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 Sailan 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 complain 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 (leucorrea), Uqr (sterility), Surate inzal (premature ejaculation) etc. It contains ingredients which are qabiz (stypic) and habis (astringent) by temperament and mugaffif (dessicant) and mugawwi (tonic) by action. It has three different muskhas 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 muskha 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 (leucorrea). 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 (leucorrhoea), 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, Bugrat (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.
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), ujp (sterility), surate inzal (premature ejaculation) etc. [3]

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.1 There are various types of sailanur rehm according to humour (khilt) involved e.g., Sailanur rehm damvi caused by excess of khile dam and the colour of discharge is reddish. Sailanur rehm safravi is caused by excess of khile safra and the colour of discharge is yellowish. Sailanur rehm saudawi is caused by excess of khile sauda and the colour of discharge is blackish. According to site e.g. Sailane farji: 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 Mumzmin. 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 Mukhrj-e-balgham (Expectorant), Muqawwi (Tonic), Habis and Qabiz (Astringent), Mudir (diuretics), Mullayin (laxative), Mus-hil (purgative), Musakkin (Algesic). 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), Gulnur (Punica granatum), Samag-e-Arbi (Acacia Arabica), Neem (Azadirica indica), Mauz (Quercus infectoria), Ajwain (Pychoitis ajowan), Shibeyamini (Alum), Kakra Seenghi (Pistacia lentiscus), Taalmaakhana (Astrachanthus longifolia), Beebandi (Sida cardifolia), Gule Supari (Accea catechu), Gule dhawa (Woodfordia fruticosa), Lodh pathani (Symlocus racemosa), Saalab misri (Orчис latifolia), Maghzh Tuhkme Tamarindini (Tamarindus indica), Tuhkme Bakain (Malia azedarach), Sandal Safaid (Santalum album), Afssanteen (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-Moohcras Halwa-e-Supari Pak Majoon-e-muqawwia-erahem Majoon-e-khabs-ul-hadeed Majoon-e-suhaag sonth Habb-e-e-Marwareed Kushta baiz-e-murg Kushta musallis Qurs-e-Kushta-khabs-ulhadeed and Sailani [8-12].

Prescriptions of Sufoofe sailan

1. NFUM17 Alqarabadeen [19] and Qarabadeen Jadeed [19] Common Nuskha:
   Ingredients: Gule dhawa (Woodfordia frutcosa L. Kurz.), Gule folaj (Areca catechu L.), Mohcras (Bombax malabaricum Dc.), Gond molsri (Mimusops elengi L.) each 6 g and Nabat saqaf (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 : Bansloochan, Beejband siyah, tukhm utangan, Tukhm khashkhash, Matioon-e-Saj Majoon, Alum, Kakra Seeng, Muthcras, Gond chinya, Gond keekar, Makhan each 25 gm 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: 1 gm with 25 ml milk or water.

3. Murakakab Advia Nuska [21]
   Ingredients: Dhaan ke pawaa ki raakh, Barg moz, kela ki Raakh, Makai ke satte, khukhli ki Raakh Each 25 gm are powdered.
   Dose: 3 gm with fresh water

4. Mukhznul Murakakab Nuska [22]
   Ingredients: Taj Qalmi, Sandal safeid, Maghzh 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 Murakakab 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 frutcosa L. Kurz.), Gule folaj (Areca catechu L.), Mohcras (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 Sufoof sailan

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Botanical name</td>
<td>Woodfordia floribunda (L.) salisb,</td>
<td>Areca catechu Linn.</td>
<td>Bombax ceiba Linn</td>
<td>Minusops elengi (L.)</td>
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<tr>
<td>Synonyms</td>
<td>Woodfordia floribunda (L.) salisb,</td>
<td>Lythrum fruticosum Linn, Grislea punctata Buch.-Ham. ex Sm.,</td>
<td>Lythrum fruticosum L. (Basionym), Woodfordia floribunda Salisb., Woodfordia</td>
<td>Areca catechu Linn.</td>
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<td>Kingdom</td>
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<td>Myrtales</td>
<td>Arecales</td>
<td>Malvales</td>
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<td>Family</td>
<td>Lythraceae</td>
<td>Arceoideae/ Araceae</td>
<td>Malvaceae (Bombacaceae)</td>
<td>Sapotaceae</td>
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<td>Genus:</td>
<td>Woodfordia</td>
<td>Areca</td>
<td>Bombax</td>
<td>Minusops</td>
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<tr>
<td>Species</td>
<td>Fructiosa</td>
<td>Catechu</td>
<td>Ceiba</td>
<td>Elengi</td>
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<tr>
<td>Vernacular names</td>
<td>English: Fire flame bush, Shiranjani tera; Persian: Gule dhana; Urdu: Dhanew ke phool; Sanskrit: Agnivala, Dhatuki, Madaniyathetu, dhoorandarah; Hindi: Davi, Dhaulo, Dhaatki ke phool, Santha, Thawi; Kannada: Belsa, Tamprapushpi; Tamil: Dhatturi, Jargi, Velakulal; Telugu: Dhatuki, Gaddaisinka, Jargi, Serinji</td>
<td>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.</td>
<td>It is widely found in temperate Asia, tropical Asia, Africa and Australia. In India, it can be found at altitudes up to 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.</td>
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### 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.
  - 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.

### Mizoj (Temperament)
- Cold 2º and Dry 2º; Cold 2º and Dry 3º
- Cold and Dry 2º or 3º; Cold 2º Dry 3º; Cold 2º Dry 2º
- Cold and Dry, Cold and Dry in 3º Cold 2º Dry 3º
- Cold and Dry 3º

### Afaal (Functions)
- Flowers are qabiz (astringent), mubarrid (refrigerant), habisud dam (haemostatic), qatil kirm shikam (anthelmintic), mujaffif.
- Flowers are mushtah (anthelmintic), balghani (phlegmatic), safravi (bilious) and
- Qabiz (constipative); qabiz ama; mujaffif (siccative); muqawwi rehm (uterine tonic); nafi sailan rehm(beneficial in
- Qabiz (constipative), habis (astringent), munsik mani, dafi jiryaan. Muqawwah bah (aphrodisiac), muqawwi meda,
<table>
<thead>
<tr>
<th>Dawai istemal (Therapeutic uses)</th>
<th>Phlegm formation</th>
<th>Mucuaff (Desiccant), mukhashin sadar (chest irritant), muzir riya (dangerous for lungs), khafgun (palpitation), sudau (headache), qoolanj qulan (collitis), sang girda wa masana (urinary bladder calculus).</th>
<th>Naffakh (Flattulent), qabiz (constipative), hazime shikm (digestive)</th>
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<td>Dried flowers are also used as</td>
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<td>Phillip (Sitz bath) in khuroojul</td>
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<td>Muzir riya (chest irritant), muzir</td>
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<td>Naffakh (flatulent), qabiz</td>
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**Adverse effects**

- **Mazarrat (Adverse effects)**

<table>
<thead>
<tr>
<th>Musleh (corrective)</th>
<th>Badal (Substitute)</th>
<th>Sandal surkh (Pterocarpus santalinus) or kishmee khuskh (Coriandrum sativum) half quantity to supari.</th>
<th>Samaaq dhaaq (Butea monospernum gum) and mastagi (Pistacia lentsicus).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zanjabeel khuskh (Zingiber officinale) or aab anar (Panica granatum Juice)</td>
<td>Gale pista (Pistacia vera)</td>
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<td>Roghan badam (Prunus dulcis oil), natab safeid (sugar) kateera (Astragalus adscendens), gond babool (Acacia nilotica) for lungs and kateera(Acacia arabica) for all conditions.</td>
<td>Shahad khali (pure honey), ghee (butter), har wa ratab advia</td>
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<td>Roghan gul (Rosa damascene oil), darchini (Cinnamomum zeylanicum), shaker (sugar), roghan badam(Prunus dulcis oil)</td>
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**Dawai istemal (Therapeutic uses)**

- **Sawda (black bile) diseases, qabiz (astringent) for oral secretions, muqavvie asnan wa lissa (strengthens the teeth and gums), musakkine hararat (febrifuge), madure boul (diuretic), habisuddam (haemostatic), nafe sailan rehm (cures leucorrhea), raada mawad, muqavvie qalb (cardiotonic) muqavvie baah (aphrodisiac), muhallile waram (anti inflammatory), and qabiz (constipative).**

- **leucorrhea); munisik mani, muqhaliz mani (increase consistency of semen); muallide mani; habise tamst (Amenorrhoea), daft fasaad khoon wa safra (purifies blood and bile); taskeen hiddat aza; muqavi anvar wa lissa (tone teeth and gums).**

- **qalb wa jigar, (stomach, cardiac and liver tonics) Muqavie dandan wa lissa (teeth and gums Tonic).**

- **Mubarrid (cooling), dafe humma (anti-putrid) muqavie qalb (cardiotonic), tiryaq (alexipharmic), muqavie meda (stomachic), qatte kieme ama (anthelmintic), qabiz(astringent), gate safra (cuts bile), nafe suzak (cures gonorrhea), nahae silanur rahem (treats leucorrhoea) Habisuddam (haemostatic), manae irq (antiperspirant) and dafae amraz balghmi wa safrawi (treats phlegmatic & bilious diseases).**

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**Phlegm formation**

- **Mujaff (Desiccant), mukhashin sadar (chest irritant), muzir riya (dangerous for lungs), khafgun (palpitation), sudau (headache), qoolanj qulan (collitis), sang girda wa masana (urinary bladder calculus).**

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**Dawai istemal (Therapeutic uses)**

- **This flower kills and excretes the intestinal worms, increase the appetite, premature ejaculation, thirst, purifies the blood, beneficial in menstruation and piles, pediatric diarrhea, pile, burns and wound healing, ishaaq (diarrhoea), kasrate tams (menorrhagia) and bawaseer damavia (bleeding piles). Abzan (Sitz bath) in khuroojul miqad (prolapse of rectum), sailanur rehem (leucorrhoea), abolishes the safra (bile) and balgham (phlegm) and act as an appetizer.**

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**Dawai istemal (Therapeutic uses)**

- **Intafakh (catartal conjunctivitis) and tarfa (haemorrhagic conjunctivitis) and other acute inflammatory conditions, foul smell of moutb 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 ashi (nervine back pain), cardiotonic and increases the vital capacity of lung, vomiting. Nausea and act as Muqavvie ama (intestinal tonic), sozish media (Gastric irritation), strengthen the teeth and gums. Excretes the bilious matter intestinal worms. jiryan, ishaaq (Diarrhoea), sailaanur rehm (Leucorrhoea), jiryan, khuroojie rehem wa miqad (Prolapse of uterus and anus) as oral powder.**

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**Dawai istemal (Therapeutic uses)**

- **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 menstruation.Nocturnal enuresis of children, jiryan, sulsuol bol (Urinary Incontinence), Kasrate tams (menorrhagia) and sailanur Rehm (leucorrhoea). It cures the stomatitis if applied locally.**

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**Dawai istemal (Therapeutic uses)**

- **Fivers, headache, throat pain, irritation and stomatitis. constipation, dysentery and diarrhea, burning micturition, renal and vesical stones. excretes the stones, pediatric dry cough, palpitation and other heart diseases, ejaculation problems. boils, ring, and other skin diseases.**

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**Dawai istemal (Therapeutic uses)**

- **Phlegm formation**

- **Mujaff (Desiccant), mukhashin sadar (chest irritant), muzir riya (dangerous for lungs), khafgun (palpitation), sudau (headache), qoolanj qulan (collitis), sang girda wa masana (urinary bladder calculus).**

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**Dawai istemal (Therapeutic uses)**

- **Naffakh (Flattulent), qabiz (constipative), hazime shikm (digestive)***

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**Dawai istemal (Therapeutic uses)**

- **Includes**

- **Mix with**

- **Use**
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.
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 Safaof 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, Safaof 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). Safaof 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. Safaof Sailan was found effective in the management of Sailanur Rehm (*Bacterial Vaginosis*)[36].

Results

Physical characteristics of samples of *Sufoofe Sailan*

Various physical standards of *Sufoofe Sailan* are given below:

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

<table>
<thead>
<tr>
<th>S.no.</th>
<th>Drug Name</th>
<th>Botanical name</th>
<th>Part used</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Gule dhawa</td>
<td><em>Woodfordia fructicosa</em> L. Kurz.</td>
<td>Flower</td>
<td>12.5%</td>
</tr>
<tr>
<td>2.</td>
<td>Gule fofal</td>
<td><em>Areca catechu</em> L.</td>
<td>Flower</td>
<td>12.5%</td>
</tr>
<tr>
<td>3.</td>
<td>Mochras</td>
<td><em>Bombax malabaricum</em> Dc.</td>
<td>Gum</td>
<td>12.5%</td>
</tr>
<tr>
<td>4.</td>
<td>Gond molsri</td>
<td><em>Minusos elengi</em> L.</td>
<td>Gum</td>
<td>12.5%</td>
</tr>
<tr>
<td>5.</td>
<td>Nabat safaid</td>
<td>Sugar</td>
<td>Crystals</td>
<td>50%</td>
</tr>
</tbody>
</table>

Table 3: Physical characteristics of *Sufoofe Sailan* [32]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean ±SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulk density/gm/cm³</td>
<td>0.48± 0.01</td>
</tr>
<tr>
<td>Tapped density</td>
<td>0.63±0.009</td>
</tr>
<tr>
<td>Hausner’s ratio</td>
<td>1.29±0.01</td>
</tr>
<tr>
<td>Compressibility index</td>
<td>23±1.0</td>
</tr>
</tbody>
</table>

Chemical Standards of *Sufoofe Sailan*

Various chemical standards of *Sufoofe Sailan* are given below:

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

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mean ±SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ash value (%w/w)</td>
<td>2.57±0.02</td>
</tr>
<tr>
<td>Acid insoluble ash value (%w/w)</td>
<td>1.19±0.00</td>
</tr>
<tr>
<td>Water soluble ash value (%w/w)</td>
<td>0.77±0.01</td>
</tr>
<tr>
<td>Alcohol soluble extractive value (%w/w)</td>
<td>10.32±0.04</td>
</tr>
<tr>
<td>Water soluble extractive value (%w/w)</td>
<td>22.18±0.09</td>
</tr>
<tr>
<td>Chloroform soluble extractive value (%w/w)</td>
<td>1.19±0.02</td>
</tr>
<tr>
<td>Petroleum ether soluble extractive value (%w/w)</td>
<td>0.45±0.01</td>
</tr>
<tr>
<td>Loss on drying (%w/w)</td>
<td>4.74±0.03</td>
</tr>
<tr>
<td>pH 1% solution (%w/v)</td>
<td>4.76±0.00</td>
</tr>
<tr>
<td>pH 10% Solution (%w/v)</td>
<td>5.23±0.00</td>
</tr>
<tr>
<td>Alkaloid (%w/w)</td>
<td>2.58±0.00</td>
</tr>
<tr>
<td>Glycoside (%w/w)</td>
<td>0.72±0.01</td>
</tr>
<tr>
<td>Tannins (%w/w)</td>
<td>10.39±0.03</td>
</tr>
</tbody>
</table>

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]

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaloids</td>
<td>+</td>
</tr>
<tr>
<td>Glycosides</td>
<td>+</td>
</tr>
<tr>
<td>Tannins</td>
<td>+</td>
</tr>
<tr>
<td>Flavonoid</td>
<td>+</td>
</tr>
<tr>
<td>Carbohydrates</td>
<td>+</td>
</tr>
<tr>
<td>Saponins</td>
<td>–</td>
</tr>
<tr>
<td>Calcium</td>
<td>+</td>
</tr>
<tr>
<td>Copper</td>
<td>–</td>
</tr>
<tr>
<td>Iron</td>
<td>–</td>
</tr>
<tr>
<td>Magnesium</td>
<td>–</td>
</tr>
</tbody>
</table>
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***

<table>
<thead>
<tr>
<th>Sample</th>
<th>Total bacterial count (cfu/g/ml)</th>
<th>WHO limit</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sufoofe sailan</td>
<td>30,000</td>
<td>10³/g</td>
<td>Within limit</td>
</tr>
<tr>
<td>Total fungal count (cfu/g/ml)</td>
<td>WHO limit</td>
<td>Inference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>10³/g</td>
<td>Within limit</td>
</tr>
<tr>
<td>WHO: World Health Organization</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 7: Presence of pathogenic bacteria in drug samples of *Sufoofe sailan***

<table>
<thead>
<tr>
<th>Pathogenic bacteria</th>
<th>Sample of <em>Sufoofe sailan</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli</em></td>
<td>Absent</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>Absent</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>Absent</td>
</tr>
<tr>
<td><em>Pseudomonas aeruginosa</em></td>
<td>Absent</td>
</tr>
</tbody>
</table>

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

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

**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 Nuska [20], Murakkabat Advia Nuska [21], Mukhzinil Murakkabat Nuska [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±0.01% respectively. The mean values of bulk density, tapped density, hauser’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 °C/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 °C/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帆anur 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

**References**