or botanical ingredients with a history of safe usage; and

(p) "Schedules" means the Schedules to these regulations.

3. General requirements.- (1) The articles of food sold in capsule format, hard or soft or vegetarian, shall comply with the general monograph and quality requirements specified for them in Indian Pharmacopoeia:

Proviclecl that the food business operator may use the approved colours and aclclitives permittee! in Schedule VF; Proviclccl further that the food business operator may use the natural flavors or nature identical 11avours or synthetic flavors in accoraclance with the provisions of regulation 3.3.1 of Food Safety and Standards (Food Product Standards and Food Aclclitives) Regulations, 2011.

(2) For the purposes of sub-regulation (l) the food business operator may declare the addition of flavour on labels of such products in accoraclance with the provisions of Food Safety and Standards (Labelling and Packaging) Regulations, 2011.

(3) The tablets, capsules and syrups shall fulfil the general quality requirements and standards as specified in Indian Pharmacopoeia, British Pharmacopoeia or United States Pharmacopoeia.

(4) The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, the stanclarcls laid clown by international tood standards body, namely, Codex Alimcutarius Commission, shall apply.

(5) In case of food products falling under health supplement categories, the individual nutrient content shall not be less than fifteen per cent of the recommended daily allowance where a nutrient content claim is being made:

Provided that, if claim of higher nutrient content is made, the nutrient content shall not be less than thirty per cent of the recommended daily allowance.

(6) For the articles of food specified in these regulations, the Food Authority may permit the food business operator to add food colours subject to the level restrictions as mentioned in Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

(7) The articles of food with standard nutrient or nutritionally complete formulation shall consist of a composition delivering the desired level of energy, protein, vitamins and minerals, and other essential nutrients required for respective age group, gender and physiological stage in accordance with the guidelines made by the Indian Council of Medical Research.

(8) The purity criteria for the ingredients used in the categories of articles of food covered under these regulations shall be as determined and notified in the official gazette by the Food Authority from time to time.

(9) In case such standards arc not specified, the purity criteria generally accepted by pharmacopoeias, namely, Indian Pharmacopoeia, Ayurvcdic Pharmacopoeia of India, relevant Bureau ofindian Standards Specifications, Quality Standards of Indian Medicinal Plants, Indian Council of Medical Reseach, British Pharmacopoeia, United States Pharmacopoeia, Food Chemical Codex, Joint Food and Agriculture Organization or World Health Organisation Expert Committee on Food Additives or CODEX Alimentarius may be adopted by food Business operators.

(10) The food business operator shall intimate the purity criteria adopted for ingredients to the Food Authority including any change when adopted.

(11) The tolerance limit for variation in case of articles of food covered in these regulations during analysis of samples of finished products, shall not be more than (-) ten per cent from the declared value of the nutrients or nutritional ingredients on the label .

(12) The manufacturing of ingredients and products

covered under these regulations shall be• carried out in compliance with the established good manufacturing practices.

(13) For purposes of these regulations, any of the ingredients specified in Schedule I, Schedule II, Schedule III, Schedule IV, Schedule VI, Schedule VII, and Schedule VIII may be used in food in accordance with the provisions of these regulations, and for the said purpose, may use additives as applicable to categories specified in Schedule VA to Schedule VF.

Explanation 1.- For the purposes of these regulations food or ingredients referred to in Food Safety and Standards Regulations, 2011, and for which standards are provided, and the plants and botanicals specified in Schedule IV of these regulations offered in normal or naturally occurring forms shall not constitute a health supplement or nutraceutical, or food for special dietary usc or food for special medical purpose.

Explanation 2.- Mere food forms such as vegetables, namely, bhindi, karela and other vegetables; cereals, namely, ragi, jowar, millets and other cereals; legumes, namely, rajmah and other legumes; spices, namely, pepper, jeera, turmeric and other spices; fruits, namely, atnla, jamun, grapes and other fruits; and other plants or botanicals, minimally processed (cleaned, de-weeded, sotted, dried or powdered), in either as juice or eoukcd form, shall not constitute 'health supplement' or 'nutraceutical' or 'food for special dietary use' or 'food for special medical purpose'.

(14) The formulation of articles of food shall be based on the principles of sound medicine or nutrition and supported by validated scientific data, wherever required.

(15) No hormones or steroids or psychotropic ingredients shall be added in any of the articles of food specified in these regulations.

(16) The label on articles of food shall specify the purpose, the target consumer group and the physiological or disease conditions which they address, recommended duration of use, and the specific labelling requirements as mentioned against each type of article of food.

(17) The label, accompanying leaflet or other labelling and advertisement of each type of article of food, referred to in these regulations shall provide sufficient information on the nature and purpose of the article of food and detailed instructions and precautions for its use, and the format of information given shall be appropriate for the intended consumer.

(18) An article of food which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated as 'health supplement' or 'special dietary' or 'special dietetic' or by any other equivalent term, and such food may bear a statement on the label that 'this food is by its nature X' ('X' refers to the essential distinguishing characteristic as demonstrated by the generally accepted scientific data), provided that the statement does not mislead the consumer.

(19) The Food Authority may suspend or restrict sale of such articles of food as have been placed in the market that arc not clearly distinguishable from articles of food for normal consumption and arc not suitable for their claimed nutritional purpose, or may endanger human health, in accordance with the provisions of the Act.

(20) The Food Authority may, at any time, direct a food business operator manufacturing and selling such special type of article of food, to furnish details regarding the history of use of the novel or modified ingredients added and their safety evaluation.

(21) The mere combination of vitamins and minerals formulated in tablets, capsules, syrup formals shall not be covered in any of the categories of these regulations except when vitamins and minerals are added to an article of food or in a food format.

(22) The labelling on the article of food shall be in accoradance with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, and the specific labelling requirements provided

in these regulations.

(23) The articles of food shall conform to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

(24) No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any food products referred to in these regulations unless they comply with the requirements laid down in these regulations.

(25) Whoever contravenes the provisions of these regulations shall be liable for punishment provided under Chapter

IX of the Act.

4. Claims.- (1) Every food business operator may make nutritional or health claims in respect of an article of food.

(2) For the purposes of sub - regulation (1), a nutritional claim shall consist of the 'Ingredients (nutrient or nutritional) content' of an article of food which shall be subject to the nutritional supplement requirements specified in Schedule I, Schedule II, Schedule III, Schedule IV, and Schedule VI.

(3) For the purposes of these regulations, health claim means any representation in respect of an article of food that states, suggests or implies that a relationship exists between the constituent of that nutrient or nutritional, health, and specific disease conditions.

(4) The health claim in respect of an article of food consists of the following two essential componei1ts, namely:- (i) nutrient or nutritional ingredients; and

(ii) health related benefits.

(5) The health claim in respect of an article of food may include the following types, but not limited to

(i) ingredients (nutrient or nutritional) function claims; (ii) enhanced function claims;

(iii) disease risk reduction claims; (iv) health maintenance claims;

(v) immunity claims- increased resistance (excluding vaccines); and

(vi) anti-ageing claims.

(6) The other claims in an article of food that are not drug claims may be allowed subject to prior approval of the Food

Authority.

(7) The health claims in respect of an article of food shall be commensurate with the adequate level of documentation and valid proof made available for review by the Food Authority when called for.

(8) To claim ingredients, nutrient or nutritional, in respect of an article of food for enhanced function and disease risk reduction, regard shall be had to-

(i) claims that led to ingredients (nutrient or nutritional);

(ii) available scientific literature including official traditional texts and post market data or consumer studies or cohort or retroactive studies based on eating pattern and health benefits, epidemiological international and national data, and other well documented data;

(iii) consensual, congruent and concurrent validity studies;

(iv) health promotive and disease risk reduction based on proof from literature and human data of efficacy and safety of the nutrient;

(v) not only controlled clinical trials for efficacy and safety data; but also nutraepidemiological data;

(vi) qualified structure function claims for specific organ or function which are comprehensible to consumer;

(vii) prohibition of implied claims for curing disease or claims of drug like efficacy such as 'Prevents bone fragility in post menopausal women';

(viii) prohibition of implied cure for disease claims by the name of the product such as cancer cure or througha pictures, vignettes or symbols, namely, electrocardiogram tracing, lipid profile; and

(ix) for structure-function claims, a case-to-case basis consumer information for specific age or gender or vulnerable population.

(9) (i) For the product led claims in respect of an article of food based on human studies with evidence

based data, regard shall be had to-

(a) valid data and suitable statistical design proving the benefit for disease risk reduction, that is, human intervention studies;

(b) ingredient, that is, nutrient or nutritional;

(c) the product compatibility for the proposed claim benefit and suitable qualifiers such as heart healthy claim on polyunsaturated fatty acids;

(d) the use of word "shown" as depicted in the example below when a single human intervention study shows significant benefit:

"Product <Name ofthe Product> is 'shown' to be helping in <keeping your heart healthy>

or <heart healthy>:

(e) the use of word "Proven" as depicted in the example below when more than one human intervention studies or epidemiological evidence on Indian population have been provided with concurrent validity:

"Product <Name of the Product> is 'proven' <to make you lose weight>:

(ii) For health claims where scientific support does not exist, or if a novel ingredient is to be introduced, there shall be a prior approval of the Authoity which shall be based on adequate scientific evidence.

(iii) If the health claims are product led, the food business operator shall notify to the Food Authority before putting the same in the market, by submitting relevant documents along with a copy of the label.

5. General principles for query or challenge.-The food business operator shall-

(i) prepare and make available the comprehensive product information, safety and claims support data and shall periodically get it reviewed and scrutinised by a scientist or expert with relevant qualifications and experience;

(ii) attach the scientific view of the reviewer on claims and its veracity along with the qualification and experience of the reviewer as an essential part of the document;

(iii) clarify, in case of a technical query from the Food Authority or on a public complaint lodged with the Food Authority, and assist the Food Authority to examine or authorise an appropriate expert group to review the case; and

(iv) alter or modify or stop claim when directed by the Food Authority which shall be based on the opinion of an expert group.

6. Health supplements.- (1) (i) Health supplements may be used to supplement the normal diet of a person above the age of five years.

(ii) the health supplements shall contain concentrated source of one or more nutrients, namely, amino acids, enzymes, minerals, proteins, vitamins, other dietary substances, plants or botanicals, prebiotics, probiotics and substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, which arc presented as such and are offered alone or in combination, but are not drugs as defined in the clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder.

(iii) the health supplements shall be marketed in single use packaging as appropriate to maintain integrity and quality of the product, or in dosage forms namely, capsules, tablets, pills, sachets; jelly or gel, semi-solids and other similar forms or any other forms of liquids and powders designed to be taken in measured unit quantities.

(iv) the health supplements shall not include any of the food products or categories of articles of food for which specific standards have been laid down in any other parts of these regulations.

(2) (i) The health supplements shall contain any of the ingredients specified in Schedule l or Schedule II or

Schedule IV or Schedule VII or Schedule VIII or enzymes only of Schedule VI.

(ii) The ingredients specified in the Schedules referred to in clause (i) of sub-regulation (2) may be used in manufacturing of health supplements without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

(iii) The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not specified, standards laid down by the international food standards body, namely, Codex Alimentarius Commission shall apply.

(iv) The food business operator shall apply to the Food Authority for inclusion of any new nutrient or other substance with a nutritional or physiological function, which has no history of use in India or that without evidence, establishing that the nutrient may result in certain nutritional and physiological benefits with justification for approval.

(v) The Food Authority may, after proper scientific evaluation, specify the nutrients approved by it from time to time.

(3) (i) The labelling, presentation and advertisement shall not claim that the health supplement has the property of preventing, treating or curing a human disease, or refer to such properties;

(ii) The statement by the food business operator relating to the structure or function or the general well being of the body may be allowed by the Food Authority if the statement is supported by the generally accepted scientific data;

(iii) Every package of health supplement shall carry the following information on the label, namely.- (a) the words "HEALTH SUPPLEMENT";

(b) the common name of the health supplement, or a description sufficient to indicate the true nature of the health supplement including the common names of the categories of nutrients or substances that characterise the product;

(c) a declaration as to the amount of the nutrients or substances with a nutritional or physiological effect present in the product;

(d) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;

(e) the quantity of nutrients, where applicable expressed in terms of percentage of the relevant recommended daily allowances as specified by the Indian Council of Medical Research and bear a warning, "Not to exceed the recommended daily usage";

(f) a statement that the health supplement is not be used as a substitute for a varied diet;

(g) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and published product or drug interactions, as applicable; and

(h) a statement that the product is required to be stored out of reach of children.

(4) No food business operator shall use additives for health supplement formulation except those specified in

Schedule VA or Schedule VE or Schedule VF.

7. Nutraceuticals.- (1)(i) The nutraceuticals shall provide a physiological benefit and help maintain good health.

(ii) A food business operator may extract, isolate and purify nutraceuticals from food or non-food sources, that is preparing amino acids and their derivatives by bacterial fermentation under controlled conditions.

(iii) A food business operator may prepare and sell the nutraceuticals in the food-format of granules, powder, tablet, capsule, liquid, jelly or gel, semi-solids and other formats and may be packed in sachet, ampoule, bottle, and in any other format as measured unit quantities except those formats that are meant for parenteral administration.

(2) (i) The nutraceuticals shall contain any of the ingredients specified in Schedule I or Schedule II or Schedule

IV or Schedule VI or Schedule VII or Schedule VIII.

(ii) A food business operator may use ingredients specified in the Schedules referred to in clause (i) of sub regulation (2) in manufacturing an article of food containing nutraceuticals without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product;

(iii) The quantity of nutrients added where applicable, shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research and in case such standards are not

specified, the standard laid down by international food standards body, namely Codex Alimentarius Commission shall apply;

(iv) A nutraceutical which is not provided in these regulations but its safety has been established in India or in any other country, shall be manufactured or sold in India only on prior approval of the Food Authority;

(v) For the purposes of clause (iv), a food business operator shall apply to the Food Authority for approval which shall be accompanied by documented history of usage of at least fifteen years in India, or thirty years in the country of origin;

(vi) The Food Authority may from time to time specify the nutraccuticals as approved by it after undertaking proper scientific evaluation.

(3) (i) No ingredient other than those specified in Schedule VI shall be used as nutraceutical with standardisation to marker compounds specified and at daily usage levels specified therein;

(ii) The ingredient for which the standardisation of the marker coumpound has not been specified shall comply with manufacturer specifications or quality requirements and purity criteria as specified in regulation 3;

(iii) For the ingredient for which the daily minimum and maximum usage levels have not been specified, the food business operator shall adopt the usage level based on relevant scientific data and retain the documentary evidence of such data;

(iv) For the purpose of clause (iii), the food business operator shall submit the documented scientific data to the

Food Authority as and when called for;

(v) No food business operator shall use the extract of ingredient as nutraceutical other than that specified in

Schedule IV;

Provided that the ingredient of plant or botanical origin specified in Schedule IV and Schedule VI may be used either in the given form, or their extract, subject to the extractive ratios in relation to the daily usage value.

(4) (i) The labelling, presentation and advertisement shall not claim that the nutraceutical has the property of preventing, treating or curing a human disease, or refer to such properties;

(ii) The statement by the food business operator relating to the structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data;

(iii) Every package of food containing nutraceutical shall carry the following information on the label, namely: (a) the word "NUTRACEUTICAL";

(b) the common name of the nutraccutical;

(c) a declaration as to the amount of each nutraceutical ingredient in the product that either has a nutritional or physiological effect;

(d) where it is appropriate, the quantity of nutrient shall be expressed in terms of percentage of the relevant recommended daily allowances as speci(ied by the Indian Council of Medical Research even when the nutrient is present along with a nutraceutical as an adjunct and shall bear an advisory warning 'not to exceed the stated recommended daily usage';

(e) an advisory warning for 'recommended usage';

(f) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;

(g) an advisory warning in cases where a danger may exist with excess consumption;

(h) an advisory warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable;

(i) a statement that the product is required to be stored out of reach of children;

(5) No food business operator shall use additives for nutraceutical formulation except those specified in Schedule

VA or Schedule VE or Schedule VF.

8. Food for special dietary usc, other than infants, and those products intended to be taken under medical advice.- (1) No food business operator shall manufacture, formulate or process an article of food for special dietary use unlcss-

(i) specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions, namely:-

(a) low weight, obesity, diabetes, high blood pressure; (b) pregnant and lactating women; and

(c) geriatric population and celiac disease and other health conditions.

(ii) The food business operator shall clearly indicate on the label whether or not the food for special dietary usc is to be taken under medical advice;

(iii) A food business operator may manufacture or sell an article of food for special dietary use in single usc packaging or in dosage form, namely, granules, capsules, tablets, pills, jelly, semi-solid and other similar forms, sachets of powder, or any other similar forms of liquids and powders designed to be taken in measured unit quantities with a nutritional or physiological effect;

(iv) A food business operator may formulate an article of food for special dietary use in formats meant for oral feeding througha enteral tubes but shall not be uscJ f01 pwcnlcJal use;

(v) An article of food for special dietary use shall not include the normal food which is merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of general health for day to day use and do not claim to be targeted to consumers with specific disease conditions and also not include the article of food intended to replace complete diet covered under food for special medical purpose specified in regulation 9.

(2) (i) The articles of food for special dietary use shall contain any of the ingredients specified in Schedules I or

Schedule II or Schedule III or Schedule IV or Schedule VI or Schedule VII or Schedule VIII.

(ii) A food business operator may use the ingredients specified in the Schedules referred to in clause (i) of sub regulation (2) in manufacturing food for special dietary use without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

(iii) For any new nutrient, which has no history of use in India or that without a proof establishing that the nutrient may result in certain nutritional and physiological benefits, the food business operator shall apply to the Food Authority with justification for approval, and the Food Authority may, from time to time specify the nutrients approved by it after proper scientific evaluation.

(iv) A food business operator may add the quantity of the nutrients at a level higher than the recommended daily allowance, but not exceeding the limits of vitamins and minerals specified in Schedule III.

(v) (i) The articles of food used as a formula food presented as a replacement for all meals of the daily diet for slimming, weight management and weight control puqJoses shall comply with the following, namely:-

(a) provide energy not less than 800 kcal (3,350 kJ) and not more than 1,200 kcal (5,020 kJ);

(b) the individual portions or servings contained in the formula food shall provide approximately one third or one-fourth of the total energy of the food in the pack depending on whether the recommended number of portions or servings per day is three or four, as the case may be, respectively.

(ii) A formula food presented as a replacement for one or more meals of the daily diet shall comply with the following, namely:-

(a) provide energy not less than 200 kcal (835 kJ) and not more than 400 kcal (1,670 kJ) per meal;

(b) when such products are presented as a replacement for the major part of the diet, the total energy intake shall not exceed 1,200 kcal (5,020 kJ).

(iii) Not less than twenty five per cent and not more than fifty per cent of the energy available from the food, when ready-to-serve, shall be derived from

its protein content and the total amount of protein shall not exceed 125 g per day.

(iv) The quality of protein shall have-

(a) the protein digestibility corrected amino acid score of 1.0 known as,the reference protein;

(b) the protein digestibility corrected amino acid score where less than 1.0, the minimum level shall be increased to compensate for the lower protein quality;

(c) the protein with a protein digestibility corrected amino acid score of 0.8 or more shall be used in a formula food for use in a weight control diet; and

(v) For improving the protein quality, the food business operator shall add only L- forms of essential amino acids except for methionine where DL form is allowed.

(vi) Not more than thirty per cent of the energy available from fat and not less than three per cent of the energy from linoleic acid in the form of a glyceride.

(vii) A formula food represented as a replacement for all meals per day, shall not have less than a hundred per cent of the reccommended daily allowance of vitamins and minerals in the daily intake.

(viii) The formula food for special dietary use shall have adequate dietary fiber.

No statement or claim shall be made on the label implying prevention, cure or treatment of any specific disease or its diagnosis or otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, unless otherwise approved by the Food Authority;

The statement by the food business operator relating to the structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data;

Every package containing food for special dietary use shall carry the following information on the label, namely:-

(a) the words "FOOD FOR SPECIAL DIETARY USE" followed by "Food for. ....." (mentioning the

pmliculm phy iulugical uJ health cumlition)";

(b) a statement "For weight control and management" in close proximity to the name of the articles of food specially prepared for weight management and control;

(c) a statement that the product is not to be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically advised;

(d) a statement on the target consumer group, rationale for usc of the product and a description of the properties or characteristics that make it useful;

(e) if the product has been formulated for a specific age group, a prominent statement to that effect;

(f) a statement specifying the nutrient which is reduced, deleted, increased or otherwise modified, relating to normal requirement, and the rationale for the reduction, deletion, increase or other modification;

(g) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;

(h) a warning in cases where a danger may exist with excess consumption;

(i) a warning that the product is not for parenteral use;

(j) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable;

(k) the quantity of nutrients expressed in terms of percentage of the recommended daily allowance where it is appropriate;

(l) information on osmolality or osmolarity or on acid-base balance where appropriate; and a statement that the product shall be stored out of reach of children.

(4) No food business operator shall use additives for food for special dietary uses, except those specified in

Schedule VB or Schedule VE or Schedule VF.

9. Food for special medical purpose.- (I) (i) Food for special medical purpose shall include food specially prepared for weight reduction and intended as total replacement of normal diet.

(ii) A food business operator may formulate food for special medical purpose in format meant for oral feeding througha enteral tubes.

(iii) The articles of food for special medical purpose shall not be used for parenteral use.

(iv) The articles of food for special medical purpose, other than those intended for infants, may either be nutritionally complete food which, when used in accordance with the manufacturer's instructions, shall constitute the sole source of nourishment for the persons for whom they are intended or nutritionally incomplete food with formulation specific for a disease, disorder or medical condition, but arc not suitable to be used as the sole source of nourishment.

(v) For the purposes of these regulations, the food for special medical purpose may be classified in to following three categories, namely:-

(a) 'nutritionally complete food with a standard nutrient formulation', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(b) 'nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended; and

(c) 'nutritionally incomplete food with a standard formulation or a nutrient-adopted formulation specific for a disease, disorder or medical condition', which is not suitable to be used as the sole source of nourishment.

Note.- the food specified in sub-clauses (b) and (c) of clause (v) may be used as a partial replacement or as a supplement to the person's diet.

(2) (i) Food for special medical purpose shall contain any of the ingredients specified in Schedule I or Schedule II

or Schedule III or Schedule IV or Schedule VII or Schedule VIII or enzymes only of Schedule VI .

(ii) A food business operator shall use only the ingredients specified in the Schedules referred to in clause (i) of sub regulation (2) in manufacturing food for special medical purpose without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

(iii) A food business operator may apply to the Food Authority for any new nutrient, which has no history of usc in India or those without proof establishing that the nutrient may result in certain nutritional and physiological benefits with justification for approval and the Food Authority may from time to time specify the nutrients approved by it after proper scientific evaluation.

(iv) The articles of food specially prepared for weight reduction and intended as total replacement of complete diet shall, apart from complying with Schedule III, shall also ensure the following, namely:-

(a) that a formula food for very low energy diet is prepared according to instructions, with a daily energy intake of 450-800 kcal as the only source of energy;

(b) that not less than 50 g protein with a protein digestibility corrected amino acid score of 1 is present in the recommended daily intake of energy, and essential amino acids may be added to improve protein quality only in amounts necessary for this purpose;

(c) for the purposes of clause (b) the food business operator shall add only L- forms of essential amino acids except for methionine where DL form is allowed.

(d) very low energy diet provides not less than (!) 3 g of linoleic acid; and

(II) 0.5 g a-linolenic acid in the recommended daily intake with the a-linoleic acid and linolenic acid ratio between 1:5 and 1:15;

(e) very low energy diet provides not less than 50 g of available carbohydrates in the recommended daily intake of energy;

(f) that the formula food for special medical purpose have adequate dietary fiber.

(v) In food for special medical purpose, nutrients may be added at levels higher than the recommended

daily allowance, but not exceeding the limits of vitamins and minerals as specified in Schedule III.

(3) Every package of food for special medical purpose shall carry the following information on the label, namely:- (a) the words 'FOOD FOR SPECIAL MEDICAL PURPOSE' printed in the immediate proximity of the name or brand name of the product;

(b) an advisory warning "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY" appearing on the label in bold letters in an area separated from other written, printed or graphic information;

(c) the statement "For the dietary management of "(with the blank to be filled in with the specific disease, disorderor medical conditionfor which the product is intended, and for which it has been shown to be effective) supported by appropriate scientific, and clinical or epidemiological data, and subject to its approval by the Food Authority;

(d) a statement 'NUTRITIONALLY COMPLETE' if the food is intended to be used as a nutritionally complete food;

(c) a statement on the rationale for use of the product by the target consumer group and a description of the properties or characteristics that make it useful;

(f) a statement if the product has been formulated for a specific age group;

(g) a statement specifying the nutrient which have been reduced, deleted, increased or otherwise modified, relatiing to normal requirements, and the rationale for the reduction, deletion, increase or other modification;

(h) the quantity of nutrients expressed in terms of percentages of the recommended daily allowances, where it is appropriate;

(i) information on osmolality or osmolarity, Renal Solute Load, Potential Renal Solute Load or acid-base balance, wherever applicable;

G) instructions for appropriate preparation, feeding, use and storage of the product after the opening of the container;

(k) a warning that the product is not for parenteral use; and

(I) a statement that the product required to be stored out of reach of children.

(4) No food business operator shall use additives for food for special medical purpose except those specified in

Schedule VC or Schedule VD or Schedule VE or Schedule VF.

(5) No food business operator shall advertise the food for special medical purpose for usc by general public.

10. Food with added probiotic ingredients.- (1) (i) No food business operator shall use probiotic ingredients in food except the probiotic culture of the microorganisms specified in Schedule VII or those probiotic microorganisms approved by the Food Authority from time to time. Probiotic preparations may contain added prebiotics permitted under these regulations.

(ii) The viable number of organisms in food with added probiotic ingredients shall be 2:.108 CFU/g:

Provided that a lower viable number may be specified with proven studies on health benefits with those numbers subject to the prior approval of the Food Authority.

(iii) The Food Authority may, from time to time, specify the probiotic microorganisms approved by it after proper scientific evaluation:

Provided that the presence of the commonly used starter cultures of lactic acid producing bacteria such as Lactococcus jJp., earlier known as Streptococcus spp., Lactobacillus spp. and other such microorganisms used in the preparation of fermented milk (dahi) and related products shall not be considered as probiotics, if the probiotic properties have not been substantiated.

Note.- The guidelines issued by the Indain Council of Medical Research and Department of Biotechnology with respect to probioties provide additional information on their use.

(2) (i) The labelling, presentation and advertisement shall not claim that the probiotic food has the property of preventing, treating or curing a human

disease, or refer to such properties.

(ii) The statement by the food business operator relating to structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data.

(iii) Every package of probiotic food shall carry the following information on the label, namely:- (a) the words "PROBIOTIC FOOD";

(b) genus and species including strain designation or culture collection number, where applicable, in brackets where probiotics are mentioned in the list of ingredients;

(c) viable numbers at the end of the shelf-life of probiotic strain corresponding to the level at which the efficacy is claimed;

(d) the recommended serving size which shall deliver the effective viable dose of probiotics related to health claims and recommended duration of use, proper storage temperature conditions, and time limit for 'Best Use' after opening the container;

(e) an advisory warning 'NOT FOR MEDICINAL USE' prominently written; and

(f) a warning or any other precaution to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable.

(3) No food business operator shall use additives in probiotic preparations except those specified in Schedule VA to

Schedule VF.

11. Food with added prebiotic ingredients.- (1) (i) No food business operator shall use prebiotics in manufacturing food containing prcbiotics except those specified in Schedule VIII or those prebiotics approved by the Food Authority from time to time.

(ii) The prebiotic component, not an organism, to which the claim of being made, shall be characterised for a given product by providing the source, origin, purity, chemical composition and structure, vehicle, concentration and amount in which it is to be delivered to the host

(2) (i) The labelling, presentation and advertising shall not claim that the prcbiotic has the property of preventing, treating or curing a human disease, or refer to such properties.

(ii) The statement by the food business operator relating to structure or function or the general well-being of the body may be allowed by the Food Authority, if the statement is supported by the generally accepted scientific data.

(iii) Every package of food containing prebiotics shall carry the following information on the label, namcly:- (a) the words "PREBIOTIC FOOD";

(b) name of prebiotic;

(c) the suggested or recommended serving size which shall deliver the effective dose of prebiotic related to the health claim;

(d) an advisory warning 'NOT FOR MEDICINAL USE' prominently written;

(c) a warning or any other precautions to be taken while consuming, known side effects, if any, contraindications, and product-drug interactions, as applicable.

(3) No food business operator shall usc additives in prebiotic preparations except those specified in Schedule VA to

Schedule VF.

12. Specialty food containing plant or botanical ingredients with safe history of usage.- (1) (i) A food business operator shall use only plant or botanical ingredients specified in Schedule IV for the preparation of specialty food containing plant or botanical ingredients.

(ii) The plant or botanical ingredient which is not specified in these regulations but its safety has been established in India or in any other country, may be manufactured or sold in India only after taking prior approval of the Food Authority.

(iii) The application for approval to the Food Authority shall be accompanied by documented history of usage of at least fifteen years in India, or thirty

years in the country of origin.

(2) The health supplement or nutraccutical or food for special dietary usc or food for special medical purpose may contain the ingredient as specified in Schedule IV, formulated either alone or in combination of ingredients or botanicals or their extracts either in unprocessed or in approved processed forms, formulated in a regular or conventional food format such as liquid or syrup, suspension or powder, granule, tablet or capsule or any other format approved by the Food Authority.

(3) (i) Every manufacturer or importer shall prepare and maintain a product information file, which shall contain information on the ingredients from Schedule IV used, finished product quality confirmation, and the test methods to demonstrate the presence of the active ingredient in the food.

(ii) The usage level of the specialty food containing plant or botanical ingredients shall not exceed those levels specified in Schedule IV:

Provided that the usage level may be distributed or provided, or formulated for delivery in one portion daily, or distributed in more than one portion to be taken in a day.

(iii) To use any other plant or botanical ingredient, which is not specified in Schedule IV, the food business operator shall seek prior approval of the Food Authority by submitting-

(a) a product information file containing information on the material used;

(b) quality confirmation, test methods to demonstrate the presence of the ingredient in the food;

(c) relevant published literature providing scientific and technical information of the material or product related to safety and health benefits; and

(d) any human intervention study published or conducted, and other relevant information.

(iv) The product information file shall be produced for inspection and review by the Food Authority as and when called for.

(v) The product information file shall primarily consist of technical and scientific information covering the following, namely:-

(a) information on quality of all raw ingredients with official scientific or botanical name;

(b) details of formulation or block diagram and brief description of the processing methods or steps adopted;

(c) shelf life study data;

(d) quality specifications and test methods for analysis of the finished product;

(e) safety and pharmacological information, literature base, and additional study, if any conducted;

(f) information on human studies, if any;

(g) regulatory status in other countries, if any; and

(h) any other relevant product information.

(4) No food business operator shall use additives for preparation of specialty food containing plant or botanical ingredients except those specified in Schedule VE or Schedule VF.

13. Novel food.- (1)(i) For the purposes of these regulations novel food is a food that- (a) may not have a history of human consumption; or

(b) may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or

(c) a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.

(ii) No novel food shall be manufactured or imported for commercial purpose without the prior approval of the Food Authority by filing an application along with all relevant documents and details as specified by the Food Authority from time to time.

(2) The labelling of novel food shall be-

(i) in accordance with the specific labelling requirements, if any; or

(ii) specific to claims relating to the novel product; or

(iii) as per the category notified by the Food Authority in the specific regulations.

For details refer: http://fssai.gov.in/home

Double Blind, Placebo Controlled Study on Stimulex Capsules in Sexual Dysfunctions in Diabetic Subjects

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Introduction

Healthy sexual functioning plays an essential role in maintaining the harmony and happiness in marital life. The absence of this function or its dysfunction may hamper the marital or interpersonal relationships. [1]

Sexual dysfunction addresses difficulties that may experienced in normal sexual activity, including physical pleasure, desire, preference and arousal. [2,3] The most common sexual dysfunctions in men include Erectile dysfunction (ED), Premature ejaculation and decreased sexual desire (loss of libido). [4] Prevalence of these conditions may increase with age and affect the physical and mental wellbeing of a man.

Diabetes (DM) has been associated with sexual dysfunction both in males and in females. [5,6] Global prevalence of DM is rapidly rising at an alarming rate, where India leads with largest number of diabetics. [7] Diabetes is an established risk factor for sexual dysfunction in men. A threefold increased risk of erectile dysfunction (ED) has been documented in diabetic men. Epidemiological studies have suggested that both type 1 and type 2 diabetes are associated with an increased risk of ED which may occur in ≥ 50% of diabetic men and also at an early age in diabetic patients. [8,9] Studies also suggest that psychological factors such as depression may play a role in sexual dysfunction. As diabetes is a chronic illness, it may cause depression accompanying low sexual performance. [10,11]

In Ayurveda, the concept of sexual health and dysfunctions are described under the aegis of Vajikaran (Aphrodisiacs), Klaivya (Male fertility issues), Shukra Dusti,(Androgen imbalance) Aharshana (Arousal Dysfunction), Napumsaka (Erectile Dysfunction), and Shukra vaha srotas dusti (Male reproductive organ dysfunctions). [12] The Vajikaran or Vrishya therapies are a clinical specialty of Ayurveda that play an important role in maintaining the sexual health and management of conditions related to sexual dysfunction. [2, 13-14,]

Though there are no direct references available in the Ayurvedic classics to say that DM or Madhumeha can lead to Klaibya or other related conditions, references suggest it may lead to male reproductive complications such as Mushka Avadarana, Vrishana Avadaranam and Bastimedhratoda. Charaka has mentioned Daurbalya as a complication of Madhumeha. Among the Dushyas of Prameha, Shukra is one, and its vitiation may ultimately lead to Klaibya. [2, 15, 16]

Ayurveda recognizes both psychological and drug based modalities for the management of these conditions. Based on these leads many polyherbal formulations are being marketed, a few of which have been tested clinically. [17] Stimulex capsules (Mdf: Dabur India Limited) is a proprietary Ayurvedic medicine that comprises ingredients traditionally used for beneficial effects in sexual health. Stimulex capsules have been found to be safe in 28 days repeated dose oral toxicity studies. [18] The current clinical study assessed efficacy of Stimulex capsules in sexual dysfunctions in Diabetic subjects.

Objective

1. To assess efficacy of Stimulex capsules in sexual dysfunctions like premature ejaculation, loss of libido and loss of ejaculation in diabetic subjects

2. To assess if Stimulex capsules plays a role in the improvement of sexual performance by influencing the fatigue and performance indices in diabetic subjects

Material and Methods

The study was conducted at SVS Marwari Hospital, Calcutta between the years 1999-2000 using a double

blind placebo controlled design

Study Product

Stimulex Capsules comprises ingredients like Ashwagandha (Withania somnifera), Shilajit (Asphaltum), Kesar (Crocus sativus), Shuddha Kuchila (Strychnous nux vomica), Jaiphala (Myristica fragrans), Akarkara (Anacyclus pyrethrum), Bala (Sida cordifolia), Goksura (Tribulus terrestris), Musali sveta (Asparagus adcendens) and Kauncha beej (Mucuna purirens) etc that are used traditionally for maintaining sexual health.

Samples of Stimulex capsule and placebo capsules for the study were provided by Dabur India Ltd. They were coded and labeled as STM A and STM B. Samples were decodified at the end of the study as STM A (Stimulex Capsules) and STM B (Placebo Capsules).

Patients

Male subjects attending the Ayurvedic OPD of SVS Marwari Hospital, Calcutta were screened for eligibility and were included if they fulfilled the inclusion and exclusion criteria's. A written informed consent was obtained from the subjects before recruitment in study.

Inclusion Criteria

Male subjects aged between 40 to 55 years, suffering from type I or II diabetes for a minimum duration of 5 years.

Exclusion Criteria

Subjects having any systemic disease, diabetes associated with hypertension or cardiac complications

Method

A total of 50 male diabetic patients were enrolled in the study. At baseline, grading of symptoms - Loss of libido, loss of erection and premature ejaculation was done on a 4 point scale as: Grade 0: Absence of symptoms, Grade 1: Mild intensity or occurring once in a while, Grade 2: Moderate intensity or occurring frequently, Grade 3: Severe and persistent symptoms. Thereafter, subjects were allocated equally (25 each) to either Stimulex capsules or placebo groups on alternative allotment basis.

Treatment Schedule

Patients in Stimulex capsules group were advised Stimulex capsules and patients in placebo group were advised placebo. Both the treatments were prescribed orally at doses of 2 capsules twice a day for a period of 12 weeks.

Response Evaluation & Patient follow up

The assessment of response was evaluated over six follow up visits from baseline at weeks 2, 4, 6, 8, 10 & 12.

Assessment Criteria At each follow up visit, the following parameters were assessed: -

1. Changes in main symptoms of sexual dysfunctions viz. Loss of libido, Loss of erection and Premature ejaculation
2. Changes in associated symptoms viz.; fatigue, headache, muscle pain, general debility, sleep abnormities, irritability and depression levels
3. Karnofsky Performance Scale Index (KPI)
4. The subjects' evaluation of therapeutic response

For the purpose of KPI, the standard format prescribed by Karnofsky [19] was used. For rest of the parameters the patients were advised to identify the intensity of the problem based on the same four point grading scale as mentioned above.

For assessing the clinical response, the criteria of grading employed was Excellent, Very Good, Poor or No Response. Response was graded as Excellent if changed from Grade III to 0, Very Good if changed from Grade III to I or Grade II to 0; Good Grade III to II, Grade II to I , Grade I to 0; Poor = no change.

Record Keeping and Statistical Analysis

The data of each patient was recorded on an individual Case Record Form. Data was analyzed using ANOVA and Dunnet's tests.

Observations & Results

A total of 50 male diabetic subjects were enrolled in this study. They were allocated equally to either Stimulex capsules or placebo groups. The mean age of all the subjects was 54 years.

The efficacy of Stimulex capsules was analyzed under two distinct heads – (i) the effect on main symptoms of sexual dysfunctions and (ii) the effect on associated symptoms and Karnofsky Performance Scale Index (KPI).

The baseline grading of the main symptoms of sexual dysfunctions viz.; loss of libido, loss of erection and

premature ejaculation is shown in Table 1. The effects of Stimulex capsules and placebo on these symptoms are shown in Table 2-4. The subjects' evaluation of therapeutic response is shown in Table 5.

Effect on Main symptoms of sexual dysfunction:

Loss of Libido was present in 22 subjects in Stimulex capsule group and 15 subjects in Placebo group. Improvement in condition in Stimulex group was observed from week 2 onwards and significant improvement from baseline was observed at study completion (week 12). However, there was no significant difference between the effects of both the groups on intergroup comparison (Table 2).

Loss of erection was present in 16 subjects in Stimulex capsule group and 14 subjects in Placebo group. Stimulex capsules showed significant improvement in loss of erection from week 2 onwards that continued throughout the study period in comparison to baseline. However, there was no significant difference between the effects of both the groups on intergroup comparison (Table 3)

Premature ejaculation was present in 23 subjects in Stimulex capsule group and 15 subjects in Placebo group. Stimulex capsules showed improvement in condition from week 2 onwards. Significant improvement in condition was observed in Stimulex group at week 12. However, there was no significant difference between the effects of both the groups on intergroup comparison (Table 4).

Effect on KPI indices

The mean of KPI was noted to be 93.6 in Stimulex capsule group and 94.8 in placebo group at the base line. The KPI indices in both the study group remained above 80 during the study which was found to be clinically optimal [19] suggesting comparable efficacy of both Stimulex capsules and placebo.

Effect on fatigue levels and other associated symptoms

The effect of Stimulex capsules and Placebo on associated symptoms viz; fatigue, headache, muscle pain, general debility, sleep abnormities, irritability and depression levels is shown Tables 6-11. A significant improvement in all these symptoms was observed from baseline at study completion with Stimulex in comparison to baseline. Between the groups analysis, however, did not show any difference between the effects of both the therapies suggesting comparable efficacy.

Subjects' evaluation of therapeutic response

Maximum subjects in Stimulex group (20) reported very good to good improvement in loss of libido as compared to 13 subjects in placebo group who reported a good response. One subject also reported an excellent response in Stimulex capsules group. A higher number of subjects in Stimulex group (15) reported a good response in loss of erection as compared to eight (08) in placebo group. Maximum subjects in Stimulex group (22), reported very good to good improvement in premature ejaculation as compared to 6 subjects in placebo group who reported good response (Table 12)

Discussion & Conclusion

Stimulex capsule is an Ayurvedic poly herbal formulation comprising ingredients like Shilajit, Ashwagandha, Kauch beej etc that are traditionally used for maintenance of sexual health. Aswagandha (Withania somnifera) is reported to possesses adaptogenic, anti oxidant, spermatogenetic, strength promoting and aphrodisiac properties. As per Ayurveda, Aswagandha is Rasayana or a substance that is nutrient to body and mind with adapto-immunoneuro-endocrino-modulator properties. [20,21] Bala (Sida cordifolia) has anti stress, adaptogenic, Rasayana, strength promoting and aphrodisiac properties. [22] Safed Musali (Asparagus adscendens) is antioxidant, strength promoting and beneficial in spermatorrhoea**.** [23] Kaunch beej (Mucuna pruriens) is attributed with antioxidant, neuroprotective effect, spermatogenic aphrodisiac, and strength promoting properties. [24-26] Shilajit (asphaltum) helps up regulate ATP synthesis in muscles, is a rasayana and aphrodisiac. [27-29] Gokshura (Tribulus terresteris) has antioxidant, anti-fatigue, and androgenic properties and is beneficial in seminal disorders like nocturnal emissions and azoospermia. [30-32] Kesar (Crocus sativus) is rasayan and stimulant,has anti oxidant activity and improves sexual functions. [33, 34] Jaiphal (Myristica fragrans) has antioxidant, and anti depressant activity, improves sexual behavior, is aphrodisiac and useful in spermatorrhoea and premature ejaculation. [35-36] Akarkara (Anacyclus pyrethrum) is anti oxidant, improves sexual behavior, strength promoter and aphrodisiac. [37] Shuddha Kuchla (Strychnos nuxvomica) helps to improve ejaculatory function and is stimulant, strength promoter, and aphrodisiac. [38]

Safety of Stimulex capsules has been established in 28 days oral toxicity studies. In the present study, efficacy of Stimulex Capsules in sexual dysfunction was evaluated in 50 diabetic subjects using a double blind placebo controlled design. Subjects were allocated equally to two groups which were given either Stimulex or placebo capsules orally at doses of 2 capsules twice a day for a period of 12 weeks. Results were assessed basis changes in main symptoms of sexual dysfunctions viz. Loss of libido, Loss of erection and premature ejaculation and associated symptoms like fatigue, headache, muscle pain and depression levels etc, the Karnofsky Performance Scale Index (KPI) and the subjects' evaluation of therapeutic response.

Improvement in all main and associated the symptoms of sexual dysfunctions was observed in both Stimulex capsules and control arm in comparison to baseline at study completion and there were no significant differences in effect of therapies on intergroup comparisons. The KPI indices in both the study arms remained above 80 during the study period suggesting comparable efficacy. The Subjects' evaluation of therapeutic response showed a better response with Stimulex capsules on symptoms like loss of libido, loss of erection and premature ejaculation in comparison to control.

Basis result of this study, Stimulex capsules were found to improve the main symptoms of sexual dysfunctions viz. loss of libido, loss of erection and premature ejaculation in diabetic subjects. Stimulex capsules also showed improvement in associated symptoms of sexual dysfunctions like fatigue, headache, muscle pain and depression levels etc in diabetic subjects. However, there were no statistical differences between the effects of Stimulex capsules and the control arm on these symptoms. A majority of subjects showed a better treatment response with Stimulex capsules on symptoms like loss of libido, loss of erection and premature ejaculation in comparison control arm at study completion. These effects may be attributed due to its ingredients like Shilajit, Ashwagandha, Kauch beej etc.

Table 1: Distribution of Symptoms of Sexual Dysfunctions in Diabetic Subjects

Parameter	Stimulex capsule (n=25)				Placebo Group (n=25)			
	Grade 0	Grade I	Grade II	Grade III	Grade 0	Grade I	Grade II	Grade III
Loss of Libido	3	16	5	1	10	6	9	0
Loss of Erection	9	16	0	0	11	8	5	1
Premature Ejaculation	2	13	10	0	10	12	3	0

Table-2: Effect on Loss of Libido

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	1.16 (.68)	.80 (.40)	.32 (.20)	.04 (47)	.04 (.20)	.04 (.20)		Is significant from other week points
Placebo	.96 (.88)	.84 (.80)	.56 (.50)	.44 (.50)	.32 (.47)	.24 (.43)	<0.001	-do-
Entire Population	.48 (.65)							
P-value	.168							
Significance	Not Significant							

* Dunnett's Test at 5%

Table 3: Effect on Loss of Erection

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	.64	.56	.20	.12	.04	.04	<0.001	Is significant from we
	(.48)	(.50)	(.40)	(.33)	(.20)	(.20)		points2,3,4&5
Placebo	.84	.76	.52	.60	.52	.52	<0.001	-do-
	(.89)	(77)	(.65)	(.64)	(.65)	(.65)		
Entire Population	.44(.62)							
P-value	0.017							
Significance	Not Significant							

* Dunnett's Test at 5%

Table 4: Effect on Premature Ejaculation

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	1.32	.84	.28	.12	.04	.04	< 0.001	Is significant from other week points
	(.62)	(.37)	(.45)	(.33)	(.20)	(.20)		
Placebo	.72	.60	.56	.56	.48	.40	< 0.001	Significant difference week point.4 &5
	(.67)	(.50)	(.50)	(.50)	(.50)	(.50)		
Entire Population	.49(.58)							
P-value	0.30							
Significance	Not Significant							

* Dunnett's Test at 5%

Table 5: Subjects Evaluation of Therapeutic Response

S. No.	Symptom	Treatment	Excellent	Very Good	Good	Poor
1	Loss of Libido	Stimulex capsule	1	5	15	1
		Placebo	0	5	8	2
2	Premature Ejaculation	Stimulex capsule	0	9	13	1
		Placebo	0	0	6	9
3	Loss of Erection	Stimulex capsule	0	0	15	1
		Placebo	0	0	8	6

* Dunnett's Test at 5%

Table-6: Effect on Fatigue Levels

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	1.08	.76	.48	.80	0	.0	< 0.001	Is significant from other week points
	(.86)	(.66)	(.50)	(.27)	(.00)	(.00)		
Placebo	1.12 .76	..60	..44	..40	.36		< 0.001	-do-
	(.88)	(.59)	(.50)	(50)	(.50)	(.48)		
Entire Population	.50 (.65)							
P-value	.07							
Significance	Not Significant							

* Dunnett's Test at 5%

Table – 7: Effect on Headache Level

Parameter	Stimulex capsule (n=25)				Placebo Group (n=25)			
	Grade 0	Grade I	Grade II	Grade III	Grade 0	Grade I	Grade II	Grade III
Loss of Libido	3	16	5	1	10	6	9	0
	3	16	5	1	10	6	9	0
Loss of Erection	9	16	0	0	11	8	5	1
Premature Ejaculation	2	13	10	0	10	12	3	0

Table-8: Effect on Muscle Pain

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	.44	.28	.08	.00	.00	.00	<0.001	Is significant from we
	(.71)	(.45)	(.27)	(.00)	(.00)	(.00)		points2,3,4&5
Placebo	.40	.32	.32	.32	.24	.28	<0.001	-do-
	(.70)	(.55)	(.55)	(.55)	(.43)	(.45)		
Entire Population	..22 (.48)							
P-value	.123							
Significance	Not Significant							

*** Dunnett's Test at 5%**

Table 9: Effect on General Debility

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	1.56	.96	.32	.12	0.4	.00	<0.001	Is significant from other week points
	(.96)	(.61)	(.47)	(.33)	(.20)	(.00)		
Placebo	1.36	.96	.76	.6	.56	.6	<0.001	-do-
	(.81)	(.45)	(.44)	(.5)	(.51)	(.5)		
Entire Population	.65 (.71)							
P-value	.003							
Significance	Not Significant							

*** Dunnett's Test at 5%**

Table-10: Effect on Sleep Abnormalities

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	.52	.32	.16	.00	.00	.00	<0.001	Is significant from other week points
	(.77)	(.47)	(.37)	(.00)	(.00)	(.00)		
Placebo	.44	.32	.32	.28	.24	.24	<0.001	-do-
	(.71)	(.47)	(.47)	(.45)	(.43)	(.43)		
Entire Population	.23 (.47)							
P-value								
Significance	Not Significant							

*** Dunnett's Test at 5%**

Table 11: Effect on Irritability

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	.52	.40	.28	.12	.12	.04	<0.001	Is significant from other week points
	(1.00)	(.76)	(.54)	(.33)	(.20)	(.20)		
Placebo	.36	.36	.32	.32	.16	.20	<0.001	-do-
	(.48)	(.48)	(.47)	(.47)	(.37)	(.40)		
Entire Population	.26 (.53)							
P-value	0.66							
Significance	Not Significant							

*** Dunnett's Test at 5%**

Table-12: Effect on Depression

Group	Mean Score (SD ±)						p -Value F test	Significance
	Base line	Wk2	Wk4	Wk6	Wk8	Wk 12		
Stimulex n=25	.40	.28	.16	.08	.08	.08	<0.001	Is significant from other week points
	(.76)	(.61)	(.37)	(.27)	(.27)	(.27)		
Placebo	.16	.12	.080	.08	.08	.08	<0.001	-do-
	(.55)	(.43)	(.27)	(.27)	(.27)	(.27)		
Entire Population	.14 (.42)							
P-value	0.438							
Significance	Not Significant							

*** Dunnett's Test at 5%**

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