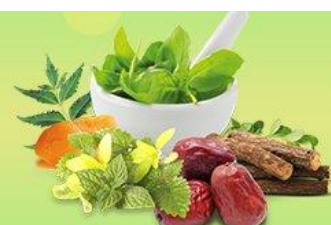


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Seema Rani
Assistant Professor,
Department of Ilmu Saidla,
Iqra Unani Medical College,
Jalgaon, Maharashtra, India

A review on *Sufoofe sailan*: A Polyherbal formulation in the management of Sailan-ur-Rehm (Leucorrhoea)

Seema Rani

Abstract

Sailanur rehm (leucorrhoea) is a gynaecological disorder from which a large number of women suffers. It is a broad term, not a single entity. In Unani system of medicine, discharges from cervix, uterus, and vagina other than blood are described as *Sailanur rehm*. It covers almost all types of genital tract infections. It is an everyday problem encountered in front of gynaecologists by a number of patients who complaints of vaginal discharge, pruritus, odour and pain. It is named by the names *Safaidi*, *Safeid Pallu*, *Sailane Abyaz*, *Parwar Rog*, *Shwet Parwar*. Many single and compound drugs have been used in Unani system of medicine since time immemorial. *Sufoofe sailan* is one of the famous and potent medicine used for this problem. Among compound preparations for the *Sailanur rehm*, *Sufoofe sailan* is one of famous formulation. It is a Polyherbal powder preparation described in various texts of Unani medicine and is used to treat *Sailanur rahem* (leucorrhea), *Uqr* (sterility), *Surate inzal* (premature ejaculation) etc. It contains ingredients which are *qabiz* (styptic) and *habis* (astringent) by temperament and *mujaffif* (dessicant) and *muqawwi* (tonic) by action. It has three different nuskhas formulas with different ingredients in different classical texts with a slight difference in their functions with one common function is the treatment of *Sailanur rehm*. It has been checked against physicochemical parameters, microbiological parameters, accelerated stability and photo stability studies in my research studies on this drug and was found to give satisfactory results and under limit set by WHO guidelines. A Clinical study on *sufoofe sailan* conducted at NIUM OPD also has been discussed. Single ingredients of NFUM nuskha for *Sufoofe sailan* are also discussed with description of all the important points. Moreover, Formulation evidence status of *Sufoofe sailan* was also found to be satisfactory. Hence *Sufoofe sailan* can be considered as a safe and effective medicine for *Sailanur rehm*.

Keywords: *Sufoofe sailan*, *Sailanur rehm*, leucorrhoea, Unani medicine, quality control

Introduction

Sufoofe sailan is one of the compound (Polyherbal) formulation among many treatment modalities and drugs are available to treat the cause and relieve *Sailanur rahem* (leucorrhea). Among all we choose this drug for a critical review due to its multipurpose use and popularity. *Sufoofe sailan* is a polyherbal powder preparation described in various texts of Unani medicine to treat *Sailanur rahem* (leucorrhea), *uqr* (sterility), *surate inzal* (premature ejaculation) etc. This formulation contains *habis* and *qabiz* drugs usually *samagiyat* (gums), *ral* (resin) with sugar which may be responsible for its early decomposition. As the name suggests it is a powder dosage form for internal use only. It is made by an intimate mixture of dry finely divided and sieved drugs. Because of greater specific surface area of powders, this dosage form disperse and dissolve more readily than compacted dosage forms. *Sufoof* is the first polyherbal dosage form used in the history of medicine. Arastu (Aristotle) has been credited for the discovery of this dosage form. According to Descaroids, Buqrat (Hippocrates) was the first who invented and used *sufoof* as a compound formulation^[13-16].

Background

Unani System of Medicine is also known by the name Greco- Arabic- Medicine. Therapeutic agents in Unani medicine are used to regain health and restore the humoral balance of the body. *Sailan-ur-rahem* is a very common gynaecological problem worldwide, which most of the women have to face in her lives. Because of many side effects in Modern system of medicine, the Unani drugs and its compound formulations can be used as good alternative for treatment of the disease^[1]. Unani drugs have long history of effectiveness in treatment of *Sailan-ur-rahem* without causing any side effect on the human body. In Unani system of medicine, this disease has wide meaning and includes all sorts of infections in the present era.

Correspondence

Seema Rani
Assistant Professor,
Department of Ilmu Saidla,
Iqra Unani Medical College,
Jalgaon, Maharashtra, India

The management and treatment of the disease mentioned by Unani physicians is very effective and comprehensive. *Sufoofe sailan* is a Polyherbal powder preparation described in various texts of Unani medicine and is used to treat *Sailanur rahem* (leucorrhoea), *uqr* (sterility), *surate inzal* (premature ejaculation) etc.^[2]

In *Sailanur rahem* terminology, *sailan* means flow and *rehm* means uterus. *Sailanur rehm* is a broad term commonly used in gynaecological disorders. It is a condition in which woman suffer from uterine, cervical and vaginal discharge other than blood due to genital tract infection or alteration in genital physiology.³ There are various types of *sailanur rehm* according to humour (khilt) involved e.g., *Sailanur rehm damvi* caused by excess of khilte dam and the colour of discharge is reddish. *Sailanur rehm balghami* is caused by excess of khilte balgham and the colour of discharge is whitish. *Sailanur rehm safrawi* is caused by excess of khilte safra and the colour of discharge is yellowish. *Sailanur rehm saudawi* is caused by excess of khilte sauda and the colour of discharge is blackish. According to site e.g, *Sailane furji*: Discharge from outer part of vagina, *Sailane mahbali*: Discharge from inner part of vagina, *Sailane rehmi*: Discharge from uterus, *Sailane unqui*: Discharge from cervix.^[4, 5]

It is a common problem in various age groups, such as, some immature girls suffer from the white discharge; this is due to worm infestation, incontinence of urine and vaginal itching etc. in young unmarried girls, discharge is caused by excessive sorrow and sadness and unhealthy condition. It happens near to menstruation, which causes irritation in the outer area of the vagina. In newly married women discharge is from inner side of the vagina found mostly in the newly married women. It is due to the inflammation of uterus that is aggravated by coitus. In this condition, the discharge is yellowish white in colour, sour in nature and causes abrasion and burning in vagina. In parous women discharge is due to cervical laceration during delivery or chronic inflammation of the mucous membrane of the uterus. It may become occasionally due to chronic gonorrhoea. In this condition, discharge is white and viscous like white part of egg that comes from the cervix and it becomes yellowish or reddish because of mixing of pus or blood. This type of sailan commonly occurs in childbearing women. In menopausal women discharge occurs in old age women due to cervical or endometrial carcinoma and rarely due to Warm Rahem Muzmin. This discharge is like curd or buttermilk^[6, 7].

In Unani medicine the line of treatment of *Sailanur Rahem* is to remove the cause at first, then patients should be advised for general measures such as to avoid coitus, Depend upon the dominant khilt (humour), disease should be treated by *munzij* & *mus-hil* therapy (concoctive and purgative) of that Khilt; and after that *farzajat* (suppositories), which are used in treatment of menorrhagia, should be given. Treatment is to use those drugs which possess the properties of *Mukhrrij-e-balgham* (Expectorant), *Muqawwi* (Tonic), *Habis* and *Qabiz* (Astringent), *Mudir* (diuretics), *Mullayin* (laxative), *Mus-hil* (purgative), *Musakkin* (Analgesic). Further, the drugs should be selected depending on the khilt involved. In the classical literature of Unani system of medicine, single and compound (poly herbal) formulations mentioned by Unani physicians.

Famous single drugs for *Sailanur Rahem* are *Anisoon* (*Pimpinella anisum*), *Gulnar* (*Punica granatum*), *Samag-e-Arbi* (*Acacia Arabica*), *Neem* (*Azadirachta indica*), *Mazu* (*Quercus infectoria*), *Ajwain* (*Ptychotis ajowan*), *Shibeyamani* (Alum), *Kakra Seenghi* (*Pistacia lentiscus*), *Taalmakhana* (*Astrachanthas longifolia*), *Beejband* (*Sida cardifolia*), *Gule Supari* (*Acecia catechu*), *Gule dhawa* (*Woodfordia fructifosa*), *Lodh pathani* (*Symplocos racemosa*), *Saalab misri* (*Orchis latifolia*), *Maghz Tukhme Tamarhindi* (*Tamarindus indica*), *Tukhme Bakain* (*Malia azedarach*), *Sandal Safaid* (*Santalum album*), *Afsanteen* (*Artemisia absinthium*), *Gule Surkh* (*Rosa domestica*), *Bakain* (*Melia azedarach*). Famous compound (Polyherbal) formulations are *Sufoofe sailan*, *Safoof-e-Sailanur Rahem*, *Kushta-e-Zaj* *Majoon-e-Supari Pak* *Kushta-e-Marwareed* *Habb-e-Sailan* *Majoon-e-Moochras* *Halwa-e-Supari Pak* *Majoon-e-muqawwia-erahem* *Majoon-e-khabs-ul-hadeed* *Majoon-e-suhaag sonth* *Habb-e- Marwareed* *Kushta baiz-e-murg* *Kushta musallas* *Qurs-e-Kushta-khabs-ulhadeed* and *Sailani*^[8-12].

Prescriptions of *Sufoofe sailan*

1. NFUM17 Alqarabadeen^[18] and Qarabadeen Jadeed^[19]
Common Nuskha:
Ingredients: *Gule dhawa* (*Woodfordia fructifosa* L. Kurz.), *Gule fofal* (*Areca catechu* L.), *Mochras* (*Bombax malabaricum* Dc.), *Gond molsri* (*Mimusops elengi* L.) each 6 g and *Nabat safaid* (Sugar) 24 g
Method of preparation: All the ingredients should be powdered and passed through 80-mesh sieve then mixed rigorously to make homogenised form.
Dose: 7 gm with fresh water
2. Qarabadeen Majeedi Nuskha^[20]:
Ingredients : *Banslooohan*, *Beejband siyah*, *tukhm utangan*, *Tukhm khashkhash safeid*, *tukhm sarwali*, *Tal makhana*, *Satawar*, *Kishneez Khushk*, *Kakra seengi*, *Mochras*, *Gond china*, *Gond keekar*, *Makhana* each 25gm and *qand safeid*(Sugar) 325 gm.
Method of preparation: All the ingredients except sugar are powdered separately and pass through seive no. 80, mix properly and preserve in Glass jar.
Dose: 1gm with 25 ml milk or water.
3. Murakkabat Advia Nuskha^[21]:
Ingredients: *Dhaan ke pawaal ki raakh*, *Barg moz*, *kela ki Raakh*, *Makai ke satte*, *khukhli ki Raakh* Each 25 gm are powdered.
Dose: 3gm with fresh water
4. Mukhzinul Murakkabat Nuskha^[22]:
Ingredients: *Taj Qalmi*, *Sandal safeid*, *Maghz Bakain* each 10gm and *sugar* 30gm are powdered.
Dose: 10 gm with fresh water in the morning

Ingredients of *Sufoofe sailan*

NFUM, Alqarabadeen, Qarabadeen Jadeed and Murakkabat Advia follows same formulae. This formula is commonly used and manufactured in various pharmacies across India. In this nuskha, four herbs namely *Gule dhawa* (*Woodfordia fructifosa* L. Kurz.), *Gule fofal* (*Areca catechu* L.), *Mochras* (*Bombax malabaricum* Dc.), *Gond molsri* (*Mimusops elengi* L.) are present in *Sufoofe sailan*. Brief Description of Ingredients of *Sufoofe sailan* is described below in Table 1.

Table 1: Brief Description of Ingredients of *Sufoofe sailan*

Index	Drug 1 [22-28]	Drug 2 [23-29]	Drug 3 [23-28, 30]	Drug 4 [23-28, 31]
Botanical name	<i>Woodfordia fruticosa</i> (L.) Kurz.	<i>Areca catechu</i> Linn.	<i>Bombax ceiba</i> Linn	<i>Mimusops elengi</i> (L.)
Synonyms	<i>Woodfordia floribundosa</i> salisb, <i>Lythrum fruitosum</i> Linn, <i>Grislea punctata</i> Buch.-Ham. ex Sm., <i>Lythrum fruticosum</i> L. (Basionym), <i>Woodfordia floribunda</i> Salisb., <i>Woodfordia fruticosa</i> var. <i>punctata</i> (Buch.-Ham. ex Sm.) Koehne.	<i>Areca catechu</i> Linn.	<i>Bombax ceiba</i> Linn, <i>Bombax malabaricum</i> Dc, <i>Salmalia malabarica</i> (DC.) Schott & Endl.), <i>Gossampinus malabarica</i> (DC.) Merr.	<i>Mimusops elengi</i> ,
Kingdom	Plantae Phylum: Tracheophyta Class: Magnoliopsida	Plantae	Plantae Division: Magnoliophyta Class: Magnoliopsida	Plantae
Order	Myrtales	Arecales	Malvales	Ericales
Family	Lythraceae	Arecoideae/ Arecaceae	Malvaceae (Bombacaceae)	Sapotaceae
Genus:	<i>Woodfordia</i>	<i>Areca</i>	<i>Bombax</i>	<i>Mimusops</i>
Species	<i>Fruticosa</i>	<i>Catechu</i>	<i>Ceiba</i>	<i>Elengi</i>
Vernacular names	English: Fire flame bush, <i>Shiranji tea</i> ; Persian: <i>Gule dhawa</i> ; Urdu: <i>Dhawa ke phool</i> ; Sanskrit: <i>Agniwala, Dhataki, Madaniyahetu, dhoorandarah</i> ; Hindi: <i>Dawi, Dhaul, Dhaatki ke phool, Santha, Thawi</i> ; Kannada: <i>Bela, Tamprapushpi</i> ; Tamil: <i>Dhattari, Jargi, Velakkal</i> ; Telugu: <i>Dhataki, Gaddaisinka, Jargi, Serinji</i>	Arabic: Fofal, Fufal. English: Areca nut or betel nut palm, areca palm, pinang palm, catechu palm, catechu tree, drunken tree, supari palm. adike, arbor areka, areca, areca nut palm, areca nut tree, areca palm, areka palm, arequero. Hindi: Supari, Chaalia. Persian: Pupal, Popal, Girdchob, Pinang. Sanskrit: Kramuka, Ghonta, Akota, Chataphata, Chikkana, Dirgha padapa, Dridha valkala, Ghonta, Gopadala, Guvaka, Kapitana, Khapura, Kramuka, Puga, Pugi, Raja Tala, Suranjana, Tambula, Tantu sara, Puwak, Pyan, Pyanbaum, Sopari and Valkataru, Puwak, Pyan, Pyanbaum, Sopari. Hindi: Supari, Chaalia, Adike, Poogi phalam, Adakka, Surattu supray. Urdu: Chhaliya, Supari.	Ayurvedic: <i>Shaalmani, Mochaa, Mochaahva, Pichhila, Raktapushpa, Sthiraayu, Kankataadhya, Tuulini, Shaalmali-veshtaka</i> (gum). Sanskrit: <i>Moca, Picchila, Raktapu Āpa</i> . English: Cotton Tree, Red Silk, Cotton Tree. Hindi: <i>Semal, Semar</i> . Urdu: <i>Sembhal, Mocharu</i> (gum). Unani: <i>Semal, Mochras</i> (gum). Siddha: <i>Mul Ilavam, Ielavampisin</i> (gum). Folk: <i>Semar</i> . Trade Name: <i>Semal</i>	Urdu: <i>Molsari</i> ; Sanskrit: Anangaka, Chirapushpa, Dhanvi, Keshu, Madhupushpa, <i>Bakulah Bakulah, Keshu kesara, Madhugandha, Udumbara</i> . English: Spanish cherry, Indian medlar tree, bullet-wood tree. Hindi: <i>Maulsari, Bakul, Bolsari, Gujarati: Babhuli, Bolsari, Varsoli, Vovoli</i> . Marathi: <i>Bakhor, Bakula, Barsoli, Ovalli, Owli, Vavoli, Wovoli</i> .
Habitat	Found in south India, eastern parts of Ravi in Himalaya up to 1400 meters altitude, upper part of Godawari, Mel ghat and in Rajputana areas. North India. It is also commonly found in lower valleys of Garhwal Himalaya and different parts of India.	Native to Philippines however cultivated in China, Indonesia, Malaysia Exotic range Fiji, India, Japan, Kenya, Madagascar, Pakistan, Papua New Guinea, Samoa, Solomon Islands, Sri Lanka, Tanzania etc. In India it is cultivated in coastal regions of Western Ghats, Assam and southern regions like Mysore, Hyderabad etc.	It is widely found in temperate Asia, tropical Asia, Africa and Australia. In India, it can be found at altitudes upto 1500 m. In peninsular India, the tree is very common in the dry as well as moist deciduous forests and near rivers.	Native in India, Myanmar and Sri Lanka but is cultivated across the tropics including Malaysia, Singapore, and Australia. It is cultivated in South India and central India especially in Madhya Pradesh, Jammu, Bihar, Mewad Awadh forests and Andaman Islands.
Part used	Flowers and gum; fruits and leaves; flower.	Nuts, flower, leaves, bark and root.	Fruits, heart wood, stem bark, root and gum.	Stem, bark, leaves, flowers, fruit seed and gum.
Mizaj (Temperament)	Cold ² and Dry ² ; Cold ² and Dry ³	Cold and Dry ² or ³ ; Cold ² Dry ³ ; Cold ² Dry ²	Cold and Dry, Cold and Dry in ³ Cold ² Dry ³	Cold and Dry ³
Afaal (Functions)	Flowers are <i>qabiz</i> (astringent), <i>mubarrid</i> (refrigerant), <i>habisud dam</i> (haemostatic), <i>qatil kirm shikam</i> (anthelmintic), <i>mujaffif</i>	Flowers are mushtahi (appetizer), cures balghami (phlegmatic), safravi (bilious) and	<i>Qabiz</i> (constipative); <i>qabize ama</i> ; <i>mujaffif</i> (siccative); <i>muqawwi rehm</i> (uterine tonic); <i>nafi sailan rehm</i> (beneficial in	<i>Qabiz</i> (constipative), <i>habis</i> (astringent), <i>mumsik mani</i> , <i>dafi jiryaan</i> . <i>Muqawwi bah</i> (aphrodisiac), <i>muqawwi meda</i> ,

	(dessicative), <i>mundamil qurooh</i> (enhance wound healing), <i>musakkin atash</i> , <i>musaffi khood</i> , Dried flowers are also used as <i>qabiz</i> (astringent), <i>qabize amaa</i> (constipating), <i>dafae taffun</i> (antibacterial), <i>dafae pechis</i> (antidysentric), <i>dafae humma</i> (febrifuge), <i>muharrik</i> (stimulant), styptic, <i>musakkine rahem</i> (uterine sedative).	sawda (black bile) diseases, <i>qabiz</i> (astringent) for oral secretions, <i>muqavvie asnan wa lissa</i> (strengthen the teeth and gums), <i>musakkine hararat</i> (febrifuge), <i>mudire boul</i> (diuretic), <i>habisuddam</i> (haemostatic), <i>nafe sailan rehm</i> (cures leucorrhoea), <i>raada mawad</i> , <i>muqavvie qalb</i> (cardiotonic) <i>muqavvie baah</i> (aphrodisiac), <i>muhallile waram</i> (anti inflammatory), and <i>qabiz</i> (constipative)..	leucorrhoea); <i>mumsik mani</i> ; <i>mughalliz mani</i> (increase consistency of semen); <i>muallide mani</i> ; <i>habise tams</i> (<i>Amenorrhoea</i>), <i>dafi fasaad khoon wa safra</i> (purifies blood and bile); <i>taskeen hiddat aza</i> ; <i>muqawi asnan wa lissa</i> (tone teeth and gums).	<i>qalb wa jigar</i> , (stomach, cardiac and liver tonic) <i>Muqawie dandan wa lissa</i> (teeth and gums Tonic). <i>Mubarrid</i> (cooling), <i>dafe humma</i> (anti-pyretic) <i>muqawie qalb</i> (cardiotonic), <i>tiryaaq</i> (alexipharmic), <i>muqawie meda</i> (stomachic), <i>qatile kirme ama</i> (anthelmintic), <i>qabiz</i> (astringent), <i>qate safra</i> (cuts bile), <i>nafe suzak</i> (cures gonorrhoea), <i>nahae silanur rahem</i> (treats leucorrhoea) <i>Habisuddam</i> (haemostatic), <i>mana' irq</i> (antiperspirant) and <i>dafae amraz balghmi wa safrawi</i> (treats phlegmatic & bilious diseases).
Dawai istemal (Therapeutic uses)	This flower kills and excretes the intestinal worms, increase the appetite, premature ejaculation, thirst, purifies the blood, beneficial in menorrhagia and piles, paediatric diarrhea, pile, burns and wound healing, ishaal (diarrhoea), kasrate tams (menorrhagia) and bawaseer damvia (bleeding piles). Abzan (Sitz bath) in khuroojul miqad (prolapse of rectum), sailanur rehm (leucorrhoea), abolishes the safra (bile) and balgham (phlegm) and act as an appetizer.	Intafakh (catarrhal conjunctivitis) and tarfa (haemorrhagic conjunctivitis) and other acute inflammatory conditions, foul smell of mouth and cures stomatitis and strengthens the teeth, It tones up the prolapsed or loose organs. It is useful in non healing ulcer, gangrene and plague, syphilitic ulcer. strengthens the teeth, tone of stomach, to reduce inflammatory conditions. stomatitis. Massage with in wajaul zuhr asbi (nervine back pain), cardiotonic and increases the vital capacity of lung, vomiting. Nausea and act as Muqavvie ama (intestinal tonic). sozish meda (Gastric irritation). strengthen the teeth and gums, Excretes the bilious matter intestinal worms. jiryaaq. ishaal (Diarrhoea), sailaanur rehm (Leucorrhoea), jiryaaq, khurooje rahem wa miqad (Prolapse of uterus and anus) as oral powder.	It cures phlegmatic cough thus used in respiratory disorders, purifies the blood and diminishes the burning due to hiddat safra for this reason it is also used as plaster. Loosen teeth and bleeding gums. diarrhoea of children. It also cures dysentery and other digestive disorders with loose motion. Puerperal discharge it is used with rasot orally. It also cures menorrhagea. Nocturnal enuresis of children, jiryaaq, sulsul bol (Urinary Incontinence), Kasrate tams (menorrhagia) and sailanur Rehm (leucorrhoea). It cures the stomatitis if applied locally.	Fevers, headache, throat pain, irritation and stomatitis. constipation, dysentery and diarrhea, burning micturition, renal and vesical stones. excretes the stones, paediatric dry cough, palpitation and other heart diseases, ejaculation problems. boils, ring, and other skin diseases.
Mazarrat (Adverse effects)	Phlegm formation ³⁴	<i>Mujaffif</i> (dessicant), <i>mukhashin sadar</i> (chest irritant), <i>muzir riya</i> (dangerous for lungs), <i>khafqan</i> (palpitation), <i>sudaa</i> (headache), <i>qoolanj qulan</i> (collitis), <i>sang gurda wa masana</i> (urinary bladder calculus).	<i>Mujaffif</i> (Dessicant)	<i>Naffakh</i> (flatulent), <i>qabiz</i> (constipative), <i>hazime shikm</i> (digestive)
Musleh (corrective)	<i>Zanjabeel khushk</i> (<i>Zingiber officinale</i>) or <i>aab anar</i> (<i>Punica granatum</i> Juice)	<i>Roghan badam</i> (<i>Prunus dulcis</i> oil), <i>nabat safeid</i> (sugar) <i>kateera</i> (<i>Astragalus adscendens</i>), <i>gond babool</i> (<i>Acacia nilotica</i>) for lungs and <i>kateera</i> (<i>Acacia arabica</i>) for all conditions.	<i>Roghan gul</i> (<i>Rosa damascene</i> oil), <i>darchini</i> (<i>Cinnamomum zeylanicum</i>), <i>shaker</i> (sugar), <i>roghan badam</i> (<i>Prunus dulcis</i> oil)	<i>Shahad khalis</i> (pure honey), <i>ghee</i> (butter), <i>har wa rataab</i> advia
Badal (Substitute)	<i>Gule pista</i> (<i>Pistacia vera</i>)	<i>Sandal surkh</i> (<i>Pterocarpus santalinus</i>) or <i>kishneez khushk</i> (<i>Coriandrum sativum</i>) half quantity to <i>supari</i> .	<i>Samaag dhaaq</i> (<i>Butea monosperma</i> gum) and <i>mastagi</i> (<i>Pistacia lentiscus</i>).	<i>Bhon phalli</i> , <i>babool ki chhaal aur phal</i> (Bark and root of <i>Acacia Arabica</i>)

Dose	4gm	3-5 gm, half darham	4-6gm, 2-3 gm	9 gm -10 gm
Famous formulation	<i>Sufoofe sailan, Majoone zanjabeel</i>	<i>Majoone supari paak, safoofe supari paak, mufarreh ahmer, sufoofe saalab, sufoofe sailan, habbe hamal, majoone muqawwi rehm</i>	<i>Majoone mochras, sufoofe sailan</i>	<i>Sufoofe sailan</i>
Phytochemical constituents	Polyphenols-ellagic acid, polytachoside and myricetin-3-galactoside, anthocyanins pelargonidine-3,5-diglucoside and cyaniding 3,5-diglucoside; octacosanol, chrysophanol-8-o-beta-d-glucopyranoside, beta-sitosterol, hecogenin, mesoinositol, flavone i.e. glycosides-quercetin-3 rhamnoside, naringenin-7-glucoside and kaempferol. A high proportion of ellagic acid and polyphenols. The flowers contain 24.1%, tannins. Dimeric hydrolyzable tannins-woodfordins a, b and c, and trimeric tannins woodfordin d and oenothin a and b. isoschimalwalin and five oligomers-woodfordin e, f, g, h and i. Ellagic acid, polystachoside, myricetin-3-galactoside and pelargonidine-3,5-diglucoside, cyaniding-3,5-diglucoside, octacosanol, b sterol and chrysophanol-8-o-b-d-glucopyranoside.	alkaloids arecaidine, arecaine, arecolidine, arecoline, guavacine, guavacoline and choline, lauric acids (19.5%), myristic acids (46.2%) and palmitic acids (12.7%), and in the unsaturated portion oleic (6.2%), linoleic (5.4%) and hexadecenoic acid (7.2%). Minor proportions of stearic, decanoic and of unsaturated monoethylenic C ₁₂ and C ₁₄ acids. The chief component glycerides are (trimyristin, dimyristins and lauroAmyristopalmitin); (hexadecenolauromyristin, with some oleo-(linoleo) myristopalmitins and dimyristins); 14% of diunsaturated-monosaturated (oleolinoleoglycerides, mostly oleolinoleopalmitin). New 5'-nucleotidase inhibitors named NF-86I, NF-86II were also isolated from the seeds of <i>Areca catechu</i> .	betasitosterol and its glucosides; contain mucilage, starch, mineral matter, tannins and non-tannins, Hydrolysis of gum yields arabinose, galactose, galacturonic acid, rhamnose and partial hydrolysis yields 6-o-(β-D-galactopyranosyl-uronic acid)-D-galacto pyranose; 2,3,4,6-tetra-, 2,6-di and 2,4-di-o-methyl-o-D-galactose and 2,3,5-tri and 2,5-di-o-methyl-L-arabinose. <i>B. malabaricum</i> gum can be substituted for gum tragacanth. Methylated <i>S. malabarica</i> gum on hydrolysis has been found to yield 2,3,4,6-tetra-, 2,6-di-, and 2,4-di-o-methyl-D-galactose and 2,3,5-tri- and 2,5-di-o-methyl-L-arabinose.	Taraxerone, taraxerol, betulinic acid and spinasterol, sodium salt of betulinic acid and ursolic acid, Fatty acid esters of alpha-spinasterol, farnan-2-one-3 betaol (mimosopfarnanol), farnan-3-one, and olean-18-en-2-one-3-ol and lup-20 (29)-en-3 beta-ol, triterpene 3β-hydroxy-lup-20(29)-ene-23, 28-dioic acid, beta amyryn, lupeol, alpha cadinol, taumurolol, hexadecanoic acid, diisobutyl phthalate, octadecadienoic acid, New gallic acid esters, (phenyl propyl gallate), Quercitol, ursolic acid, dihydro quercetin, quercetin, β-d glycosides of βsitosterol, alphaspinasterol, mimosops acid and mimosopsic acid, mimugenone, pentacyclic triterpenes 3beta,6beta,19alpha,23-tetrahydroxy-urs-12-ene and 1beta-hydroxy-3beta-hexanoyllup-20 (29)-ene-23, 28-dioic acid, mimosops, mimos., misaponin A 16 alpha-hydroxy misaponin A, taxifolin, alpha-spinasterol glucoside, Miglycoside 1, mimosopside A and B, Hentriacontane, carotene and lupeol.
Pharmacological activities	Antibacterial, hepatoprotective, antitumor, antiproliferative, DNA inhibitory, cytotoxic, antioxidant, anti ulcer, immunomodulatory activities has been proven.	Antiplatelet activity, memory enhancing activity, antinociceptive activity, anti-allergic activity, hepatoprotective activity, anti-inflammatory and anti-melanogenesis activity, antifertility activity, anti ovulatory activity, anti diabetic activity, wound healing activity, anti-oxidative, free radical scavenging, and anti-hyaluronidase activity, anti-aging activity, antiulcerogenic activity, ulcerogenic activity, antimicrobial study, cytotoxicity activity, carcinogenic, toxicity study.	Hypotensive, antioxidant, anti-inflammatory, antipyretic, antiangiogenic, anti bacterial, cytotoxic, analgesic, hepatoprotective, diuretic, ⁸⁷ anthelmintic, anticancer, spermatogenic and cure sexual dysfunctions and anti- <i>Helicobacter pylori</i> activities.	Antimicrobial, antifungal, antioxidant and free radical scavenging, anti-inflammatory analgesic and antipyretic, antiuroliathatic, cytotoxic, diuretic, neuroprotective, anti-amnesic, effect on memory, cognitive enhancing, antihyperglycemic, antihyperlipidemic, hypotensive, antiulcer, anthelmintic, antitumor, wound healing, and larvicidal activities.

Methodology in various studies

Preparation of *Sufoofe sailan*

The plant material for the formulated drug was procured from the herbalist/raw drug dealer at Bangalore, Karnataka and identified and authenticated by the pharmacognosist. A specimen of each plant material used was deposited in the

drug museum, National Institute of Unani Medicine, Bangalore (voucher specimen no. 19/IS/Res./2014), for future reference. All ingredients were rinsed with running tap water and dried at 60 °C. Each ingredient was powdered and passed through no. 80 mesh sieve and mixed in the ratio mentioned in NFUM.

Table 2: Ingredients of *Sufoofe sailan* and their Proportion [32]

S.no.	Drug name	Botanical name	Part used	Proportion
1.	<i>Gule dhawa</i>	<i>Woodfordia fructosa</i> L. Kurz.	Flower	12.5%
2.	<i>Gule fofal</i>	<i>Areca catechu</i> L.	Flower	12.5%
3.	<i>Mochras</i>	<i>Bombax malabaricum</i> Dc.	Gum	12.5%
4.	<i>Gond molsri</i>	<i>Mimusops elengi</i> L.	Gum	12.5%
5.	<i>Nabat safaid</i>	Sugar	Crystals	50%

1. Standardisation studies

Standardisation of *Sufoofe sailan* by Organoleptic description, physico-chemical parameters i.e loss of weight on drying, total ash, acid insoluble ash, water soluble ash, bulk density, tapped density, hausner’s ratio, compressibility index, pH of 1% and 10% solution, Extractive values in chloroform, petroleum ether, alcohol and aqueous solvents, Qualitative analysis of all major organic and inorganic constituents done. Quantitative analysis for total alkaloids, total glycoside, and total tannins done. Desitometric HPTLC analysis, Microbiological analysis for total bacterial count, total fungal count and specific pathogens of three batches of *Sufoofe Sailan* [33].

2. Accelerated Stability studies

Finished formulation of *Sufoofe Sailan* was packed in three air tight transparent PET containers. One pack was analyzed just after manufacturing and remaining two packs were kept in stability chamber at 40°C ± 2°C/75% ± 5% RH, and analyzed after the competition of three and six months. Organoleptic, physico-chemical, microbiological parameters along with HPTLC were evaluated. All physico-chemical parameters showed changes <5%, HPTLC fingerprinting showed minimum changes and microbial studies were in confirmation to the WHO. SS confirmed to the ICH Guideline for accelerated testing of the pharmaceutical product and as per the Grimm’s statement shelf life of SS may last 20 months. [34]

3. Photostability studies

Test drug *Sufoofe Sailan* was prepared in house and evaluated for base line characters by physico-chemical parameters, HPTLC analysis and microbiological analysis. For photo challenge test drug was packed in two air tight PET container and kept in stability chamber at 40±2°C and relative humidity at 75±5%. One pack was exposed to overall illumination of 1.2 million lux hours and UV energy of 200 watt hours/square meter. Another pack was exposed to 2.4 million lux hours with UV energy of 400 watt hours/square meter. All Physico parameters tested do not show more than 5% change and were under the limit. SS confirmed to the ICH Guideline for photostability testing of pharmaceutical product [35].

Clinical study

The efficacy of Safoof Sailan in the management of Sailanur Rehm (*Bacterial Vaginosis*) has been evaluated already as a single blind, randomized placebo controlled trial was carried out on 60 patients of bacterial vaginosis at NIUM Hospital. In test group, Safoof Sailan consisting of Gule Dhawa (*Woodfordia fructicosa*) and Mocharas (*Salmalia malabarica*) 6 gm, twice daily was administered orally for 4 week. In control group, placebo was given for the same period of time. The test drug formulation was found to be more effective than control drug in Sailanur Rehm (p<0.01). Safoof Sailan was more effective than placebo in

eliminating clue cells (p<0.01) and amine odour (p<0.01) after the completion of treatment. Patients in which the test drug was found effective were followed to see the recurrence. However, only 15.7% patients had recurrence after one month of the follow up. Safoof Sailan was found effective in the management of Sailanur Rehm (*Bacterial Vaginosis*) [36].

Results

Physical charaterstics of samples of *Sufoofe sailan*
various physical standards of *Sufoofe sailan* are given below;

Table 3: Physical charaterstics of samples of *Sufoofe sailan* [32]

Parameters	Mean ±SEM
Bulk densitygm/cm3	0.48± 0.01
Tapped density	0.63±0.009
Hausner’s ratio	1.29±0.01
Compressibility index	23±1.0

Chemical Standards of *Sufoofe sailan*

Various chemical standards of *Sufoofe sailan* are given below;

Table 4: Chemical evaluation of samples of *Sufoofe sailan* [32]

Parameters	Mean ±SEM
Total ash value (% w/w)	2.57±0.02
Acid insoluble ash value(% w/w)	1.19±0.00
Water soluble ash value (% w/w)	0.77±0.01
Alcohol soluble extractive value (% w/w)	10.32±0.04
Water soluble extractive value (% w/w)	22.18±0.09
Chloroform soluble extractive value (% w/w)	1.19±0.02
Petroleum ether soluble extractive value (% w/w)	0.45±0.01
Loss on drying (% w/w)	4.7±0.03
pH 1% solution (% w/v)	4.76±0.00
pH 10% Solution (% w/v)	5.23±0.00
Alkaloid (% w/w)	2.58±0.00
Glycoside (% w/w)	0.72±0.01
Tannins (% w/w)	10.39±0.03

Phytochemical screening of *Sufoofe sailan*

All phytochemicals qualitatively checked whether they are present in samples of *Sufoofe sailan*.

Table 5: Phytochemical screening of *Sufoofe sailan* [32]
Microbiological testing of *Sufoofe sailan*:

Parameters	Results
Alkaloids	+
Glycosides	+
Tannins	+
Flavonoid	+
Carbohydrates	+
Saponins	–
Calcium	+
Copper	–
Iron	–
Magnesium	–

Total bacterial and fungal count in drug samples of *Sufoofe sailan* is enlisted in Table 6 and Presence of pathogenic bacteria in drug samples of *Sufoofe sailan* is enlisted in Table 7.

Table 6: Total bacterial and fungal count in drug samples of *Sufoofe sailan* ^[32]

Sample	Total bacterial count (cfu/g/ml)	WHO limit	Inference
Sufoofe sailan	30,000	10 ⁵ /g	Within limit
	Total fungal count (cfu/g/ml)	WHO limit	Inference
	20	10 ³ /g	Within limit
WHO: World Health Organization			

Table 7: Presence of pathogenic bacteria in drug samples of *Sufoofe sailan* ^[32]

Pathogenic bacteria	Sample of <i>Sufoofe sailan</i>
<i>Escherichia coli</i>	Absent
<i>Salmonella</i>	Absent
<i>Staphylococcus aureus</i>	Absent
<i>Pseudomonas aeruginosa</i>	Absent

Table 8: Formulation evidence status Summary of *Sufoofe sailan*

Formulation evidence status	<i>Sufoofe sailan</i>
Century old use	Yes
Clinical trial conduct	Yes
Established Standard	Yes
Established shelf life	Yes
Repeated activity in animal model	No
Consistency of ingredients used	Yes
Case studies	Yes from classical books
Others	No

Discussion

Though, *Sufoofe sailan* is very efficacious medicine, the prescription of sufoofe sailan is mentioned in various classical texts. It is observed that NFUM ^[17] Alqarabadeen ^[18] and Qarabadeen Jadeed ^[19] has common nuskha with a dose of 7 gm with fresh water while Qarabadeen Majeedi Nuskha ^[20], Murakkabat Advia Nuskha ^[21], Mukhzinul Murakkabat Nuskha ^[22] with dosages of 1gm with 25 ml milk or water, 3gm with fresh water, 10 gm with fresh water in the morning respectively.

It was evaluated for various organoleptic and physicochemical parameters. Finished product was light brown (7.5YR5/6-Panton colour chart), odourless and pleasantly sweet in taste. The physicochemical parameters expressed as mean values of the three readings calculated showed loss of weight on drying, total ash, acid insoluble ash, water soluble ash as 4.7±0.03%, 2.57±0.02%, 1.19±0.00% and 77±0.01% respectively. The mean values of bulk density, tapped density, hausner's ratio, compressibility index were 0.48±0.01gm/ml, 0.63±0.00gm/ml, 1.29±0.01 and 23±1.0% respectively. pH of 1% and 10% solution were 4.76±0.00 and 5.23±0.00 respectively. Extractive values in chloroform, petroleum ether, alcohol and aqueous solvents by non successive extraction method were 1.19±0.02%, 0.45±0.02%, 10.3±0.04%, 22.18±0.09% respectively. Qualitative analysis showed presence of all major organic constituents except saponins and steroids. In inorganic one calcium was present and magnesium, copper and iron were absent. Quantitative analysis for total alkaloids, total glycoside, and total tannins

were 2.58±0.00%, 0.72±0.01% and 10.39±0.03% respectively ^[33, 34]. Microbiological analysis showed total bacterial count 3×10⁴cfu/g, total fungal count 20cfu/g and specific pathogens were absent. Various methods and parameters for the assessment of powder dosage form are mentioned in different guideline and in the view of these guideline test drug was evaluated to set its standards, which was found in accordance to WHO standards. As no such physico-chemical profile of Suffofe Sailan is reported till date, these data could be used to lay down a set of Pharmacopoeial standards for the formulation and could be taken as standard for quality control purpose to achieve optimum efficacy and safety of medicine ^[35].

To confirm the shelf life/stability of product, change in assay from its initial value should not vary more than 5% and meet the acceptance criteria like for appearance, physical attributes etc. As the aforementioned physico-chemical changes are less than 5% and total microbial count was within the limitations offered by WHO, *sufoofe sailan* confirms to the ICH Harmonised Tripartite Guideline ^[27] for accelerated stability and photostability testing of pharmaceutical product. Grimm mentioned that predictive factor for zone IV is 3.3 of accelerated study period. It means, if product is stored for 6 months at 40 °C/75%RH, its shelf life will correspond to 20 months at 30 °CC/70% RH (of climatic zone IV). As India is assigned to climatic zone IV, according to Grimm the shelf life of SS will be 20 months at room temperature i.e. 30 °CC/70% RH (climatic zone IV-India). However, in ICH Harmonised Tripartite Guideline further it is mentioned that if no significant change at accelerated condition is found the retest period or shelf life would depend on the nature of the long-term and accelerated data. Therefore additional long term or real time stability study should be carried out. Further biologically active molecules in the formulation should be identified and its thermal/humidity and light dependent qualitative/quantitative variation along with time should be evaluated. Degradation products in the samples should be detected by appropriate physicochemical and biochemical methods to confirm whether it is toxic ^[32].

Clinical study confirmed that Safoof Sailan was found effective in the management of Sailanur Rehm (Leucorrhoea) in the dissertation work themed 'clinical Study of Sailanur Rehm and its Management with Unani Formulation' conducted at NIUM OPD. The subjective and objective parameters (Amsel's criteria) were assessed. Response to the therapy was evaluated weekly during the trial. Chi square test with Yate's correction and Fisher's exact test were used for statistical analysis. A 0.05 level was used to define statistical significance.

Formulation evidence status was checked against various parameters like Century old use, Clinical trial conduct, Established Standard, Repeated activity in animal model, Consistency of ingredients used, Case studies and found to be positive and satisfactory.

Conclusion

Sailanur rehm (leucorrhoea) is a gynaecological disorder from which a large number of women suffers and *Sufoofe sailan* is one of the famous drug for *Sailanur rehm* and mentioned in classical texts. *Sufoofe sailan* was found effective in the management of *Sailanur Rehm* since time immemorial, so it has been found to be a time tested drug. Moreover it has been checked against quality control as

standardisation studies, accelerated stability and photostability studies in my own research on this drug and was found to give satisfactory results under limit set by WHO guidelines. Formulation evidence status of *Sufoofe sailan* was also found to be satisfactory. Hence *Sufoofe sailan* can be considered as a safe and effective medicine for *Sailanur rehm*.

Conflict of Interest

None

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