Standardization of Some Ayurvedic Formulation Used in Covid-19

Akansha Kushwaha¹, Devender Pathak², Sunam Saha^{3*}, Shivendra Kumar⁴, Kuldeep Singh⁵

 ^{1,2,3}Department of Pharmaceutical Chemistry, Rajiv Academy for Pharmacy, Mathura Uttar Pradesh (India)
^{4,5}Department of Pharmacology, Rajiv Academy for Pharmacy, Mathura Uttar Pradesh (India)

*Corresponding Author: - sunamsaha488@gmail.com

*Corresponding author: Sunam Saha

Department of Pharmaceutical Chemistry Rajiv Academy for Pharmacy, Mathura, India **E-mail address:** <u>sunamsaha488@gmail.com</u> Tel: +918794435507, + 918273427624.

Abstract

COVID-19, a severe global catastrophe spread by the corona-virus which causes severe acute respiratory syndrome (SARS-CoV-2) has emerged as one of the most dangerous transmitted diseases. Natural products and their use in respiratory infections with low toxicity is seen. In the present scenario health care system is turning to medicinal plant products. Herbal medicine includes multiple active constituents for a variety of diseases, but proper information is needed for the preparation of herbal regimens; otherwise, active constituents would be negatively affected. So, this keep in mind, Standardization parameter like ash value, acid insoluble value, acid value saponification value is discussed here. Ayurvedic Formulation like Ashwagandha, Gilroy, Tulsa, Neem, clove, pepper, Licorice is standardized for their quality, purity, inorganic content and lack of chemical constituents which causes severe problem after administration. Many preclinical and clinical trials conducted to evaluate the effect of herbal drugs which can cure and prevent the COVID-19. The herbal constituent extracted from different plant part is standardized like stem, root, leaves for their qualitative analysis which is effective against COVID-19. This review article discussing about the quality and purity and talk about the pros and cons of the herbal drug and its effect.

The use of herbal drug for Ayurvedic formulation show potent effect for mild, moderate and severe effect of COVID-19, inflammation, respiratory distress, cough, cold and loss of senses. Some Ayurvedic formulation which is present in market is gauche, Gilroy Ghavami, Tulsa Ghavami, neem Ghavami, ashwagandha Ghavami, Yoshimatsu, lixivia's rasa, Sudarshan Ghavami can be directly used to boost the immunity in long term.

Keywords: Acid value, Ayurvedic formulation, Basma, herbal formulation, SARS-CoV-2

1. Introduction

COVID-19 is still adversely affecting the human health, and economic system of the country, created a drastic change in the lifestyle and habit of the people. ^[1, 2] The novel corona virus disease (COVID-19) pandemic began in December 2019, has posed a significant threat to public health worldwide. Till now 47.2% infection cases and mortality rate is 60.9% ^[3]. Now no targeted drugs for COVID-19 have been approved with the exception of diagnosis and management such as infection, prevention, control measures and life-sustaining care by putting mask and maintaining distance from crowd of people^{.[4]} Nowadays, Herbal remedies are playing a vital role in present health care systems. ^[5] With the present demand of herbal medicine, it is important first to check about its quality and effectiveness to reduce the side effect of toxicity. With the increased use of herbal medicine, concern about quality, effectiveness with less toxicity is increased^[6] In recent days ayurved asystem of medication, standardization is a fresh and novel topic There is limited research available on the standardization parameters of Amasova, i.e., Kankava, to make sure the product's quality and safety for the consumer^[7] For thousands of years, medicinal herbs have been used as traditional treatments for a diversity of social diseases. Various part of the plant contains secondary metabolites which shows medicinal activates^[8] Organoleptic analysis, loss on drying and presence of foreign matter, and physiochemical analysis are the parameters preferred by WHO guidelines.^[9] The American Herbal Product Association defines standardization as: "It is an analytical procedure required for detecting the naturally occurring drugs for their adulteration and inorganic content. This is accomplished by using quality assurance practices in agricultural and manufacturing processes to reduce the intrinsic variation in natural product composition".^[10] The standardization of Ayurvedic formulation is necessary to formulate the herbal remedies which are collected and identified from the various region and their chemical and physical nature is scientifically checked and observed and the chemical nature and its efficacy is scientifically selected and final raw material is selected for their finished product and for mass manufacturing.^[11] Standardization only considered the isolated compound present in Ayurvedic drug which are having the therapeutic effect and less side effect. Standardization is divided in two types, one which shows therapeutic activity based on active constituent and other on marker compound which tell about the character and compound present in it.^{[12] Herbal} drug is standardized on the basis of their data present in medico-botanical, with their identification, authentication. Testing of those drugs are based according with the pharmacopoeia and pharmacogenetic survey and also by chromatographic method, testing of heavy metals physics-chemical testing, pesticide residue, microbial testing, aflatoxins analysis etc.^[13] Standardization requires good manufacturing practices for herbal drugs.^[14] The herbal drug is prepared by processing harvesting, drying and storing of plant part in suitable manner.^[15] For using Ayurvedic formulation it is compulsory to prove or identify the quality and purity of herbal drug by preparing the drug of good quality, checking organoleptic properties of drug, moisture content, contamination, ash value etc. The various external factors responsible for change in drug quality like pest, different diseases all these things are directly interlinked and deals with purity. ^[16] Phytochemical, pharmacogenetic and pharmacological studies is required for evaluation of herbal drug due to largely use of toxic drug which is unknown and misunderstood by various culture and society which is now reduced because of identification and standardization.^[17]

An increase in demand of natural drugs around the world many formulations are present.[18] SARS-CoV-2 and Human Influenza virus infection can be prevented and inhibited by use of Ayurvedic drugs^[19] From its initiation, indigenous system of medicine like Ayurvedic, yoga, unani, siddha, homeopathy (AYUSH) plays crucial role in the health care system^{.[20]}

2. Application of Ayurvedic Formulation by Aayush Used in Covid-19

2.1 Aayush kwath

AYUSH promoted the use of AYUSH kwath, marketed formulation consist of mainly four herbal species *Ocimum sanctum, Zingiber officinale, Piper nigrum, Cinnamomum verum.* It is present in powder and tablet form and used to boost immunity. ^[21,22,23,24] Ramayana drugs prepared from Gauche (Tinospora cordifolia), Ashwagandha (Withania somniferous) Yastimadhu (Glycyrrhiza glabra) were found to be effective in management of tuberculosis with anti-Koch's treatment ^[25]

2.2 Samshamani Vati

Guduchi Ghana vati (samshamani vati) is used fever. It is made up of aqueous extract of *Tinospora cordifolia* which is immuno-modulator and used in viral infection. Its composition like *Alstonia scholaris*, *Picchoriza*, *swertia chirayita*, caesalpinia crista is effective against asthma and boost immunity. Agastya Haritaki Ramayana is made up of 15 ayurvedic ingredients and used for management respiratory treatment like asthma, inflammation and also used in managing symptomatic condition of COVID-19. ^[26]

2.3 Triphala

Triphala composition like *Phyllanthus emblica*, *Terminalia bellerica*, *Terminalia chebula*. It is used in many therapeutic potentials like it shows antioxidant and antidiabetic and antimicrobial activity.^[27]

2.4 Yasthimadhu

Ayurvedic drug Yasthimadhu is used since ancient time for the use of viral diseases. Yasthimadhu is potential Ramayana used in cough, cold, sore throat and used for food supplement throughout the world. In marketed preparation it is also used as natural sweetening agent in candy, chocolate etc. It is used in various types of respiratory problem. ^[28] Yasthimadhu contain active constituent Glycyrrhizin which is active against SARS-CoV-2 and also inhibit entry of the virus in early stage.

2.5 Ayush-64

AYUSH-64 is marketed preparation from AYSUH. It is polyherbal Ayurvedic formulation and it contains *Alstonia scholaris*, *Picrorhiza kurroa*, *Swertia chirayita*, *Caesalpinia crista*. It has

been reported that it shows antimalarial activity and also used to boost immunity. It can be used in all type of COVID-19 stages mild, moderate and severe. AYUSH 64 enhances the recovery rate if administered for 14 days and if necessary, administered for 12 weeks, 500mg of dose is prescribed twice daily with warm water after meal. It is now available in market in any Ayurvedic pharmacy. It should be taken after consultation with qualified AYUSH physicians. Patient whom having initially RT-PCR report positive with symptoms like fever, nasal congestion, headache and cough can take AYUSH -64. It not only gives relief in COVID-19 and also gives better results in fatigue, anxiety, stress, appetite and also provide peaceful sleep^{.[29]}

2.6 Anuthaila

The ayurvedic practice for medications has been used from ancient times, nasya therapy i. e. for nasal drug delivery systems. Anu taila has been used in the form of nasal drops for the treatment of specific diseases like mucus discharge and many more symptomatic diseases like COVID-19. Maharishi Charka, principal contributor of Ayurvedic system of medicines has addressed the medicinal significances of Anu Taila in healing of nasal congestions. Anu taila is made with about 24 compositions. It is polyherbal formulation which inhibit the proinflammatory cytokines cell signalling molecule (TNF- α , INF- γ , 1 β , IL-8, IL-4) responsible for inflammation. Most of the potent herbal plant like Asparagus recemosus, Aquilaria agallocha, cedrus deodara, Cinnamomum verum, Coleus vettiverodes, cyperus esculentus, cyperus rotundus, Desmodium gangeticum, Elettaria cardamomum, Embelica ribes, Glycyrrhiza, Nelumbo nucifera, Ocimum sanctum, and pogostemon cablin. Anu taila consist main 20 ingredient and out of all Leptadenia reticulate shows great effect on allergy, cough relief, nasal congestion, bronchitis, upper respiratory problem. likewise, Sesamum indicum oil is used for dilating the bronchi for rough and dry cough and the infection caused by the Corona virus and Ocimum sanctum is mostly used in fever, cough and throat infection. all these ingredients used in Anu taila has been accepted scientifically in using in mild, moderate and severe condition of COVID-19.^[30]

2.7 Swasri Ras Rablet

Swasari ras tablet formulation is formulated by Patanjali research institute, and is poly-herbal. The ingredients of Ayurvedic drug are primitive and used widely for the prevention and cure relative to respiratory infection which causes severe distress and problems in lungs like bronchitis, asthma, cough. It is pre-clinically tested in Patanjali centre over thousands of patients by the research scientist.

Mulethi well known used in many formulations, the main constituent of swasri ras which is used to prevent excessive cough caused by viruses. *Glycyrrhiza glabra* interfere with the pathogenic and changeable effect (variant) of COVID-19 virus. It inhibits many viruses involving HIV, H1N1 influenza a virus syncytial (large cell of virus with many nucleus) due to anti-oxidant effect of bioactive constituents involved in Glycyrrhiza glabra like glycyrrhizin, glycyrrhizin acid, flavonoids, iso-flavonoids. This constituents from ancient time effective in treating cough, cold and chronic obstructive pulmonary disease. *Cinnamomum zeylanicum* is another most effective constituent in Swasri ras tablet, the bark is used in formulation for its analgesic and antipyretic activity. The bark contains the trans-cinnamaldehyde, eugenol as

main metabolite, which shows antioxidant, anti-inflammatory activity. It inhibits the many inflammatory mediator like IL-1 β , IL-6. Oil of cinnamon bark is effective against viral and fungal infection.^[31]

Karkatashringi is an ancient Ayurvedic herb, its gall is widely used in indigestive and respiratory problem. Its botanical name is *Pistacia integerrima* belongs to the family Anacardaceae. The oil of *Karkatashringi* is used in various types of respiratory problems, it suppresses the level of cytokins like TNF- α , IL-1 β , IL-6 which is responsible for the inflammation in lungs. The bioactive compound ethyl gallate present in galls of karkatashringi which is helpful in lung injury with the help of NF-E2-related factor 2 (Nrf2), which control the anti-oxidant factor.^[32]

The medicinal herb Rudanti or Rudravanti *Cressa cretica* is very famous herb well known for its properties for asthma, dyspepsia, bronchitis. The whole part of the plant can be used, Cressa *cretica* present with many benefits, most eminent and powerful activity for lungs. It dilates the bronchi and trigger the mast cell activity. Its better result is shown when it taken with the anti-tubercular drugs, it is best mucolytic agent, used in chest pain in lungs. The physio-chemical parameters study as follows: Table 1. The bioactive chemical constituent which shows mucolytic properties are β -sitosterol, β -sitosterol glucoside, noctacosanol-1, kaempferol and rutin possess anti-oxidant properties. ^[33]

Zingiber officinale well known by its name Ardraka or Ginger is used in household Remedies. It is anti-inflammatory activity, analgesics, anti-tumor. Its oil is used in flavouring agent and in spices. It is used to treat cough, throat infection due to its pungent effect. The main active constituents of ginger in Swasari ras tablet is 6-gingerol which is used to suppress the inflammatory cytokines TNF- α , IL-1 β , IL-12. ^[34] The various physio-chemical parameters of *Zingiber officinale* for the determination of quality and purity as follows: Table No.2

The botanical name Pippali is *Piper longum* (long pepper). which is very powerful stimulating herbal drug used in many types of aliments like in indigestion and respiratory disorder. It is very helpful in various diseases like bronchitis, in asthma, tuberculosis, severe sputum secretion. Due to its alkaloidal properties, it shows good anti-oxidative and anti-inflammatory activity. The main constituent of *Piper longum is* piperine, piperlonguminine prevents cytokines to cause inflammation in lungs. ^[35] The physio-chemical parameters as follows.

Table.3

Lavanya is used in Ayurveda in many ailments like digestive and respiratory disorder. Botanical name is *Syzygium aromatic*. The active constituents present in Lavanya is eugenol which is polyphenolic in nature and in *S. aromatic* it is present in 45-90%. It is basically used in spices as a flavouring agent. Its oil is very effective in muscle pain toothache The anti-inflammatory effect of lavanga is capable of inhibiting the inflammatory mediator and cytokines. Lavanga shows best result in inhibiting influenza HIV. ^[36]

The Akarkara is steroidal in nature as it similar to testosterone due to its steroidal nature, it is eminent for immune system. The active metabolites like N-isobutyldienediynamide, saponins, inulin. It exerts anti-oxidant property, it is used to treat cold, cough and rhinitis. It is used to treat toothache and also used as spices in food. ^[37]

Abhraka bhasma is rich in calcium, and present as calcined mica ash, which is helpful in many respiratory disorders. Mukta shukti bhasma is obtained and prepared from pearl oyster.

Kapardak bhasma is prepared and obtain from the shell of the sea animal *Cypraea moneta*. In Hindi it is known as cowry. It is effective for asthma. The Godanti bhasma is prepared from combining different material like gypsum and by mixing with the aloe-vera extract. It helps in treating the chronic lung infection by suppressing the cytokines and inhibits inflammation. The polyherbal extract of all the herbs and bhasma used in swasri ras tablet (marketed herbal formulation).^[38]

3. NEED FOR STANDARDIZATION OF HERBAL FORMULATED DRUGS

For the effective formulation the various safety measures is very important to follow for good quality drug. Proper aseptic condition and presence of appropriate and analytical procedure is required for standardization. Need for standardization of formulated drug can be standardized as the quality of traditional drug changes due to modern evolution and this become challenge, time and environment also changes the properties of the traditional drug. The seasonal variation, collecting time, sunlight, rainfall, drought. Secondary metabolites plant part like stem, root, bark, leaf contain different number of metabolites these changes account for the variation and need standardization. *"Standardization" is a procedure for providing good quality material with the help of different procedure like physical, chemical and organoleptic properties and to detect the different harmful and toxic material"*.^[39] Different standardization parameters are discussed.

3.1 Total Ash

It is used to find out the inorganic materials from organic plant material. To calculate the total ash, take 2 gm of powdered drug material and transfer it in silica crucible and now incinerate it in muffle furnace at 450 0 C up to white and the cool it in desiccator and weigh the total ash on the basis of dried drug.

3.2 Acid-Insoluble Ash

It is used to find out the impurity which is insoluble in acid. To calculate the acid-insoluble ash add 25 ml of hydrochloric acid and boil for 5 min and transfer it to silica crucible and incinerate it in muffle furnace at 450 0 C and cool it in desiccator and again weigh the ash on the basis of dried drug.

3.3 Water-Soluble Ash

It is used to determine the earthy matter remains after incineration. To calculate the value of water-soluble ash, add 25ml of distilled water and boil for 5 min now, transfer it to ashless filter paper and put it in silica crucible incinerate it at 450 0 C until it converts into white completely, cool it in desiccator and weigh it on the basis of dried drug.

3.4 Water-Soluble Extractive Value

To calculate the water-soluble extractive value, take 5gm of coarse powdered drug and transfer it into 100 ml of distilled water in stoppered conical flask for 24 hours after than filter it with filter paper than pipette out 25 ml of the extract solution in china disc and heat this disc up to evaporation dry this extract at 105 $^{\circ}$ C weigh it on the basis of dried drug.

3.5 Alcohol-Soluble Extractive Value

Same as water-soluble extractive value in place of water as a solvent extract with alcohol.

4. Conclusion

Study of various physicochemical parameters of naturally occurring drugs such as total ash, acid insoluble ash, water-insoluble ash, alcohol soluble-extractive value, water soluble-extractive value can be used for standardization of antiviral Ayurvedic drugs. Different limits obtain from this parameter indicates the drug quality and purity for COVID-19 Ayurvedic drugs. Various phytochemical constituents show antiviral activity with less side effect are having scope to use in COVID-19. Many formulated drugs in market are used in COVID-19, it is necessary to standardized them. Herbal remedies available is useful which shows less side effect and promote the immunity many Ayurvedic formulation like swasri ras, AYUSH-64, Anu-taila, Tri-phala, giloy ghanvati, Tulsi ghanvati, Neem ghanvati, Aswagandha is present and can be useful in curing and preventing the SARS-CoV-2 virus and its variant before spreading.

Conflict of interest

Author having no conflict of interest.

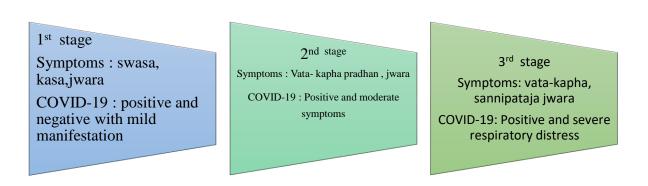


Fig.1 Flowchart for stages in COVID-1

S. No	Physicochemical parameters	Percentage limit (%)
1.	Total ash	5.23%
2.	Acid-insoluble ash	1.24%
3.	Water-insoluble ash	0.87%
4.	Sulphated ash	3.12%
5.	Water soluble-extractive value	27.7%

Table. No 1

Table. No 2

S. No	Physicochemical parameters ^[187]	Percentage limit (%)	
1.	Total ash	4.9%	
2.	Acid-insoluble ash	1.35%	
3.	Water-soluble ash	1.65%	
4.	Moisture content	4.41%	

S. No	Physicochemical parameters [API-vol-4] ^[190]	Percentage limit (%)
1.	Total ash	7%
2.	Acid-insoluble ash	0.5%
3.	water-soluble extractive value	7%
4.	Alcohol-soluble extractive value	5%

Table. No 3

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