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Physicochemical Evaluation of *Sindhuvaradi Agada* - A Polyherbal Ayurvedic Formulation

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Abstract: **Quality of drugs is the primary and basic needs of today's pharmacies to ensure the safety and efficacy of drugs when it comes to herbal origin. Though the ayurveda has explained numerous formulations to counteract the disease by adopting the assessment criteria are set in those days, there is a need of a hour to validate them based on modern tool for their safety. To assess the quality of drugs, standardization of herbal formulation is essential. This article reports on physicochemical analysis of Sindhuvaradi Agada, a polyherbal Ayurvedic medicine indicated in cobra envenomation and used by traditional Keralian Visha Vaidyas. Sindhuvaradi Agada was prepared as per classics. In-house preparation has been assessedon the basis of organoleptic characters, physical characteristics, Physico-chemical properties and Thin layer chromatography (TLC) methods. The set parameters can be used as reference for standardisation of this formulation.**

Keywords: **Sindhuvaradi Agada, Quality standards, Agada Tantra.**

1. INTRODUCTION

The Ayurvedic system of medicine gained worldwide attention due to increased side effects of drugs, lack of remedy for several chronic diseases, microbial resistance, high cost of synthetic drugs and emerging diseases. These are some facts for public interest in traditional medicines. With increase demand for safer drugs, attention has been drawn to the quality, safety, efficacy, and standards of the Ayurvedic formulations.[2]

The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy.[3]The need of quality control for Ayurvedic drugs is due to the fact that the preparation of drug according to the ancient method has been reduced due to the modernization of Ayurvedic pharmacy in present eraand there is a need of a hour to validate them based on modern tools.[4]

Sindhuvaradi Agada (SA), an Ayurvedic polyherbal formulation, consists of 3 herbs [Table 1].It is indicated in *darvikara damsha* (i.e. cobra envenomation).[1]The ingredients of SA individually exhibited antioxidant, anti-inflammatory, immuno-modulatory, analgesic activity.

Table no 1

Sl.no	Drug Name	Latin Name	Part Used	Quantity
1.	*Sindhuvara*	Vitex negundo Linn.	*Mula* (Root)	1 part
2.	*Vacha*	Acorus calamus Linn.	*Kanda*(Rhizome)	1 part
3.	*Aparajita*	Clitorea ternatea Linn.	*Mula* (Root)	1 part

The present study carried out to develop quality control parameters of *Sindhuvaradi Agada*.

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2. MATERIALS AND METHODS

Collection and Identification of plant materials:

The raw drugs used for preparation of *Sindhuvaradi Agada* were procured from available sources nearby Belgaum, Karnataka, India and authenticated by AYUSH approved Drug Testing Laboratory, KLEU's Shri. BMK Ayurved Mahavidyalaya and Research Centre, Belgaum, Karnataka.

Preparation of *Sindhuvaradi Agada:*

All the authenticated drugs were powdered separately, passed through 120 # sieve and then mixed together in specified proportions to get uniformly blended churna. To this *churna*, *bhavana* (Trituration)was given with freshly prepared *kashaya* (Decoction) of raw drugs of the same daily 6 hrs for 3 days. The rolled *Gullika* (Tablets) were shade dried and was packed in a tightly closed glass containers for further use.

Figure 1: Final product after 18Hrs of *Bhavana.*

CHEMICALS:

Solvents and chemicals of analytical grade were procured from E. Merck and S.D. fine chemicals, Mumbai.

Test Solution: Alcohol extract of raw drug and *Sindhuvaradi agada*.

Stationary Phase: Silica gel GF_{254} for TLC plates with aluminium sheet support (0.2mm thickness) (E. Merck) were used.

Mobile Phase- Toluene:Ethyl acetate (9:1v/v) was selected as solvent system through trial and error method. The developed plates were visualised under short UV (254nm), long UV (366nm) and RF values were recorded.

PHYSICO CHEMICAL EVALUATION:

SA was subjected to various analytical parameters as follows –

Organoleptic parameters: *Rupa* (colour), *Rasa* (Taste), *Gandha* (odour), *Sparsha* (Touch),[5]Physico-chemical Parameters: pH% w/v of aqueous solution.[6] Loss on drying at 110°C.[7] Ash value.[8] Acid insoluble ash.[9] Water soluble extractive.[10] Hydro alcoholic soluble extractive, methanol soluble extractive.[11]

Qualitative test for *Gullika*: Weight variation test[12] Tablet hardness test.[13] Tablet disintegration time.[14]Qualitative test for various functional groups.[16-17]

Microbial limit Test was carried out for Fungal and Bacterial study.[18]

3. RESULTS AND DISCUSSION

Organoleptic characters for finished product of SA shows - Surface was uniform and without any cracks, waslight brown in colour, SA was pungent, bitter in *Rasa* due to the ingredients as all were having bitter taste, SA having characteristic *Gandha* (odour) due to the specific ingredients,SA was harder in *Sparsha* because of reduction in particle size due to more *Mardana*. [Table2]

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TABLE 2: ORGANOLEPTIC CHARACTERS OF SA

Sr. No.	Parameters	SA
1	Colour	Light brown
2	Odour	Characteristic
3	Taste	Pungent, Bitter
4	Consistency	Hard

Physico chemical analysis – SA was made into pills of 1gm which showed reduction in weightafter drying, which indicates reduced moisture content and thus prevents the microbial content, in SA it was 2.8%w/w. Presence of inorganic substances in the formulations expresses determination of Ash value, which plays important role in standardization, more the ash value, higher the inorganic substances.In present sample Ash value was 6.71%w/w. Various components have different solubility media, present formulation solubility wasobserved for water and alcohol. Water and alcoholsoluble extractive value of SA was 39.42% and 22.31% respectively which shows that SA having morewater soluble compounds than ethanol. [Table 3]

TABLE 3: PHYSICOCHEMICAL PROPERTIES OF SA

Sr. No.	Parameters	SA
1	pH at 5% aqueous solution	7.21
2	Loss on Drying at 110^0C (% w/w)	2.80
3	Total Ash (% w/w)	6.71
4	Acid Insoluble Ash (% w/w)	4.94
5	Water Soluble Extractive (%w/w)	39.42
6	Alcohol Soluble Extractive (%w/w)	22.31

Average Weight, Disintegration time, Hardness of SA were given in [Table 4], the weight variation is +/- 2%, by this proper fixation of therapeutic dose can be achieved. Hardness and Disintegration of SA is more due to more *Mardana.*

TABLE 4: QUANTITATIVE PARAMETERS OF SA 160

Sr. No.	Parameters	SA 160
1	Wt. Variation Test	+/- 2%
2	Tab. Disintegration Time (min)	40
3	Hardness (Kg/cm^2)	10

Qualitative analysis of raw drugs as well as SA shows presence of Carbohydrates, reducing sugar, alkaloids, proteins, amino acids, fats and oils, steroids, Flavonoids, Saponins was present given in Table 5 and 6 respectively.

TABLE 5: QUALITATIVE PARAMETERS OF RAW DRUGS & SA– ORGANIC TEST

Sr. No.	Parameters	*Sindhuvara*		*Vacha*		*Aparajita*		SA	
		Aq	Al	Aq	Al	Aq	Al	Aq	Al
1	Carbohydrates	+	+	+	+	+	+	+	+
2	Reducing Sugar	+	+	+	+	+	+	+	+
3	Non reducing sugar	-	-	-	-	-	-	-	-
4	Proteins	+	-	+	-	+	-	+	-
5	Amino Acids	+	+	+	+	+	+	+	+
6	Fats and Oils	+	+	+	+	+	+	+	+
7	Volatile oils	-	-	-	-	-	-	-	-
8	Steroids	+	+	+	+	+	+	+	+
9	Glycosides	-	-	-	-	-	-	-	-
10	Saponins	+	+	+	+	+	+	+	+
11	Flavonoids	+	-	+	-	+	-	+	-
12	Alkaloids	+	+	+	+	+	+	+	+

+ Present, - Absent, Aq – Aqueous, Al – Alcoholic

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TABLE 6: QUALITATIVE PARAMETERS OF IINGREDIENTS &SA - INORGANIC TEST

Sr. No.	Parameters	*Sindhuvara*	*Vacha*	*Aparajita*	SA
1	Carbonate	-	-	-	-
2	Calcium	-	-	-	-
3	Magnesium	-	-	-	-
4	Potassium	-	-	-	-
5	Iron	+	+	+	+
6	Sulphate	+	+	+	+
7	Chloride	+	+	+	+
8	Nitrate	-	-	-	-
9	Sodium	+	+	+	+
10	Phosphate	+	+	+	+

+ Present, - Absent

Findings of Microbial limit test (MLT) is given in Table7. MLT showed there was no growth of organisms after 24hrs of incubation as per IP.

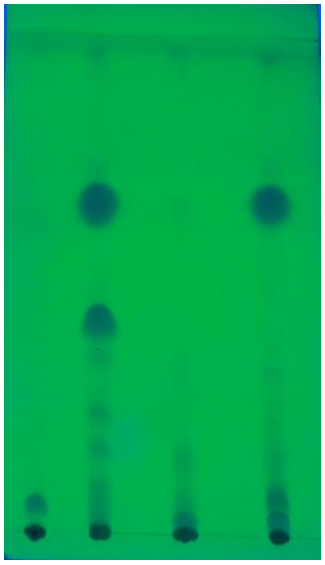
TABLE 7: MICROBIAL LIMIT TEST OF SA

Sr. No.	Pathogens	Limits (As per IP)	Results
			SA
1	E coli	Absent	Absent
2	S aureus	Absent	Absent
3	P aeruginose	Absent	Absent
4	S abony	Absent	Absent

TLC analysis – Rf values and TLC plate photograph is shown in Table 8 and Figure 2 and 3respectively.

TABLE 8: TLC - RF VALUES OF RAW DRUGS and SA

Drug	Extract	Solvent System	Spots at UV 254 nm	Spots at UV 366 nm
Sindhuvara	Ethanol extract	Toulene:Ethyl Acetate (9:1)	0.03, 0.20, 0.45, 0.63, 0.74, 0.93	0.02, 0.18, 0.42, 0.61, 0.66, 0.75, 0.90
Vacha			0.06, 0.16, 0.45, 0.68, 0.76, 0.94	0.03, 0.14, 0.20, 0.44, 0.55, 0.74, 0.88
Aparajita			0.03, 0.12, 0.23, 0.35, 0.45, 0.54, 0.68, 0.77, 0.92	0.05, 0.15, 0.28, 0.42, 0.66
SA			0.13, 0.21, 0.31, 0.45, 0.47, 0.76	0.08, 0.20, 0.32, 0.52, 0.82



UV – 254nm

Samples
Ethanol Extract of Raw drugs & *Sindhuvaradi Agada*

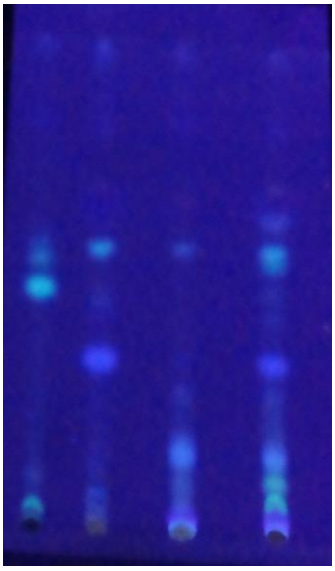
Solvent System

Mobile phase
Toulene : Ethyle Acetate[9 : 1]

Stationary phase
Pre-coated thin films of Silica plates of length 15mm

Development
Stepwise in Stahl chamber

Visualization
Under UV chamber
Short wave – 254nm
Long wave – 366nm



UV – 366nm

4. CONCLUSION

Present work carried out for development of quality standards of *Sindhuvaradi Agada*. Physicochemical, preliminary phytochemical studies and TLC profile have been useful for identity of polyherbal formulation. The results obtained from this study could be utilised for the standardization of formulations.

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