Int J Trans Res Ind Med 2020, 2(1): (P) 15 - 20

Research Article

ISSN 2582-0109

International Journal of Translational Research in Indian Medicine
www.ijtrim.com
Volume 2, Issue 1 – 2020

STANDARDIZATION AND PHYTOCHEMICAL EVALUATION OF TRADITIONAL SIDDHA FORMULATION KANA KUDINEER IN ACCORDANCE WITH ASU REGULATORY GUIDELINE

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ABSTRACT

Siddha system of medicine attains global importance in recent times as it greatly helps in management of epidemic disease control though its multiple sectorial mechanism of action. Still most of the traditional medicines are not regulated for its quality and potential as it was believed that medicines that complies the standard can be able to reach the global consumers to a greater extent. Standardization is a critical measure of ascertaining the quality of the raw material and as well as the finished formulation. Good manufacturing practice essentially impact the distribution of genuine product with high standards. Quality assessment involves series of procedure that includes identification, authentication, concentration of active principle and physicochemical norms etc. In the present study the formulation Kana Kudineer (KK) were subjected to phytochemical and physicochemical analysis in accordance with AYUSH – PLIM guidelines. Organoleptic evaluation of the formulation KK indicated with dark brownish less viscous liquid and also possess strong characteristic aromatic odor which confirms the genunity of the drug. The results obtained from the physicochemical evaluation reveals that total ash value of KK was found to 20.4%. In which the acid insoluble ash was 0.41 %. Similarly, loss on drying value at 105oC was found to be 2.5 % respectively. The results of water soluble extractive of KK were 36.6% and similarly the alcohol soluble extractive value of KK were found to be 19.53 % w/w. The result of the qualitative phytochemical analysis indicates that the formulation KK shows the presence of biologically significant phytochemicals such as steroids, triterpenoids, coumarin, phenols, tannins, saponins and sugars. From the result analysis of the present investigation it was evident that the formulation KK possess versatile bioactive phytocomponents and the physicochemical data reveals the quality and genunity of the formulation that compiles with the regulatory standards.

KEY WORDS: ***Siddha formulation, Standardization, Kana Kudineer (KK), Physicochemical, Phytochemical, Regulatory guideline***

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1. Introduction

Herbal drugs have been used since the inception of human beings on this planet and as a result is almost as old as life itself. In the modern world, the traditional (herbal) medicines assumed a significant proportion of> 83 billion dollars annual production (2008), increasing exponentially [1]. In developing countries, 70-95% of the population relies on herbal medicines for primary care mainly due to cost imperatives or unavailability of conventional drugs [2]. In India, in spite of over 80% of the population dependent upon herbal drugs; it occupies less than 2.5% of the global market share [3].

Indian system of medicine pioneers the traditional therapy in the India, of which siddha system of medicine known for serve for the humans since several centuries. Herbal medicines are popular as remedies for diseases by vast majority of world's population. Polyherbal preparations are products from medicinal plants. These are considered as safe since they are natural products. Herbal formulations which have reached widespread acceptability as therapeutic agents in India include anti-infective, immune booster, rejuvenators, antidiabetics, hepatoprotective agents, lipid lowering agents etc. Pharmacological effects of many plants have been studied in various laboratories in India [4]. However, there are many limitations regarding quality, safety and efficacy of several preparations. Knowledge about active principles and physicochemical properties of herbal preparations greatly helps in understanding the category of therapeutic that actually involved in fetching the desired pharmacological action.

Herbal medicines usually tend to have several broad complementary or synergistic actions on physiological systems at the same time which are usually in the same general therapeutic direction, and often non-specific [5-8]. Herbal medicine actions are too complex and usually cannot be adequately described in this context several attempts have been made globally to elucidate the mechanistic action of several traditional drugs against specific ailment [9-10]. WHO 1993 guidelines stated that the responsibility of quality assurance of herbal medicinal products has to be shared equally by manufacturers and regulatory bodies [11]. It is the responsibility of regulatory authorities to establish guidelines on diverse aspects of quality assurance, dossiers and data evaluation and evaluation of post marketing compliance of products with the specifications set out by the producers as well as compliance with GMP [12-14].

Kana Kudineer is a versatile polyherbal preparation which majorly comprises of the ingredients such as Ocimum sanctum, Centella asiatica, Aegle marmelos, Syzygium cumini, Aloe vera, Cyperus rotandus and Myristica fragrans. Decoction of this formulation widely used as an ailment for treating many number of disease and disorders. The objective of the present investigation is to systematically standardize the formulation Kana Kudineer (KK) as per AYUSH – PLIM guideline and to explore the physicochemical and phyto-therapeutic profile present in the formulation.

2.Materials and Methods

2.1. Ingredients [15-17]

The major ingredient present in the formulation Kana Kudineer are Ocimum sanctum, Centella asiatica, Aegle marmelos, Syzygium cumini, Aloe vera, Cyperus rotandus and Myristica fragrans

2.2. Source and authentication of raw drug

Raw drugs were bought from Indigenous authentic country drug shop at Chennai, Tamil Nadu, India. Herb were identified and authenticated by the Botanist of Central Council for Research in Siddha, Tamil Nadu, India.

2.3. Method of preparation

The above mentioned raw drug were purified as per the standard operating procedure and subjected to formulation.

Figure 1: Crude Drug and Decoction form of Kana Kudineer - KK

2.4. Physicochemical Evaluation [18,19]

Organoleptic evaluation of the drug was made with respect to state, appearance, nature and odor etc.

2.4.1. Percentage Loss on Drying

Test drug was accurately weighed in evaporating dish. The sample was dried at 105oC for 5 hours and then weighed.

2.4.2.Determination of Total Ash

Test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

2.4.3.Determination of Acid Insoluble Ash

The ash obtained by total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in crucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

2.4.4.Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

2.4.5.Determination of Water Soluble Extractive

Test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand and for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

2.5. Preliminary Phytochemical Investigation [20]

Test for alkaloids

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarin

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids

To the test sample, 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

Aanthocyanin

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100ºC. Formation of bluish green colour indicates the presence of anthocyanin.

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

3.Results

3.1. Results of Physicochemical Analysis of KK

Organoleptic evaluation of the formulation KK indicated with dark brownish less viscous liquid and also possess strong characteristic aromatic odor which confirms the genunity of the drug. The results obtained from the physicochemical evaluation reveals that total ash value of KK was found to 20.4%. In which the acid insoluble ash was 0.41 %. Similarly, loss on drying value at 105oC was found to be 2.5 % respectively. The results of water soluble extractive of KK were 36.6% and similarly the alcohol soluble extractive value of KK were found to be 19.53 % w/w. As shown Table 1.

Table 1: physicochemical evaluation of *Kana Kudineer*

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	2.5 ± 0.360
2.	***Total Ash (%)***	20.4 ± 27.37
3.	***Acid insoluble Ash (%)***	0.4133 ± 0.11
5.	***Alcohol Soluble Extractive (%)***	19.53 ± 1.097
6.	***Water soluble Extractive (%)***	36.6 ± 5.451

3.2. Qualitative Phytochemical evaluation of KK

The result of the qualitative phytochemical analysis indicates that the formulation KK shows the presence of biologically significant phytochemicals such as steroids, triterpenoids, coumarin, phenols, tannins, saponins and sugars. The results were tabulated in Table 02 and shown in figure 2.

Table 2: Preliminary phytochemical analysis of *Kana Kudineer*

S.NO	TEST	OBSERVATION
1	ALKALOIDS	-
2	FLAVANOIDS	-
3	GLYCOSIDES	-
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANIN	+
9	PROTEIN	-
10	SAPONINS	+
11	SUGAR	+
12	ANTHOCYANIN	-
13	BETACYANIN	-

+ -> Indicates Positive and - -> Indicates Negative

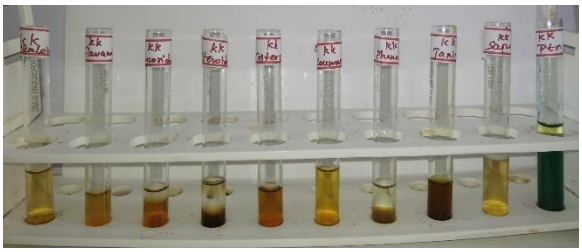

Figure 2: Preliminary phytochemical observation of Kana Kudineer

4.Discussion

It was evident from the literature that nearly 80% to 90% of the population around the globe are majorly depend on herbal drugs for most of their primary healthcare needs. But it is also a fact that in these populations, the herbal drugs are not much regulated [21]. It was reported "that about 80% of people in developing countries depended on herbs but contributed only 7.2% to the trade in 1999. By contrast, the developed nations, where people relied less on herbs, contributed 55.2% Asia, less Japan and South Korea, contributed 37.6% [22] These vast difference can be attributed to the regulation of herbal drugs in developed countries where herbal drugs are produced and utilized in accordance with good manufacturing practice (GMP) and good clinical practice, respectively. In Asian countries like China, India, and Korea, traditional is treated with same respect as modern pharmaceutical and are also included in the national health scheme.

Phytochemical constituents such as alkaloids, flavonoids, tannins, phenols, saponins, and several other aromatic compounds are secondary metabolites of plants that are tend to possess several biological applications in treating disease of humans and also involved in protecting herbs from stressful condition [23]. The medicinal properties and pharmacological actions of these phytocomponents are well-known to Indian traditional medicine. Medicinal herbs are known to contain various active principle of therapeutic value and possess biological activity against a number of diseases [24]. The result of the qualitative phytochemical analysis of the present study indicates that the formulation KK shows the presence of biologically significant phytochemicals such as steroids, triterpenoids, coumarin, phenols, tannins, saponins and sugars.

Quality control on herbal formulation ensures standard of the products by following well-structured and standard specifications. Such information about standard specifications can be found in official pharmacopeias, monographs, handbooks, etc [25]. To check the quality of herbal products, various analytical techniques may be used. While choosing analytical methods, factors such as validity, precision, accuracy, and robustness of the method must be considered. With the advent of sophisticated techniques, it is possible to identify as well as quantify the test substance [26].

Physicochemical analysis is one such prescribed standard available to validate the quality and genunity of the prepared formulation. In the present investigation organoleptic evaluation of the formulation KK indicated with dark brownish less viscous liquid and also possess strong characteristic aromatic odor which confirms the genunity of the drug. The results obtained from the physicochemical evaluation reveals that total ash value of KK was found to 20.4%. In which the acid insoluble ash was 0.41 %. Similarly, loss on drying value at 105oC was found to be 2.5 % respectively. The results of water soluble extractive of KK were 36.6% and similarly the alcohol soluble extractive value of KK were found to be 19.53 % w/w.

5.Conclusion

Globalization and scope of Indian medicine in the international forum occupies considerable significance due to high therapeutic index against several disease and disorders. Hence systematic studies of documenting the profile of each viable formulation has to be made by the researcher and physicians in the field of Indian medicine. Traditional preparation is in potential need of standardization in order to showcase the benefits to the global consumers. It was well established through the present study that the siddha formulation KK possess biologically active phytocomponents such as steroids, triterpenoids, coumarin, phenols, tannins, and saponins further results on physicochemical analysis explorate the standard and genunity of the formulation as per the guideline.

Acknowledgement

We wish to acknowledge my thanks to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, Tamil Nadu, India and The Noble research solutions, Chennai, Tamil Nadu, India for their support.

6. References

1. National policy on traditional medicine and regulation of herbal medicines: Report of a WHO global survey. Geneva: World Health Organization, “Introduction”; 2005. p. 143.
2. WHO Traditional medicine strategy 2002–2005. Geneva: World Health Organization, “Global review”; 2002. p. 66.
3. Guidelines on registration of traditional medicines in the WHO African Region. Brazzaville: World Health Organization Regional Office for Africa,” Background and Purpose”; 2004. p. 40.
4. B Ravishankar. Indian Systems of Medicine: A Brief Profile. Afr J Tradit Complement Altern Med. 2007; 4(3): 319–337.
5. Nasri H. Cisplatin therapy and the problem of gender-related nephrotoxicity. J Nephropharmacol 2013; 2(2): 13-4.
6. Haq I. Safety of medicinal plants. Pak J Med Res 2004; 43(4): 203-10.
7. Nasri H. Renoprotective effects of garlic. J Renal Inj Prev 2012; 2(1): 27-8.
8. Kazemipoor M, Radzi CW, Cordell GA, Yaze I. Safety, efficacy and metabolism of traditional medicinal plants in the management of obesity: a review. Int J Chem Eng Appl 2012; 3(4): 288-92.
9. Rafieian-Kopaie M. Medicinal plants for renal injury prevention. J Renal Inj Prev 2013; 2(2): 63-5.
10. Hajian S. Renoprotective effects of Green tea. J Nephropharmacol 2013; 2(2): 21-2.
11. Geneva: World Health Organization; 1993. World Health Organization. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.
12. De Smet PA. Herbal remedies. N Engl J Med. 2002;347:2046–56.
13. Chadwick L, Fong H. Herb quality assurance and standardization in herb-drug interaction evaluation and documentation. In: Lam YW, Huang SM, Hall SD, editors. Herbal Supplement-Drug Interactions. Taylor and Francis: New York; 2006. pp. 191–203.

14. Geneva: World Health Organization; 1998. World Health Organization. Regulatory Situation of Herbal Medicines. A Worldwide Review.
15. Kuzhanthai maruthuvam(Balavagadam),Maru.Pon.Guru Sironmani,Page no.-194
16. Suraj Gupta Textbook of Paediatrics –Page no.1056
17. Pillai pini maruthuvam part-II, Dr.A.Sundararajan, Page no.-172,173,259,260,385.
18. India Pharmacopeia I Volume I, Government of India, Ministry of Health and Family welfare, Indian Pharmacopeia commission, 2014.
19. Pharmacopoeial Laboratory for Indian Medicine (PLIM) Guideline for standardization and evaluation of indian medicine which include drugs of Ayurveda, Unani and Siddha systems. Department AYUSH .Ministry of Health & Family Welfare, Govt. of India
20. Brain KR, Turner TD. The Practical Evaluation of Phytopharmaceuticals. Bristol:Wright-Scientechnica; 1975:36-45
21. WHO. Traditional Medicine. WHO Fact Sheet No. 134.www.http://tinyurl.com/5mrd5 .
22. Ameh SJ, Obodozie OO, Abubakar MS, Garba M. Current phytotherapy – An inter-regional perspective on policy, research and development of herbal medicine. J Med Plants Res. 2010;4:1508–16.
23. Bonjar GH, Nik AK, Aghighi S. Antibacterial and antifungal survey in plants used in indigenous herbal-medicine of south east regions of Iran. J Biol Sci. 2004;4:405–12.
24. Ayyanar M, Ignacimuthu S. Pharmacological actions of Cassia auriculata L. and Cissus quadrangularis Wall: A short review. J Pharmacol Toxicol. 2008;3:213–21.
25. Manila: World Health Organization, Western Pacific Region; 2000a. World Health Organization. Traditional and Modern Medicine, Harmonizing the Two Approaches.
26. New Delhi: Regional Office for South-East Asia; 2003b. World Health Organization. Guidelines for the regulation of herbal medicines in the South-East Asia Region.