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Review

# Review on shilajit used in traditional Indian medicine

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ABSTRACT

*Ethnopharmacological relevance:* Shilajit is a multi-component natural occurring mineral substance used in Ayurveda and Siddha systems of medicine which originated in India. Its source can be traced to the mountainous regions, where the hilly tribes first identified its beneficial use. Shilajit is aptly referred to as '*rasayana*'/'*rasayanam*' in Ayurveda and Siddha literature which means rejuvenator because it prevents ailment and enhances the quality of life.

*Materials and Methods:* An attempt has been put forth to review shilajit pertaining to its origin, synonyms, varieties, physical properties, chemical constituents, therapeutic properties and important biological properties to affirm its *rasayana* property. All relevant information on shilajit was collected from classical texts including pharmacopoeias, formularies, etc. Moreover, select doctoral thesis from Banaras Hindu University, Varanasi and Gujarat Ayurved University, Jamnagar were also scanned. Published papers on shilajit were collected from important databases for biomedical sciences. Amongst, the various biological properties of shilajit, antioxidant activity and immuno-modulatory activity were focused as it is closely related to its *rasayana* potential.

*Results:* This review finds that shilajit is used in twenty Sastric formulations and twenty-four proprietary drugs for extraneous indications. Even-though, there is a long history of use of shilajit in traditional Indian *materia medica*, shilajit unfortunately lacks scientific evaluation and systematic documentation. *In vivo* antioxidant activity of shilajit has been studied at an irrelevant dose and without using a positive control. The immuno-modulatory activity does not stand the test of critical assessment and currently may be considered as unproven.

*Conclusion:* Based on the earlier studies, the bioactivity of shilajit lacks substantial evidence. Nevertheless, further studies are imperative to overcome the lacuna in establishing the antioxidant property of shilajit and more specific assays are needed to vouch shilajit as an immuno-modulator which may be of use to establish its *rasayana* potential.



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"One that cures physical ailment is medicine

One that cures psychological ailment is medicine

One that prevents ailment is medicine

One that bestows Immortality is medicine"

Saint Thirumoolar

## 1. Introduction

According to the World Health Organization (WHO), traditional medicine (TM) incorporates health practices of plant, mineral and animal based medicines, applied singularly or in combination to treat and prevent illnesses/maintain well-being (World Health Organization, 2000). The WHO estimates that approximately 80% of the earth's inhabitants rely on TM for their health needs (Kamboj, 2000). In this connection, growing research is being conducted worldwide with respect to plant based medicines neglecting the other two components of TM i.e., mineral and animal based medicines. This paper focuses on a specific mineral substance, shilajit. In the armamentarium of Siddha pharmacopoeia, out of the 220 mineral and metal substances used in traditional Indian medical systems, shilajit is a broadly used natural mineral (Thiyagarajan and Sunderrajan, 1992). Shilajit in the capacity of *rasayana*, prevents ailments and enhances the quality of life, the two major attributes of Indian Ayurvedic and Siddha medicine (Ghosal et al., 1991). Even though shilajit is described in traditional literature, it is so far mostly unknown in the West. For nearly more than 3000 years, shilajit plays a vital role with soaring economic value in the folk medicine of the former Soviet Union and also in traditional Indian medicine and Tibetan pharmacology. It is also used as growth accelerator even for plants (Scholz-Böttcher et al., 2005). Avicenna in Canon Medicinae wrote that shilajit possesses the ability to resorb tumours and pimples (Schepetkin et al., 2002). Currently, shilajit is prohibited to be exported from the Soviet Union because it is being considered as a 'treasure of the country' (Garedew et al., 2004).

Amongst the numerous active principles of shilajit, fulvic acid and humic substances are important. In Tajikistan, it is part of the routine diet of the general population to use shilajit. Many bioactive dietary supplements or food additives contain shilajit which have been patented are manufactured in Tajikistan. Shilajit is used in the form of an aqueous extract for therapeutic applications such as, immuno stimulants and anabolic food additives (Schepetkin et al., 2003). Shilajit, is prescribed for varied disorders of different aetiology in Russia, notably, a few of them are genitourinary diseases, diabetes, angina, jaundice, digestive disorders, nervous diseases, chronic bronchitis, anaemia, menorrhagia and osteoporosis (Schepetkin et al., 2002).

Shilajit is described as a sticky, brown to blackish (Figs. 1 and 2) physiologically active organic matter exuded from steep rocks in mountainous regions of the world (Garedew et al., 2004) especially in Central Asia (Himalaya, Pamir and Altai) and of unclear age (Ghosal, 1990; Kwon et al., 2004; Sharma, 2004; Scholz-Böttcher et al., 2005). In other words, shilajit is a tarry, solid or elastic natural product (Rakhmatullaeva and Aminov, 2005) typically in the form of shapeless pieces with non-uniformly porous or smooth surface having a characteristic balsamic odour (Frolova and Kiseleva, 1996). The organic exudate may vary in colour from blackish to brown and is found at high altitudes between 1000 and 5000 m on the walls of caves embedded in rocks or as rock exudates with specific weather conditions concerning summer and winter temperatures, duration of sunshine and amount of precipitation (Ali et al., 2004; Garedew et al., 2004). Shilajit is commonly found in the Himalayas, from Arunachal Pradesh in the East to Kashmir in the West. It is also found in other countries, such as Afghanistan (Hindukush), CIS (Tien Shan, Ural), Tsao-Shing (Ghosal, 1990) Australia (Agarwal et al., 2007) Mongolia, China, Bhutan, Nepal, Pakistan (Bowman et al., 2000) Tajakistan (Zarafshan) (Khalikov and Alieva, 2003) and Tibet-Himalayan belt (Kwon et al., 2004). It is also available in Japan, Algeria (Garedew et al., 2004) and Saudi Arabia known as momia imported from Yemen or India (Al-Himaidi and Mohammed, 2003).

### 1.1. Origin of shilajit

There are several schools of thought regarding the origin of shilajit. It was originally thought as a plant fossil, a substance of mixed plant and animal origin (Ghosal, 1990; Ali et al., 2004). Many researchers claim that shilajit exudates from a layer of rocks of mountains with plant secondary metabolites (Ghosal et al., 1991; Bowman et al., 2000). Ancient texts of Rasarangini and Sushruta samhita mention that during the month of May and June the sap or latex juice of plants emerges as a gummy exudate from the rocks of mountains due to the sun's strong heat, and Dwarishtarang and Rasarangini also convey that shilajit is an exudation of latex gum resin, etc., of plants which comes from rocks of mountains under the presence of intense scorching heat (Agarwal et al., 2007). The characteristic constituents of soil and shilajit are mainly composed of humus together with other organic constituents. Latex bearing plants, such as *Euphorbia royleana* Boiss and *Trifolium repens* occurring in the vicinity of the shilajit bearing rocks, the most likely source of shilajit (Schepetkin et al., 2003). Claims are put-forth that the mosses of species such as *Barbula*, *Fissidenc*, *Minium*, *Thuidium* and species of Liverworts like *Asterella*, *Dumortiera*, *Marchantia*, *Pellia*, *Plagiochasma* and *Stephenrencella-Anthoceros* were present in the vicinity of shilajit-exuding rocks and these bryophytes are responsible for the formation of shilajit (Agarwal et al., 2007). The

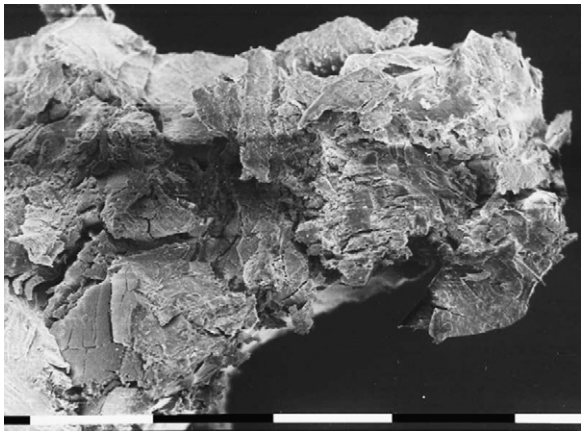

**Fig. 1.** SEM photograph of a piece of raw shilajit. White and black bars correspond to 0.1 mm.
*Source*: Garedew et al. (2004).

**Fig. 2.** Purified bar of shilajit (in cm) used at Apeiron Handels GmbH & Co. KG, Germany to prepare the dietary supplement for pilot clinical trial.

**Table 1**
Synonyms of shilajit.

| Language | Synonyms in Vernacular | References |
|---|---|---|
| Sanskrit | Shilajatu, shilaras, silajit, silaras | Ghosal (2006), Nadkarni (1954) |
| Hindi | Shilajit, ral-yahudi | Ghosal (2006), Nadkarni (1954) |
| English | Asphalt, mineral pitch, jews pitch, bitumen | Nadkarni (1954), Sudarshan (2005) |
| Latin | *Asphaltum punjabinum* | Ghosal (2006) |
| Bengali | Silajatu, shilajit | Ghosal (2006), Nadkarni (1954) |
| Gujarati | Silajita | Nadkarni (1954) |
| Tamil | Perangyum, uerangyum, kalmatam | Nadkarni (1954), Sudarshan (2005) |
| Arabic | Hajar-ul-musa | Ghosal (2006), Nadkarni (1954) |
| Persian | Momiai-faqurul-yahud | Nadkarni (1954), Sudarshan (2005) |
| Russian | Myemu and mumie | Agarwal et al. (2007), Ghosal et al. (1993) |
| German | Mumie or salhumin | Ghosal (2006) |

elemental concentration such as copper, silver, zinc, iron, lead, etc., of the bryophytes and shilajit are similar and confirm the above hypothesis.

Currently, there are three major theories explaining the origin of shilajit namely biological, geological and bio-mineralogical. Accordingly, the biological hypothesis of shilajit represents as a product of biological conversion occurring under certain physiochemical conditions of dead plant residues or animal excrements or both. In contrary to this hypothesis, the geological theory considers shilajit as a product of geological processes. Finally, the bio-mineralogical speculation is based on the assumption that shilajit is a secondary product, in which the mineral components are formed as a result of various migrations for example by mechanical contamination of a liquefied shilajit precursor (Frolova and Kiseleva, 1996). In addition, according to Ghosal (2006) shilajit is of marine animal origin–dead/fossil invertebrates, amongst which mollusks/ammonites constitute the major contributors. However, the widespread distribution of shilajit in sedimentary rocks all over the world, the strikingly similar nature of principal active constituents and its large abundance in the interior of the rocks at high altitudes and locations not negotiable by land animals convey that shilajit is derived from rocks (Ghosal, 2006).

### 1.2. Synonyms

Several synonyms for shilajit are tabulated in Table 1. In traditional Indian medicine, synonyms are of prime importance because they convey the characteristic features of each drug. In Sanskrit, it is called shilajatu, shilaras, adrija and girija, all meaning 'derived from rock' (Ghosal, 2006). In Arabic arakul-dzhibol means 'sweat of mountain' whereas Tibetan or Mongolian brag-shun or brag-zhun means 'juice of rock' and Burmese kao-tui or chao-tui implies 'blood of the mountains' (Frolova and Kiseleva, 1996). Shilajit in Tamil language implies that it is the 'essence from the mountain'. The second-most common name being mumie, mumiyo or mummiyo means 'mountain balsam' or 'mountain tears' (Thiyagarajan and Sunderrajan, 1992). The terms jatu, laksha, niryas in Sanskrit language indicates its form and consistency. Jatu and laksha means lac like gummy substance and niryas means exudation which oozes out from the mountains. Some of the synonyms like ushnaja and shiladhatu-asmajam give information about its time and season of emergence. Ushnaja is the combination of two words ushna and ja which means hot and birth respectively, indicating that shilajit exudates from the rocks during hot season (Murthy, 2008). The terms suvarnaja, raupyaja, tamraja and lohaja indicate the presence of its metallic contents namely gold, silver, copper and iron respectively. Shilajit comes in contact with these metal ores as it exudates from the mountains, the source of metals and mineral (Sudarshan, 2005).

In Greek, it is called as mumijo which means 'saving body' or 'protecting organism' (Frolova and Kiseleva, 1996). In Sanskrit, shilajit means 'destroyer of weakness' (Scholz-Böttcher et al., 2005). Shilajit is referred as dathuras and dathusara and the word 'dhatu' is also being used as a synonym of shilajit which means 'body tissue' just to emphasize its capability as *rasayana*, one that tonifies the activity of the seven body constituents (sapthadhatus) namely plasma, blood, muscle, fat, bone, bone marrow and reproductory fluids of the body according to the concept of traditional Indian medicine (TIM) (Agarwal et al., 2007; Heinrich, 2007).

### 1.3. Varieties of shilajit

There are two distinct types of shilajit, one as a semi-hard, brownish black to dark, greasy resin with a distinct coniferous smell and bitter taste (gomuthira shilajit) and a white variety with camphor odour called karpura shilajit (Thiyagarajan and Sunderrajan, 1992; Saleem et al., 2006; Agarwal et al., 2007). Gomuthira shilajit is again classified into four types according to the predominance of the metal ore found in the mountains from where shilajit exudates. Gold ore shilajit, silver ore shilajit, copper ore shilajit and iron ore shilajit. Gold ore shilajit is red in colour and is supposed to treat deranged wind humour associated with heat e.g. haemorrhoids, silver ore shilajit is white in colour and expected to be helpful for the treatment of vitiated phlegm humour associated with heat e.g. allergic rhinitis, while the copper ore shilajit is blue in colour and is supposed to balance deranged phlegm humour e.g. asthma. Finally the iron-containing shilajit (Nadkarni, 1954; Sudarshan, 2005; Ghosal, 2006) is dull-blackish in colour and is expected to be useful in the treatment of vitiated wind (e.g. Pain syndrome), heat (e.g. Hypertension) and phlegm (e.g. Diabetes) humours according

to the principles of traditional Indian medicine (TIM). However, gold, silver and copper varieties are seldom found excluding the iron ore shilajit which is commonly found and is widely used (Thiyagarajan and Sunderrajan, 1992). In addition, Sushruta and Vagbhatta have mentioned two more varieties namely tin and lead ore shilajit (Bhishagratna, 1998).

### 1.4. Physical properties

Shilajit samples from diverse regions of the Earth have similar physical properties and qualitative chemical composition, but they vary vividly in percentage ratio of components. Solubility in water demonstrates that nearly 30–50% of the weight of shilajit passes into the supernatant liquid, and the remains includes mineral and plant residues in quantities depending on the purity of shilajit (Schepetkin et al., 2003). Shilajit is a sticky and tenacious material with a shiny and polished surface, easily soluble in water, alcohol and acetone. The studies of Garedew et al. (2004) reveal that only about 60% of the raw material is soluble in water. The pH of 1% aqueous solutions varied in the shilajit obtained from different countries, namely, 6.2 for India (Kumoan), 7.5 for Nepal (Dolpa), 6.8 for Pakistan (Peshawar) and 8.2 for Russia (Tien-Shan) (Agarwal et al., 2007). When shilajit samples were subjected to thermal analysis, simultaneous thermal analysis curves differed between various heating runs indicating that samples of shilajit are not uniform but expressed batch dependence. The differences were prominent in intensity and signal form especially at higher temperatures. In an oxidizing atmosphere, only exothermal processes occur except during the dehydration range up to 150 °C (about 7% $H_2O$). This indicates that shilajit predominantly consists of organic matter and the total mass loss in air amounts to 67.6%. In an inert atmosphere, a completely different behaviour is observed (Garedew et al., 2004). Thus, physical properties like solubility, pH, thermal analysis, etc., are some of the preliminary and mandatory tools for quality control and to minimize batch to batch variation.

### 1.5. Chemical constituents

Shilajit is composed of three primary chemical units namely, (1) low and medium molecular weight non-humic organic compounds comprising free and conjugated (e.g. fattyacyl, aminoacyl, lipoidal), dibenzo-α-pyrones. (2) Medium and high molecular weight DCPs (dibenzo-α-pyrones-chromoproteins), containing trace metal ions and colouring matter such as carotenoids and indigoids and (3) metallo-humates like fulvic acids and fusims with dibenzo-α-pyrones in their core nuclei (Ghosal, 2006). The chemical content of shilajit is controlled by several factors such as adjacent plant-species, geological environment of the rock and soil, temperature, humidity and altitude, etc. (Ghosal et al., 1991). For example, shilajit obtained from India in the region of Kumoan contains a higher percentage of fulvic acids (21.4%) compared with shilajit obtained from Nepal (15.4%), Pakistan (15.5%) and Russia (19.0%). However, the bioactive low molecular compound was found in high quantities in shilajit obtained from Nepal. Similarly, humic constituents in shilajit samples obtained from these countries also varied (Agarwal et al., 2007).

Shilajit from different regions contained a large variation of organic compounds that can be broadly grouped into humic (80–85% of total organic mass) and non-humic (15–20%) substances (Ghosal, 1990; Kwon et al., 2004). Generally, shilajit contains 14–20% humidity; 18–20% minerals; 13–17% proteins (with marked α amylase activity); 4–4.5% lipids; 3.3–6.5% steroids; 18–20% nitrogen-free compounds; 1.5–2% carbohydrates; and 0.05–0.08% alkaloids, amino acids and other compounds (Garedew et al., 2004). Moreover, diverse amino acids and 65 organic compounds are listed, amongst them albumins, coumarins, free fatty acids, organic acids including adipic, succinic, citric, oxalic and tartaric, waxes, resins, polyphenols, essential oils and vitamins like $B_1$ and $B_{12}$ (Frolova and Kiseleva, 1996; Al-Himaidi and Mohammed, 2003). Most likely, the active constituent of shilajit consists of dibenzo-α-pyrones and related metabolites, tirucallane triterpenes, small peptides consisting of non-protein amino acids, some phenolic lipids, small tannoids and fulvic acid. This might be due to the process of humification which may lead to the appearance of any substance both simple and more complex than initial bio-molecules. As humus matter consists of organic residues that have lost their original structure after decomposition in the environment (Schepetkin et al., 2002).

Several phenylpropanoid-acetate-derived aucuparins, oxygenated biphenylcarboxylates, isolated and characterized as their permethylated derivatives, and oxygenated dibenzo-α-pyrones were found to occur ubiquitously, albeit in different amounts, in all authentic samples of shilajit (Ghosal, 1990; Jaiswal and Bhattacharya, 1992). Moreover, 2-Chloro-10-(3-Dimethylaminopropyl)-Phenothiazine was identified and isolated from the organic extract of shilajit. Further, a chemical process was developed to isolate pure vitamin $D_3$ from mumiyo asil (Khalikov and Alieva, 2002; Khalikov and Alieva, 2003). On the basis of chemical data analyses and chemical reactions, Ali et al. (2004), identified six new compounds named as shilajityl acetate, shilajitol, shilacatechol, shilaxanthone, shilanthranil and naphsilajitone along with pyrocatechol and their stereostructures.

## 2. Therapeutic properties

According to traditional Indian knowledge, shilajit exerts action as a tonic, laxative, expectorant, diuretic, anti-bilious, immuno-modulator, lithotriptic and anti-hypertensive when given internally and it acts as antiseptic, analgesic, deobstruent and germicide when applied externally. Shilajit is given along with milk to control diabetes, and to treat fractures shilajit is prescribed along with *Commiphora wightii* (Arn.) Bhand. (guggulu). It is believed that it promotes the formation of callus (Thiyagarajan and Sunderrajan, 1992; Agarwal et al., 2007).

Shilajit is mentioned under *rasayana* category in Charaka Samhita, the oldest text of Ayurvedic system of medicine. Charaka has stated that shilajit can be used in several diseases by altering the anupana (vehicle) and adjuvant in combination with several drugs. Sushruta has described shilajit in madhumeha chikitsa (diabetes mellitus). In his text, purified shilajit is advocated in madhumeha along with the decoction of *Shorea robusta* group of plants (Murthy, 2008).

Shilajit is one of the ingredients in many herbo-mineral formulations. Amongst the many Ayurvedic formulations containing shilajit, classical sastric formulations available in the market are tabulated in Table 2 along with its dose, anupana (vehicle) and therapeutic properties. Moreover, proprietary products containing shilajit as one of the ingredients, manufactured by prominent pharmaceutical companies along with its use are tabulated in Table 3.

## 3. Antioxidant activity

Preclinical studies in adult male Wistar rats revealed that processed shilajit provides complete protection to methyl methacrylate against hydroxyl radical-induced polymerization. Shilajit in the dose of 20 and 50 mg/kg/day, i.p., for 21 days induced a dose related increase in superoxide dismutase (SOD), catalase (CAT) and glutathione peroxidase (GPX) activities in frontal cortex and striatum of rats when compared with the control. The resulting values were comparable to those of (−)deprenyl 2 mg/kg/day,

**Table 2**
Sastric formulations containing shilajit. *Source*: The Ayurvedic Formulary of India (2003).

| S. No. | Name of the formulation | Dose/vehicle | Therapeutic indication |
|---|---|---|---|
| 1 | Satavari Guda | 6 g<br>Milk | Dysuria, bleeding disorder, chronic obstructive jaundice/chlorosis/advanced stage of jaundice, pthisis, burning sensation of feet, disorder of female genital tract, menorrhagia or metrorrhagia or both, urinary disorders, obstructed movement of vata dosha, jaundice, menstrual disorder, discharge from bones, disease due to vata dosha and pitta dosha, used as a rasayana (nutrient to body and mind with adapto-immuno-neuro-endocrine-modulator properties) |
| 2 | Siva Gutika | 12 g<br>Milk, meat soup, juice of pomegranate seeds, grapes and suitable asavas and arishtas | Disorder of liver and spleen, diseases of abdomen/enlargement of abdomen, hiccup, hernia, abdominal lump, chronic rhinitis/sinusitis, cough, anaemia, heart disease, vomiting, gout, stiffness in thigh muscles, epilepsy, mania/psychosis, diseases of skin |
| 3 | Traikantaka Ghruta | 12 g<br>Warm water, warm milk | Dysuria, urinary disorders, urinary calculus, urinary disorders |
| 4 | Vastyamayantaka Ghruta | 12 g<br>Warm milk | Dysuria, urinary calculus, urinary disorders, disorder of urinary tract and bladder due to vata pitta dosha |
| 5 | Kaccuradi Curna | Applied externally on the head, with breast milk, castor oil or butter | Hiccup, chronic rhinitis/sinusitis, fever, headache due to vata dosha, headache due to pitta dosha, dementia, eye disorder, disease of ear, disease due to kapha dosha |
| 6 | Candraprabha Vati | 250–500 mg<br>Water, milk | Constipation, distension of abdomen due to obstruction to passage of urine and stools, colicky pain, cyst, anaemia, jaundice, dysuria, urinary disorders, calculus, haemorrhoids, tumour, urinary obstruction, hernia, lower backache, diseases of skin, itching, disorder of spleen, ascites associated with splenomegaly, fistula-in-ano, dental disease, eye disorder, tastelessness, impaired digestive fire, gynaecological disorders, dysmenorrhoea, vitiation of semen, weakness |
| 7 | Prabhakara Vati | 125–250 mg<br>Water, potion of *Terminalia arjuna*, milk | Heart disease |
| 8 | Manasamitra Vataka | 1 g<br>Milk | Mental disorder, mania/psychosis, epilepsy, retarded intellect, disorder of speech, gastro-enteritis with piercing pain, intoxication, syncope, coma, psychological disorder, snake poison |
| 9 | Siva Gutika (Laghu) | 6 g | Anaemia, diseases of skin, fever, bronchial asthma, haemorrhoids, fistula-in-ano, dysuria, tuberculosis, urinary disorders, splenic disease. |
| 10 | Kantavallabha Rasa | 125 mg<br>Honey | Impaired digestive fire, mal-absorption syndrome, abdominal lump, disorder of spleen, ascites associated with splenomegaly, anaemia, cough, dyspnoea/asthma, pthisis, haemorrhoids, fistula-in-ano, fever, tastelessness, emesis, diseases of skin, pain due to vata dosha, weakness, emaciation, oligospermia |
| 11 | Arogyavardhini Gutika | 250–500 mg<br>Ginger juice, honey, juice of *Azadiracta indica* (neem), water, milk | Chronic fever, disorder of adipose tissue, diseases of skin, disorder of liver |
| 12 | Vataraktantaka Rasa | 500 mg<br>Leaf/flower/bark juice of neem | Gout, disease due to vata dosha |
| 13 | Varisoshana Rasa | 62.5–125 mg<br>Trikatu potion, Triphala potion, juice of *Ficus hispida* | Malabsorption syndrome, anaemia, ascites, inflammation, pleural effusion/hydrothorax, diseases of skin, digestive impairment, splenic disease, gastric ulcer/duodenal ulcer/colic, diseases of abdomen/enlargement of abdomen, general weakness |
| 14 | Indu Vati | 1 pill of 250 mg size<br>Disolved in 12 g juice of Indian gooseberry consumed in the morning | Tinnitus and diseases related to the ears |
| 15 | Pramehakulantaka Rasa | 500 mg<br>Goat's milk, lukewarm water, juice of Indian gooseberry | Genito-urinary disorders, burning micturition, urolithiasis, jaundice, anaemia |
| 16 | Vedvidya Vati | 375 mg<br>Honey, juice of Indian gooseberry | Genito-urinary disorders |
| 17 | Mehavajra Rasa | 4 g<br>Honey | Genito-urinary disorders and burning micturition |
| 18 | Shilajatu Vatika | 1 g<br>Juice of pomegranate, milk | Anaemia, fever, leprosy, enlargement of spleen, piles, breathing troubles, urinary and sperm related troubles, bronchitis, menorrhagia and leucorrhoea |
| 19 | Shilajatvadi Lauham | 500 mg<br>Honey or milk | Tuberculosis |
| 20 | Shilajatu Rasayana | 12 g<br>Potion of Pterocarpus marsupium group of drugs | Diabetes, obesity, leprosy, scrofula, fistula-in-ano, filiariasis and dropsy |

i.p., for 21 days, a selective monoamine oxidase-B inhibitor, in respect of SOD and CAT activities. Nevertheless, unlike processed shiljait (−)-deprenyl had only a marginal effect on the GPX activities in these tissues. The increase in the enzyme activities on processed shilajit treatment compared to the control was in the levels of SOD (51.25% and 71.25%); CAT (51.4% and 87.2%); GPX (53.1% and 196.8%) respectively. Shilajit unlike (−)-deprenyl, had no monoamine oxidase-inhibiting effect (Bhattacharya and Sen, 1995).

Clinical study with shilajit exhibited its effect on antioxidant activity in diabetic subjects. 61 diabetic subjects of either sex, aged 31–70 years were administered shilajit as two capsules (500 mg each; Dabur, India) twice daily for 30 days. Treatment with shilajit exhibited a significant decrease in values of malondialdehyde

**Table 3**
Proprietary drugs containing shilajit.

| S. No. | Drug name | Indication | Manufacturer |
|---|---|---|---|
| 1 | Tablet Abana (Heart Care) | Hypertension, hyperlipidemia and cardio-protection | Himalaya Drug Company, Bangalore, India |
| 2 | Tablet Cystone (Uricare) | Urolithiasis, non specific urethritis including dysuria and chronic urinary tract infection | Himalaya Drug Company, Bangalore, India |
| 3 | Tablet Diabecon (Gluco care) | Non-insulin dependant diabetes mellitus | Himalaya Drug Company, Bangalore, India |
| 4 | Syrup Evecare (Menstri care) | Dysmenorrhoea, menorrhagia and uterine tonic | Himalaya Drug Company, Bangalore, India |
| 5 | Syrup and Tablet Geriforte (Geri care) | Geriatric stress and general anxiety disorders | Himalaya Drug Company, Bangalore, India. |
| 6 | Tablet Lukol | Non-specific leucorrhoea and pelvic inflammatory disease | Himalaya Drug Company, Bangalore, India |
| 7 | Tablets Nefrotec DS | Urolithiasis, diuretic and urinary antiseptic | Himalaya Drug Company, Bangalore, India |
| 8 | Tablet Pilex (Vein care) | Haemorrhoids and varicose veins | Himalaya Drug Company, Bangalore, India |
| 9 | Tablet Rumalaya (Joint care) | Arthalgia, osteoarthritis and cervical spondylosis | Himalaya Drug Company, Bangalore, India |
| 10 | Tablet Tentex forte (Vigour care for men) | Male sexual weakness | Himalaya Drug Company, Bangalore, India |
| 11 | Capsule Shilajit Gold | Pre-mature ejaculation, erectile dysfunction and increases the quality of the sperm | Dabur India, Ltd, New Delhi, India |
| 12 | Capsule Addyzoa | Oligospermia, asthenospermia, teratospermia and management of male functional infertility | Charak Pharma Pvt. Ltd. Mumbai, India |
| 13 | Tablets Femiforte and Femiplex | Excessive vaginal discharge due to fungal/bacterial/protozoal infection and recurrent vaginitis | Charak Pharma Pvt. Ltd. Mumbai, India |
| 14 | Tablet Hyponidd | Mild diabetes mellitus and polycystic ovarian syndrome | Charak Pharma Pvt. Ltd. Mumbai, India |
| 15 | Tablet Neo | Nocturnal semen emission and premature ejaculation | Charak Pharma Pvt. Ltd. Mumbai, India |
| 16 | Tablet Pallrywyn Forte | Premature senility or loss of libido in both sexes | Charak Pharma Pvt. Ltd. Mumbai, India. |
| 17 | Tablet Pigmento | Vitiligo | Charak Pharma Pvt. Ltd. Mumbai, India |
| 18 | Tablet Prosteez | Benign prostatic hyperplasia | Charak Pharma Pvt. Ltd. Mumbai, India. |
| 19 | Capsule Shilajeet | Adaptogen | Charak Pharma Pvt. Ltd. Mumbai, India |
| 20 | Capsule Ji Gold | Aphrodisiac | Ban Labs Ltd., Rajkot, India |
| 21 | Shilajeet oil | Hypertension | Cinnabaris spagyrics (Herbals), Pune, India |
| 22 | Capsule Shilajit (3% fulvic acid) | Anti-stress, enhances memory and intellectual functions | Renaissance Herbs, California, USA and Dhanvantri Botanicals, Bangalore, India |
| 23 | Capsule Mumijo | Asthma, osteoporosis and diabetes | Apeiron Handels GmbH & Co. KG, Wallenhorst, Germany |
| 24 | Capsule Shilajit | Natural energy enhancer and aphrodisiac | Dabur International Limited, KBC Harrow Exchange, 2 Gayton Road, Harrow HA1 2XU, UK |

compared with their higher pretreatment values, whereas values of catalase in diabetic subjects were significantly increased after treatment with shilajit (Saxena et al., 2003).

Antioxidant properties of shilajit extract can be attributed to the presence of dibenzo-α-pyrones and fulvic acid (Schepetkin et al., 2002). The effect of dibenzo-α-pyrones and dibenzo-α-pyrones-chromoproteins on chronic stress, which induces oxidative stress, have been determined in rat brain frontal cortex and striatum. Currently, it is known that many different stress induced diseases are due to oxidative stress. Chronic stress was found to induce significant increase in cortical SOD, with concomitant decrease in CAT and GPX activities and an increase in lipid peroxidase activity. Both dibenzo-α-pyrones and dibenzo-α-pyrones-chromoproteins significantly mitigated chronic stress-induced perturbations by normalizing SOD activity and reversed the stress effects on CAT and GPX, and finally reducing the lipid peroxidase. Dibenzo-α-pyrones-chromoproteins appeared to be more effective, in terms of doses used, than the dibenzo-α-pyrones. A causal relationship between the increase in the activity of antioxidant enzymes (SOD, CAT and GPX) and longevity was established. On the other hand, their depletion was found to be associated with geriatric complaints and ageing. Also a decrease in their activities in specific brain areas has been postulated to be an aetiological factor in neurodegenerative diseases, such as Alzheimer's disease and Parkinsonism induced by neurotoxic free radicals (Knoll, 1992).

The *in vivo* antioxidant activity of shilajit has been studied, nevertheless, at an irrelevant dose up to 50 mg/kg/day. Moreover, the antioxidant effect was not compared with a positive control such as vitamin C (ascorbic acid) instead, (−)deprenyl, a selective monoamine oxidase (MAO)-B inhibitor, was only used as the standard. However, the traditional use of shilajit as a '*rasayana*' against oxidative stress-induced diseases and geriatric disorders could be correlated (Ghosal et al., 1991). Considering the above facts, further studies are imperative to overcome the lacuna in establishing the antioxidant property of shilajit.

## 4. Immuno-modulatory activity

Pure shilajit was found to supplement the lytic potential of activated lymphocytes and produced T-cell mediated cytotoxicity. This was evident from the ability of the shilajit – treated lymphocytes to lyse $^{51}Cr$ labelled tumour cells. Both fulvic acids (FAs), containing minor amounts of dibenzo-α pyrones (DBPs) and 3,8-dihydroxydibenzo-α pyrones in doses of 400 μg/mouse i.p, inhibited the proliferation of Ehrlich ascites tumour cells without significantly affecting the number of dead cells suggesting that the action of the shilajit constituents was mediated by immunoregulation (Ghosal, 2000).

The immuno-modulatory effect in mice that were given either shilajit extract or placebo was evaluated. White blood cell activity was studied and monitored before and at intervals after receiving the shilajit extract or a placebo. Shilajit extract increased the white blood cell activity and the experimental activity was dose dependant and related to the time of exposure. Shilajit and its combined constituents elicited to different degrees murine peritoneal macrophages and activated splenocytes of tumour-bearing animals at early and later stages of tumour growth (Agarwal et al., 2007). Moreover, Ghosal (1990) evaluated the effect of shilajit in rats pertaining to the levels of brain monoamines. Shilajit at a dose of 25 and 50 mg/kg i.p. for 5 days significantly lowered the level of 5-hydroxy tryptamine and 5-hydroxy indole acetic acid and raised the

level of dopamine, noradrenaline and its metabolites in rat brain. These changes in neurotransmitter levels are similar to those seen in cases of increased humoural (immune) activity (Ghosal, 1990).

Interestingly, in the Leningrad Zoo (St. Petersburg, Russia) chinchilla puppies were bottle-nursed with addition of shilajit solution for the stimulation of immunity (Schepetkin et al., 2002). Shilajit extract was considered as a prospective inhibitor of analgesic tolerance to morphine. In Swiss mice, the concomitant administration of processed shilajit with morphine, from day 6 to day 10, resulted in a significant inhibition of the development of tolerance to morphine induced analgesia (Tiwari et al., 2001). There are many research studies supporting the hypothesis that there are bi-directional circuits between the immune system and the central nervous system (Jankovic, 1985). In this perspective, it is very important to note that the reported immuno-modulatory property of processed Shilajit could play a role in the inhibition of development of analgesic tolerance to morphine (Tiwari et al., 2001).

Shilajit is endowed with immuno-potentiating property that enhances the immune system, which may complement conventional HIV therapy. Clinical studies in HIV patients with a compound formulation containing processed shilajit as one of the essential constituents revealed distinct improvement in the symptoms and augmentation of CD4 and CD8 cell counts. In 22 subjects treated with the above formulation for 6 months, CD4 cell counts increased from $259 \pm 119$ to $356 \pm 203$ and CD8 cell counts from $733 \pm 483$ to $984 \pm 356$ respectively (Ghosal, 2006; Agarwal et al., 2007; Gupta et al., 2010).

The key active principles of shilajit responsible for immuno-modulatory activity are bis-dibenzo-α-pyrone ferrate complex structures and the DCPs. In high dilutions, the phenolic ligands, e.g. hydroxyacetophenones and phenolic acids from both the bioactive agents are replaced by aquo-ligands to form hydrated complexes. These complexes, with part of the iron coordination sphere being exposed, offer interaction with oxygen in the singlet state, or systemic hydrogen peroxide would produce phagocytic agents that would oxidize/destroy the noxious particles. In the presence of the bulky L-groups (dibenzo-α-pyrones, hydroxyacetophenones and phenolic acids), the interaction with the cell receptors and the extraneous agents would be entirely different, the iron coordination site(s) being protected from Fenton-Haber Weiss type reactions. Therefore, moderate to high concentrations of shilajit would produce conformational changes resulting in morphological transformations in the exposed cells. The complex 'transition states' would involve a number of bonds with selective oxido-reductase functions. So dose- and time-dependant exposures of immune systems to shilajit would be expected to exhibit in recipients, different biological manifestations. At the same time, it is necessary to carefully determine the dose and duration of administration of different formulations of shilajit to avoid the risk of any impairment of immune system (Ghosal et al., 1995; Ghosal, 2006).

Nevertheless, the *in vivo* immuno-modulatory activity stated does not depict the exact dosage studied. It is essential that the *in vivo* dosage studied be physiological (<20 mg/kg) and nontoxic. Moreover, negative controls such as carrot extract should be used during its evaluation. In addition, no analyses of endotoxin contamination by residual microorganisms were observed. Even though, Ghosal (2006) has reported modulation of phagocytosis as an indicator of immuno-stimulation, it may be inappropriate for organic compounds like shilajit that potentially also damage tissues and thus indirectly lead to activation of the innate immune system. According to Gertsch et al. (2010), the search for phagocytosis stimulating compounds as therapeutically useful immuno-stimulants may be problematic in the light of the general lack of mechanistic insight. Further, the pharmacokinetics of shilajit is neglected as usual and the immuno-stimulatory component is not orally bioavailable. Therefore more specific assays are needed to vouch shilajit as an immuno-modulator such as to test the possible enhancement of a humoural or cellular response against a specific antigen or the rejection of transplanted tumours. In this direction, structurally characterized natural products should meet the experimental strategies to "proof" immuno-stimulation most importantly through *in vivo* studies (Gertsch et al., 2010). Considering the above facts, shilajit does not stand the test of critical assessment for immuno-modulatory activity and currently may be considered as unproven.

## 5. Conclusion

Shilajit is an exudate of variable consistency, found at high altitudes between 1000 and 5000 m. During hot summer months, shilajit trickles down crevices and spreads on the rock surface (Heinrich, 2007). There are three major theories explaining the origin of shilajit as in Section 1.1. However, the widespread distribution of shilajit in sedimentary rocks all over the world at high altitudes signifies that shilajit is derived from rocks (Ghosal, 2006). This fact can be understood from the synonyms of 'shilajit' described in Section 1.2 which means 'derived from rocks', 'essence of mountains', etc. (Thiyagarajan and Sunderrajan, 1992). Shilajit is often tagged as '*rasayana*' of traditional Ayurvedic and Siddha systems of medicine that has attracted the common man at large in India (Ghosal, 2006). The word 'dhatu' means 'body tissue' is being used as a synonym of shilajit, since shilajit as *rasayana* improves the quality of 'rasa' (plasma) and strengthens the health of all tissues of the body (Heinrich, 2007). But scientific evaluation on shilajit reviewed so far indicates that it fails to live-up to the expectation of a *rasayana.*

Based on the odour, there are two distinct varieties of shilajit dealt under Section 1.3 and the one with a distinct coniferous smell is branded as gomuthira shilajit and the second variety with camphor odour is known as karpura shilajit. Nevertheless, earlier studies carried out on the aforesaid varieties of shilajit have shown that the odour of shilajit has nothing to do with either cow's urine or camphor. The origin and the process of transformation of shilajit in its natural habitat contribute to the odour of shilajit (Ghosal, 2006). Amongst the four types of gomuthira shilajit, iron ore variety is commonly found and is widely used (Thiyagarajan and Sunderrajan, 1992). Saleem et al. (2006) studied the chemistry and pharmacology of karpura shilajit bhasma (calcined oxide) but have conversely discussed the pharmacological studies pertaining to gomuthira shilajit. In this regard, it is pertinent to have a clear-cut understanding about the different varieties of shilajit and its characteristic identification features which is the first step in assuring the quality, safety and efficacy of traditional medicines as per WHO guidelines (World Health Organization, 2000). Moreover, care is essential during testing of genuine shilajit as per traditional protocol (Thiyagarajan and Sunderrajan, 1992).

Shilajit samples obtained from different countries have similar physical properties and qualitative chemical composition, but they vary in percentage as depicted in Section 1.4. For example, solubility in water varies depending on the purity of shilajit (Schepetkin et al., 2003). Therefore, physical properties like solubility, pH, etc., are some of the vital parameters essential for quality control. Shilajit is a natural mineral substance with various bioactive constituents (Section 1.5) mainly low and medium molecular weight non-humic organic compounds, medium and high molecular weight dibenzo-α-pyrone-chromoproteins, and metallo-humates (fulvic acid). Moreover, humification process and residence time on different rock surfaces would result in shilajit of different grades and composition of desirable and undesirable constituents. Henceforth, purification and standardization of shilajit based on its bioactive and related constituents is mandatory prior to its therapeutic usage.

Shilajit is currently available in the market as one of the ingredients in various herbo-mineral formulations in both traditional sastric as well as proprietary OTC (over the counter) products. Amongst the twenty sastric formulations, eighteen are poly herbo-mineral formulations otherwise known as herbo-mineral products (HMP's) and two are exclusive mineral preparations namely kantavallabha rasa and shilajatu rasayana. There are nineteen internal dosage forms and one external dosage form as documented in Table 2. Moreover, the therapeutic properties of shilajit containing formulations are indicated for different diseases which are non-specific and extraneous. Even though, shilajit containing formulations are presently used both by traditional practitioners and the public, standardization of poly herbal formulation and herbo-mineral products becomes a strenuous task and it is difficult to study the efficacy of shilajit in isolation because 3 HMP's contain more than 50 herbs as ingredients, 3 more HMP's contain 20–29 herbs while 5 HMP's contain 10–19 herbs and 7 HMP's contains in-between 2 and 9 herbs. In this regard, the need of the hour is to convert the experience-based medicine to evidence based medicine by the process of reverse pharmacology (Fonnebo et al., 2007).

In Section 3, antioxidant activity of shilajit was reviewed through *in vivo* assays because screening with in vitro assays has little meaning, nevertheless, at an irrelevant dose and without using a positive control. In this connection, steps be taken to avoid the pitfalls in evaluating the antioxidant property of shilajit. With respect to immuno-modulatory activity dealt under Section 4, Ghosal (2006) has reported modulation of phagocytosis as an indicator of immuno-stimulation, which may be inappropriate for organic compounds like shilajit that indirectly lead to activation of the innate immune system. According to Gertsch et al. (2010), the search for phagocytosis stimulating compounds as therapeutically useful immuno-stimulants may be problematic in light of the general lack of mechanistic insight. In this direction, structurally characterized natural products should meet the experimental strategies to "proof" immuno-stimulation most importantly through *in vivo* studies.

Since the antioxidant and immuno-modulatory claims of shilajit are based on shallow and weak evidence, currently, shilajit cannot be labelled as a *rasayana*, emphasizing the need for more systematic research to explain the mechanism of shilajit's action as a rejuvenator.

## Conflict of interest

None.

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## Glossary

*Curna:* Fine powder
*Ghruta:* Medicated ghee
*Guda:* Electuary
*Gutika:* Tablet or pills
*Laghu:* Minor/lesser variety
*Lauham:* Formulations containing Iron as the main ingredient
*Rasa:* Mineral drugs as main ingredients (pill form)
*Rasayana:* Semi-solid preparation, electuary
*Vataka:* Jaggery (sugar) coated pills
*Vati:* Tablet or pills