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SAFOOF-E-SHARMA; A MAGICAL POLYHERBAL FORMULATION

MUDASSAR MAZHER*

Department of Pharmacognosy, faculty of pharmacy, University of Karachi, Karachi. Department of Pharmacy, the University of Chenab, Gujrat. *Corresponding Author Email: mudassar.mazhar@uol.edu.pk

MUHAMMAD TANVEER KHAN

College of Pharmacy, Lahore College for Women University, Lahore.

MUHAMMAD KASHIF

Department of Pharmacy, The University of Chenab, Gujrat.

ABDUL QUDDOOS

Department of Pharmacy, The Sahara University, Narowal.

REHAN AFSAR

Institute of Radiological Sciences & Medical Imaging Technology, The University of Chenab, Gujrat.

ZAFAR IQBAL

College of Pharmacy, Bahawalpur Medical and Dental College, Bahawalpur.

NAVEED ULLAH KHAN*

Department of Pharmacy, CECOS University of IT and Emerging Sciences, Peshawar.
*Corresponding author Email: naveedkhan1676@hotmail.com

Abstract

Polyhedral formulations have been used globally with as per documented records especially in Greek, ancient Chinese, Indian and Egyptian systems of medicines for diverse therapeutic purposes. According to World Health Organization: 80% of the world's population use traditional medications. In *Ayurveda*, Siddha and Unani system of medicines, single or multiple herbs (polyherbal) crude drugs belonging to any of 5 sources of medicines i.e., plants, animal, metals and minerals, marine and microorganism are used for the treatment. Use of only bioactive compounds of plants is not sufficient to attain desired therapeutic effects. Combinations of multiple herbs in a specific ratio often provides better therapeutic efficacy with reduced toxicity. This review mainly focuses on importance and clinical significance of Safoof-e-Sharma. The Safoof-e-Sharma (Muayyan-e-Hamall) is a polyherbal formulation that was formulated by Hakeem Hans Raj Sharma to treat the women suffering from Leukoria, Gonorrhea, recurrent miscarriage, menstrual disturbances, premature birth and infertility. The regional practices declare that if the drug is used immediately after the completion of menstual cycle, for 7 days the female would definitely conceive within one or otherwise three months. Also, the fetus will always be a male baby or with XY gene combination. It is consisted of 4 crude drugs named as aerial roots of *Ficus religiosa,*seeds of *Skimmia laureola* and *Mesuea ferra* and tusks of *Elephas maximus*.

1. INTRODUCTION

Infertility can be defined as the failure to conceive normally after 1 year of regular exposed intercourse. Infertility is a degree of subfertility in which one out of seven couples conceives by adopting guidelines of a specialist. The probability of being conceived also

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depends upon sexual exposure, couple's age and frequency of coitus. The normal couples conceive after unprotected intercourse of one moth duration with 25% chances, after 6 months with 70% and after one year with 90% chances. Defective ovulation, transport and implantation are 3 main categories of causes of infertility (Taylor, 2003).Defective ovulation includes endocrine disorders, physical disorders and ovarian disorder and endometriosis. Defective transport includes Pelvic Inflammatory Disease like gonorrhea, fimbrial adhesions, peritonitis, and previous tubal surgery. Defective Implantation includes Congenital anomaly and fibroids (Taylor, 2003).

To treat female infertility problems like Leukoria, Gonorrhea, recurrent miscarriage, menstrual disturbances, premature birth and infertility several sigle and multiple herbal formutions are used.Among these formulation Safoof-e-Sharma is one of the most widely used effective polherbal formulation (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984).The families of Indo-Pak region who have no male but all female off-springs face socio-economic issues. This is especially true for the females who are affected by this situation and consequently start visiting to herbal practitioners and spiritual healers to cop the situation. Having no baby boy is itself considered as a disease for those females (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984).

Safoof are solid dosage forms containing the fine powder of herbal preparations made of plant, marine, animal and mineral origin crude drugs usually for internal as well as external use. Churan, phanki and phakki are other names of safoof. The term safoof is mostly used for the powders intended to be used internally but few powders used externally for example Safoof-e-kharish and Safoof-e- Barg-e-Hina are also called "safoof" (Chaudhary et al., 2013). The Safoof-e-Sharma (Muayyan-e-Hamall) is a polyherbal drug that was formulated by Hakeem Hans Raj Sharma to treat the women suffering from Leukoria, Gonorrhea, recurrent miscarriage, menstrual disturbances, premature birth and infertility. The regional practicesdeclare that if the drug is used immediately after the completion of menstual cycle, for 7 daysthe female would definitely conceive within one or otherwise three months. Also, the fetus will always be a male baby or with XY gene combination (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984).

1.1 Composition of the polyherbal medicine

The Safoof-e-Sharma is a combination of a number of natural crude drugs. The ingredients of the polyherbal formulation, their botanical or zoological origin, part used and quantity in the preparation are given in Table 1.

Table 1: Ingredients of Safoof Sharma (Dunyapuri, 1975; Dunyapuri et al. , 2003)

Common names	Botanical or zoological origin	Part used	Weight (g)
Peepal tree	*Ficus religiosa*	Aerial roots	48
Tusks of elephants	*Elephas maximus*	Powder	48
Sholangi	*Skimmia laureola*	Seeds	12
Nag-Kaiser	*Mesuea ferra*	Seeds	12

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1.1.1. Ficus

Ficus religiosa is an important member of the family moraceae and the genus ficus. Ficus is the biggest genus of angiosperms which contains approximately 800 species of various shrubs, numerous trees, and epiphytes in tropical region around the globe and subtropical regions around the world (Loutfy et al., 2005; Rønsted et al., 2008). Moraceae family covers 38 genera and 1,180 species (Christenhusz and Byng, 2016).

Figure 1&2: Aerial roots of *Ficus religiosa*

1.1.1.1. Ethno medicinal uses

The Ethno medicinal uses of *Ficus religiosa* have a great importance in traditional systems of medicine like, Siddha, Ayurveda and Unani, etc. (1995; Kirtikar and Basu, 1993; Zhou and Gilbert, 2003). *Ficus religiosa* is good in skin ailments (astringent, cooling, burns, scabies, wounds and refrigerant), gastric problems (diarrhea, dysentery, hemorrhoids, gastrohelcosis, laxative, digestive, purgative, hiccup and vomiting), analgesic (neuralgia, migraine and toothache), sexual, infertility problems (gonorrhea, hematuria and aphrodisiac), respiratory diseases (asthma, cough, hiccup and tuberculosis) (Khanom et al., 2000),miscellaneously as antibacterial, anti-inflammatory (1995; Kapoor, 2000; Kunwar and Bussmann, 2006; Warrier et al., 1993), eye troubles (Kapoor, 2000; Kunwar and Bussmann, 2006; Warrier et al., 1993), fever, paralysis (Khanom et al., 2000) and for hemorrhages (1995; Kapoor, 2000).

1.1.1.2. Phytochemical constituents

The bark of *Ficus religiosa* is composed ofβ-sitosterol-d-glucoside, bergaptol andlupen-3-one stigmasterol lanosterol, β-sitosterol and bergapten (Ambike and Rao, 1967; Swami and Bisht, 1996). The bark also has leucoanthocyanin, tannin, wax, leucoanthocyanidin, β-sitosterol, lupeol, lupeol acetate, ceryl behenate, α-amyrin acetate and saponin (Babu et al., 2010; Husain, 1992; Jiwala et al., 2008). Leavescontain n-octacosan, glycinestigmasterol, n-nonacosane, proline isofucosterol, valine, α-amyrin, tryptophan, lupeol, methionine, tannic acid, arginine, serine, tryosine aspartic acid, alanine, leucine, isoleucine, threonine, hexa-cosanol, n-hentricontanen and campestrol (Behari et al., 1984; Panda et al., 1976).

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Fruits of the *Ficus religiosa* has undecane, asgaragine, tetradecane, tyrosine, β-pinene, α- thujene, dendrolasine, γ-cadinene, limonene, α-copaene, α-trans bergamotene, β-bourbonene, α-pinene, δ-cadinene, bicyclogermacrene, dendrolasine, tridecane, α-terpinene, alloaromadendrene, germacrene, α-ylangene, β-caryophyllene, α-humulene and aromadendrene (Grison-Pige et al., 2002). Seeds of *Ficus religiosa* contains few chemical entities threonine, Alanine and another named as tyrosine (Ali and Qadry, 1987).

1.1.1.3. Pharmacological studies

An extensive literature reports broad spectrum of pharmacological action of various parts of the plant. Pharmacologically *Ficus religiosa* is found to be analgesic (Sreelekshmi et al., 2007), anti-inflammatory (Sreelekshmi et al., 2007), anti-amnesic (Kaur, Harjeet et al., 2010), anti-ulcer (Khan et al., 2011), bronchospasm (Ahuja et al., 2011), antioxidant (Ambike and Rao, 1967; Anandjiwala et al., 2008; Kirana et al., 2009; Smitha et al., 2009), anticonvulsant (Singh and Goel, 2009), antimicrobial (Aqil and Ahmad, 2003; Dwivedi and Venugopalan, 2001; Hemaiswarya et al., 2009; Iqbal et al., 2001; Uma et al., 2009; Valsaraj et al., 1997), wound healing (Charde et al., 2010; Roy et al., 2009), anti-amnesic (Kaur, H. et al., 2010), anti-acetylcholinestrase (Vinutha et al., 2007) and proteolytic (Williams et al., 1968).

1.1.1.4. Toxicity

The extensive history of traditional usage shows no side effects. No signs of toxicity were perceived in most toxicity studies performed on *Ficus religiosa*. In acute toxicity investigation, it was observed harmless at 10 folds of its active doses. The extract expressed none of the neurotoxic effects in rodents at their effective doses (25mgl/kg, 50mg/kg and 100 mg / kg) (Singh and Goel, 2009). The extract of bark aqueous in nature was observed innocuous to a dose of 2000 mg; p.o. in the acute toxicity investigation conducted on Swiss female albino mice (Deshmukh et al., 2007; Pandit et al., 2010).Administration of 2000 mg/kg drug extract did not expressed any acute toxicity in albino mice (Saha and Goswami, 2010). Orally given drug ranged from 50–2000 mg/kg of extract did not induce any significant variations in the autonomic or behavior reactions in rats (Yadav, 2015). In acute oral toxicity investigation, the *Ficus religiosa* extract administered rats were detected for death up to 48 hrs. There was no death or any signs of behavioral variations seen after administration of methanolic extract of the *Ficus religiosa* up to a dose of 5000 mg/kg body mass (Parameswari et al., 2013).

1.1.2. Ceylon iron wood

Mesua ferra belongs to family clusiaceae. It is usually known as Nagakesara and its English name is Ceylon iron wood (Kirtikar et al., 1975). Clusiaceae contains about 13 genera and nearly750 species (Kirtikar, 1935).

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Figure 3: Fruit of *Mesua ferra*

1.1.2.1. Ethno medicinal uses

The plant is anti-inflammatory (Rai et al., 2000),antiseptic, purgative, blood purifier, anthelminthic, tonic(Baruah and Sarma, 1984), anti-asthmatic, carminative, expectorant, cardio tonic, diuretic, antipyretic (Medicine, 2005), antidotes (snake bite and scorpion sting), stomachic, expectorant, astringent, bitter tonic (Husain, 1992; Nadkarni and Nadkarni, 1994; P. P. Joy, 1998; Sahni, 1998; Santamaría, 1978), spasmolytic, diuretic (Husain, 1992; P. P. Joy, 1998) and abortifacient (Nath et al., 1992). It is also used in dyspepsia, renal disorders, gastritis, cutaneous infections, sores, scabies, wounds and rheumatism (Husain, 1992; Kumar et al., 2006; Nadkarni and Nadkarni, 1994; P. P. Joy, 1998; Sahni, 1998; Santamaría, 1978). *Mesua ferra* is a constituent of several ayurvedic preparations like dasa moolarishta (Sharma and Sharma, 2007), mahakaleshwara rasa (Dasa, 2001) and in manychurnas (Acharya, 2000; Joseph et al., 2010). Ayurvedic formulations comprising this drug showed hemostatic and astringent characteristics which are useful in bleeding from uterus (Husain, 1992; P. P. Joy, 1998). It is also a part of many Unani formulations for example “Jawarish Shehryaran” a good tonic for stomach and empowering the liver, “Habb Pachaluna”, a good appetizer, “Halwa-i-supari pak” a common body tonic (P. P. Joy, 1998; Thakur et al., 1989).

1.1.2.2. Phytochemical constituents

The kernels contain approximately 75% of fixed oil, comprising of the glycerides of general the long chain fatty acids: arachidic acid, oleic acid, stearic acid and linoleic acid. Additional secluded ingredients may be euxanthone, mesuaferrol and mesuone and leuco anthocyanidin etc. Existence of derivatives of xanthone and their isolated essential oils had been informed for various portions of the herb (Bandaranayake et al., 1975; Chow and Quon, 1968; Govindachari et al., 1967; Raju et al., 1976; Sharma et al., 2002). Leaves have the flavonone glycosides– mesuein. Stem-bark has bis-xanthones – mesuabixanthone-A and another bis-xanthones mesuaferrone-B (SS Handa 1992). Flowers have volatile oil. Stamens comprise of mesuaferrone-A, mesuaferrone-B, mesuaferrol, β– sitosterol, α-amylin, β-amylin and mesuanic acid. Root bark contains two novel pyroxanthones- mesuaferrin A and mesuaferrin B (INDIA, 1962; Rastogi and Mehta, 2004; Rastogi et al., 1993; Teh et al., 2011).

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1.1.2.3. Pharmacological studies

The pharmacological activities of *Mesua ferra* includes disinfection (Adewale et al., 2011), antioxidant (Jayanthi et al., 2011; Sandeep et al., 2009; Surveswaran et al., 2007), hepatoprotective (Sandeep et al., 2009), analgesic (Hassan et al., 2006), antispasmodic (Prasad et al., 1999), anti-venom (Uawonggul et al., 2006), cancer chemotherapy (Saxena et al., 2008), immunomodulatory (Chahar et al., 2012; Tharakan et al., 2006; Tharakan, 2004), anti-neoplastic (Mahavorasirikul et al., 2010; Masud Rana et al., 2004), anti-convulsant (Tiwari et al., 2012), anti-inflammatory (Gopalakrishnan et al., 1980), anti-ulcer (Gopalakrishnan et al., 1980), anti-arthritic (Jalalpure et al., 2011), anti-microbial (Adewale et al., 2012; Jayanthi et al., 2011; Mazumder et al., 2004; Parekh, 2007; Parekh and Chanda, 2008; Sohel and Yeasmin, 2004; Verotta et al., 2004)in sore throat, cough and asthma (Bala and Seshadri, 1971; Sharma et al., 2002; Singhe et al., 1975).

1.1.2.4. Toxicity

Acute toxicological linvestigations on *Mesua ferra* has been studied out on rodents of different species. In case of study on rats, petroleum ether, ethyl acetate and alcoholic extracts of *Mesua ferra* showed no symptom of toxicity after the 24 hours of the administration and none of the treated rat was dead (Jalalpure et al., 2011). In the same way, acute toxicological investigation of *Mesua ferra* flowers was carried out on Swiss albino mice by the administration of doses i.e., 50mg/kg, 500mg/kg and 2000 mg/Kg. All the groups, showed no symbols of toxicity and none of the mice was dead. Moreover, no variations in hematological and biochemical parameters of treated group and control group mice found, correspondingly (Asif et al., 2017; UDAYABHANU et al., 2014).

1.1.3. Ner

Skimmia laureola belongs to the family rutaceae (Chase et al., 1999; Mabberley, 2008). The family is characterized generally by big herbs shrubs, big trees, and woody creepers and it has 161 genera and almost 1815 species which are native of tropical region and of subtropical area (Chase et al., 1999; Hegnauer, 1973; Mabberley, 2008).The dried ripe fruits of *Skimmia laureola* are shown in Figure 4.

Figure 4: Fruits of *Skimmia laureola*

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1.1.3.1. Ethnomedicinal uses

Skimmia laureola are used for ornamental purposes (He et al., 1995),as a condiment as a flavoring agent, to purify the air (He et al., 1995), insecticide, pesticide, for body pain, for cold (Epifano et al., 2015), influenza, headache (Waseem et al., 2006), fever (Ahmed et al., 2004; Qureshi et al., 2009; Sultana, 2013), smallpox, antidote(snake and scorpion bites) (Prakash et al., 2011), diabetes (Waseem et al., 2006), ver-mifuge for livestock (Hamayun, 2007), stopping, treating excessive bleeding, severe gastritis, gastrorrhagia, acute stomach, duodenum ulcers, chronic colitis and inflammation (Epifano et al., 2015).

1.1.3.2. Phytochemical constituents

Skimmia laureola is a good foundation for coumarins, triterpenes, alkaloids (Sultana and Khan, 2005), steroids (He et al., 1995) and essential oils (Atta-ur-Rahman et al., 1998; He et al., 1995; Rahman et al., 1998). Quinolone alkaloids4 in number were acquired from the alcoholic extract of *Skimmia laureola* and called them methyl isoplaty-desmine 20, orixiarine 9 and ptelefoliarine 6, acetoxyedulinine 8 and acetoxyptelefo-liarine 7. Furthermore, 2extra quinoline-alkaloids, ribaliprenylene 11 and acetyl ribalinine 10 have been separated (Sultana and Khan, 2005). Existence of two supplementary quinoline alkaloids in addition to dictamnine 12 and 6–8, and 11, methyl isoplatydesmine 20 have been secluded (Sultana et al., 2007). Phytochemical examination on the ingredients of *Skimmia laureola* resulted in identification and isolation of 4 alkaloids (Niu and Gilbert, 2004).

1.1.3.3. Pharmacological studies

An extensive literature reports broad spectrum pharmacological action of various parts of the plant, which includes the antioxidant activity (Gondwal et al., 2012; Irshad, 2012), antibacterial activity (Shah et al., 2013; Zeb et al., 2015), antifungal activity (Ahmad and Sultana, 2003; Saksena and Saksena, 1984; Shah et al., 2013; Ullah et al., 2015; Zuo et al., 2012), anthelmintic activity (Mehmood et al., 2011; Ullah et al., 2015), antinociceptive (Muhammad et al., 2013; Ullah et al., 2015), antipyretic activity (Muhammad et al., 2013; Ullah et al., 2015), enzyme inhibitory activity (Atta ur et al., 2006; Sultana and Khalid, 2008; Sultana and Khan, 2005), insecticidal activity (Mehmood et al., 2012), cytotoxic activity (Ullah et al., 2015), phytotoxic activity (Ullah et al., 2015) and antispasmodic activity (Ullah et al., 2015).

1.1.3.4. Toxicity

Cytotoxic prospective of the extracts and oil of *Skimmia laureola* were assessed by using the brine shrimp assay by ensuing the method of Attaurrahman (Atta-ur-Rhman Choudhary and Thomsen, 2001).Acute toxicity investigation of herbs and natural medicines were assessed for their probable adversarial properties (Combes et al., 2004; Ullah et al., 2011) utilization of faunae in toxicity investigations in acute systemic is still favored (Ekwall et al., 1998). Alcoholic extract of *Skimmia laureola* at doses of 500mg/kg, 1000mg/kg and 2000 mg/kg body mass were assessed for their toxicity properties. No death or injury was detected after the 24 hours of the treatment, displaying that this herb

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is harmless for human usage (Magaji et al., 2007; Ullah et al., 2011). Phytotoxicity studies of *Skimmia laureola* were conducted on the test species; *Lemna minor*. A noteworthy dose-dependent phyto-inhibition was professed. Essential oils obtained from the leaves were also testified to be phyto-toxic. This indicates that *Skimmia laureola* has good potential as herbicides or weedi-cides (Ibrar and Muhammad, 2011; Ullah et al., 2011).

1.1.4. Tusks of Elephants

The tusks of the Elephants are obtained from *Elephas maximus* family elephantidae and is used after grinding and mixing it with other ingredients of the formulation Safoof-e-Sharma (Muayyan-e-Hammal) (Shoshani and Eisenberg, 1982).The pieces and powder of tusks of *Elephas maximus* are shown in Figure 5.

Figure 5: The pieces and powder of tusks of Elephas maximus

No literature is available on medicinal uses and pharmacological activities of Tusks of Elephants

1.2. Monograph of Safoof-e-Sharma

1.2.1. Method of preparation

The plant parts were collected, garbled, dried under the shade and ground to a fine powder. The powdered parts are passed through the sieve of Mesh # 120 and mixed in blender for a minimum of 3 h and divided into 21 doses.

1.2.3. Pharmacological effects

According to Tibb-e-Unani, the temprament of SS is “uzlati asabi”. It acts as an emmenagogue and changes the temprament of the female to allow the survival of sperms in the uterus that have XY character (Dunyapuri, 1975).

1.2.4. Mechanism

Qanoon Mufrid Eza (theory of Tibb) (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984) has set the temperaments of all the edible things such as drugs and foods. The temperament of male is Uzlati Ghudi (UG: dry 70% and hot 30%) and female is Ghudi Asabi (GA: hot 70% and wet30%). Because of this temperament, males and females are considered different from each other in characters and features (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984). When a human being is on

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its assigned temperament i.e. male: UG and female: GA, he or she will peruse his/ her normal life and will suffer no disease until the temperament is not changed due to the diet or disease. An herbal physician treats a patient; he changes his temperament through diet or medicines. If the temperament of females is changed to dry and hot, they will adopt male physique and voice. The same is true for the males (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003; Sharma, 1984). In Tibb, following ways are adopted to change the temperament of the females for baby boy (Arif, 2010; Duniyapuri, 2005; Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003).

1.2.4.1. Medicines

The use of several medicines to change the temperament of the female is one of the first methods, adopted for baby boy. The famous Unani medicines used for this purpose include Habb-e-Nareena, Habb-e-Muqawwi Khas, Safoos-e-Sharma, and Muayyan-e-Hammal, Dawa-ul-Misk, Barshiaasa and Laboob-e-Kabeer (Arif, 2010; Duniyapuri, 2005; Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003).

1.2.4.2. Diet

For few people who think that medication is not good during pregnancy because of their toxic abortificiant and teratogenic effects, use of specific diet and prevention from certain foods is done to get the temperament changed (Arif, 2010; Duniyapuri, 2005; Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003). The recommendeddiet plan to get the temperament changed is gven in Table 2.

1.2.4.3. Fasting

Fasting is another technique used by the herbal physicians to get the temperament changed from Ghudi to Uzlati. Fasting and use of foods having dry temperament produces dryness which results in the change of temperament from Ghudi to Uzlati (Arif, 2010; Duniyapuri, 2005; Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003).

1.2.4.4. A combination of diet and medicines

It is considered as the best technique to change the temperament of body. Use of prescribed drugs along with specific diet is proven to be much effective compared to other methods (Arif, 2010; Duniyapuri, 2005; Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003).

1.2.5. Dosage and administration

The recommended dose of SS is 3.888 grams, three times a day,for 7 consective days. The drug is to be consumed with the decoction of cinnamon and clove,milk or milk butter of the cow who has given birth to a male calf (Dunyapuri, 1975).

1.2.6. Precaution

Along with the medication, the patients are advised to include such foods in the diet that have the UG or GA temperament (Dunyapuri, 1975; Hakeem Muhammad Shareef, 2003;

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Sharma, 1984). The compelete diet plan for the patient recieveing treatment with SS is given as Table 2.2.

1.2.7. Storage condition

The formulation is stored at a cool, dry and dark place at room temperature (Dunyapuri, 1975; Health and Affairs, 1983; Kabir, 2003; Medicine and Homoeopathy, 1999).

Table 2: Diet plan for the patient recieveing treatment with Safoof-e-Sharma

Breakfast	Murabba amla (Indian Gooseberry), murabba halela (Myrobalan), peanuts, currants, fried eggs, sand roasted grams, dried dates, yogurt, butter-milk, fruit salad, dahibhalla (Vada soaked in Curd) and decoction of clove and cinnamon
Lunch	Meat (mutton or beef),fried or boiled eggs, bitter melon, fish, potato, cauliflower, eggplant, pickle, mustard leaves, onion, garlic, red chili, pakoray, gram pulses, vinegar, maze, bread of grams flour
Dinner	Meat (mutton or beef),fried or boiled eggs, bitter melon, fish, potato, cauliflower, eggplant, pickle, mustard leaves, decoction of cinnamon and clove, citrus fruits, apple, Jambolan, Grewia, plum, sour pomegranate, lemonade, pineapple, peach, tamarind and dried plum dissolved water.
Prohibited food	Milk, milk cream, butter, sweets, pudding of carrot, semolina and almond, murabba carrot and apple, reddish, carrot, turnip, Indian squash, ridge gourd, pumpkin, winter melon, ladyfinger, Taro root, rice and ice cream

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