e-ISSN: 2249 – 7781
Print ISSN: 2249 – 779X

International Journal of Pharmaceutical Research & Analysis
www.ijpra.com

Research Article

COMPARATIVE MONOGRAPH ANALYSIS OF COMMERCIALLY AVAILABLE KABASURA KUDINEER

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ABSTRACT

Kabasura Kudineer is the siddha formulation which is in the form of powder, capsule, tablet etc. These formulations consist of 13 to 15 different plant extract which shows the suitable efficacy. It is used to treat fever and respiratory problem. Thus, it has Anti-oxidant, Anti-inflammatory, Anti-pyretic property. During the previous outbreak of dengue, chikungunya and swine flu in Tamil Nadu Kabasura kudineer were used to control the dreadful disease. The present pandemic has increased the public attention towards the benefits of Kabasura kudineer in Tamil Nadu. It is used in COVID 19 as prophylactic and as a treatment. There are various commercially available of Kabasura kudineer in market. To check its standards, here we conduct different monograph analysis for some available marketed brands compare with the standard reference. The physicochemical and phytochemical characterization of the samples was carried out in accordance with the standards laid down by Indian Pharmacopoeia (IP) 2018. HPTLC profiling of key constituents including phenol, flavonoids, tannin, steroids and alkaloids were also carried out in accordance with IP 2018 monographs. The chromatographic analysis showed the presence of all major ingredients in both commercially available sample and the standard and all the physicochemical and phytochemical properties were also found similar among preparations. Our findings may boost the global recognition of Kabasura kudineer is used to increase the immune system.

Keywords: Kabasura kudineer chooranam, High Performance Thin Layer Chromatography, Polyherbal formulation, physiochemical evaluation.

INTRODUCTION

The alarming increase in the disease rates and the global population that are vulnerable to disease nowadays in attributed to population, unhealthy lifestyle and environment toxin created by mankind itself.

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To control and eliminated the deadly disease the concept ‘immunization’ is brought up. Immunization is increased by the concept of ‘immune booster’ which is popular of its vast knowledge and exposure in the field of medicine and healthcare. Alternative medicines have proven to boost immune reactions over the diseases. Plant based drugs are deemed safe to humans and their surrounding compared to other artificial formulation in so called modern era in which people live today. During an earlier epidemic of dengue, chikungunya and swine flu in Tamil Nadu, Kabasura kudineer Chooranam (KSK) were

used to control the febrile disease. The present covid pandemic has increased the public attention towards the benefits of Kabasura kudineer in Tamil Nadu. It will be increasing the immunity level and controlling the spread of community disease among general public**.** Considering the importance by the government of Tamil Nadu and the government of India on recommending Kabasura kudineer as a mean to fight viral infection and improve immunity. [1]. Due to its diverse therapeutic effect is great important to scrutinize the commercial formulations KSK chooranam.

KABASURA KUDINEER

Kabasura Kudineer, reported in Siddha texts as "Citta Vaittiyattirattu", is used for Aiyacuram (phlegmatic fevers) and is a potential medicine for cough, sore throat, high fever and difficulty in breathing. It consists of 15 distinct herbal ingredients, each of them having unique characteristic features of its own. "Kabasura Kudineer" in Siddha means fever due to immoderate accumulation of "Kapha" and this chooranam works by settling the "kapha dosha" which is infamous for infecting the respiratory system. The chooranam is highly effective for providing symptomatic relief in conditions associated with respiratory ailments such as fever, cough and cold, breathing difficulty and treating flu [2].

Kabasura Kudineer decoction may be given two times a day, after food to paediatrics (5 mL for <5 years, 10 mL for 5-12 years age group), adolescents (30 mL), adults (60-90 mL for 18-60 years age group) and geriatrics (60 mL for >60 years). The chooranam is generally available in powdered form and consumed after pouring it in lukewarm water and making a decoction or kadha like consistency. At present, limited standards are available for Siddha polyherbal preparations. Presently, it is very difficult to identify the presence of all the ingredients as claimed in a polyherbal formulation. Hence, the prime task is to evolve such parameters by which the presence of ingredients can be checked. Assessment of physicochemical properties and various chromatographic methods can be attempted to generate pattern for identifying the presence of different ingredients [3].

This study is carried out in the context of growing public interest for traditional systems of medicine. In present study, we characterized the commercially available Kabasura Kudineer Chooranam with respect to its physicochemical properties (organoleptic properties, pH, loss on drying, total ash, ethanol soluble extractives and water-soluble extractives) and HPTLC profiling of key marker compounds as per pharmacopoeial methods. The standardization of Kabasura kudineer were depicted in table 1.

MATERIALS AND METHODS

Collection of herbal formulation for monograph analysis

The five different marketed formulations of Kabasura kudineer were procured from Pharmacy Shop, among the five formulations, IMCOPS product was used as a Reference Standard material for monograph analysis. Other formulations were named as Sample 1, Sample 2, Sample 3, Sample 4.

DIFFERENT MONOGRAPH ANALYSIS METHOD

- Organoleptic evaluation
- Powder microscopic evaluation
- Proximate analysis
    1. Ash value
    2. Extraction value
    3. Moisture content
- Extraction process
- Preliminary phytochemical screening
- Estimation of total phenolics and flavonoids
- High Performance Thin Layer Chromatography

The above-mentioned methods are done with standard procedures.

RESULTS

The obtained results for comparing standard and sample were tabulated in table 2 (organoleptic character), table 3 (powder microscopy), table 4 (ash value), table 5 (moisture content), table 6 (ethanolic extractive value), table 7 (water soluble extractive value), table 8 (Preliminary phytochemical screening).The total phenolic content and flavonoid content using UV spectroscopy for sample 1-5 were performed and compared with standard. The standard curve for total phenolic and Flavanoid content were given in figure 1 & 2. The results obtained from standard curve were given in table 9.

DERIVATIZATION WITH ANISALDEHYDE SULPHURIC ACID @520 nm

Derivatization with Anisaldehyde sulphuric acid @520 nm were performed and the obtained results of visualization, fingerprinting, peak display were figured in figure 3. The Rf and area were tabulated in table 10. The most intense peak of STD and sample of KSK after derivatization @520nm were track 1 (4 peaks) track 2 (2 peaks) track 3(5 peaks) track 4 (6 peaks) and track 5 (4 peaks).

DERIVATIZATION WITH 5% FERRIC CHLORIDE REAGENT @520nm

Derivatization with 5% Ferric Chloride Reagent @520 nm were performed and the obtained results of visualization, fingerprinting, peak display were figured in figure 4. The Rf and area were tabulated in table 11. The most intense peak of STD and sample of KSK after

derivatization @520nm were track 1 (1 peaks) track 2 (1 peaks) track 3 (1 peaks) track 4 (1 peaks) track 5 (2 peaks).

DERIVATIZATION WITH ALUMINIUM CHLORIDE @366nm

Derivatization with aluminum chloride @366nm were performed and the obtained results of visualization, fingerprinting, peak display were figured in figure 5. The Rf and area were tabulated in table 12. The most intense peaks were track 1 (1 peaks) track 2 (1 peaks) track 3 (1 peaks) track 4 (1 peaks) track 5 (2 peaks).

DERIVATIZATION WITH LIBERMAN BURCHARD REAGENT @366nm

Derivatization with Liberman Burchard Reagent @366nm were performed and the obtained results of visualization, fingerprinting, peak display were figured in figure 6. The Rf and area were tabulated in table 13. The most intense peaks were track 1 (9 peaks) track 2 (11 peaks) track 3 (11 peaks) track 4 (8 peaks) and track 5 (7 peaks).

DERIVATIZATION WITH DRAGENDORFF REAGENT @520nm

Derivatization with Dragendroff's reagent @520nm were performed and the obtained results of visualization, fingerprinting, peak display were figured in figure 7. The Rf and area were tabulated in table 14. The most intense peaks of track were track 1 (2 peaks) track 2 (4 peaks) track 3 (2 peaks) track 4 (2 peaks) and track 5 (3 peaks).

Table 1: Standardized Ingredient of Kabasura Kudineer Chooranam (Kopala Narayana Sunil Kumar et al., 2021)

S.NO	Botanical name of the plant	Family	Category	Constituents Reported
1.	Justicia Achatina	Acanthaceae	Flavonoid	Quercetin
2.	Anacyclus Pyrethrum	Asteraceae	Sterol	Coumestrol
3.	Coleus amboinicus	Lamiaceae	Monoterpene	Carvacrol
4.	Piper longum	Piperaceae	Alkaloid	Piperine
5.	Tinospora cordifolia	Menispermaceae	Sesquiterpene	Tinocordifolin
6.	Cyperus rotundus	Cyperaceae	Flavanoid 8-c-glycosides	Vitexin
7.	Clerodendrum infortunatum	Verbanaceae	Flavonoids	Apigenin
8.	Saussurea lappa	Asteraceae	Sesquiterpene	Costunolide
9.	Andrographis paniculata	Acanthaceae	Terpene	Ninandrographolide
10.	Terminalia chebula	Combretaceae	Phenol	Ellagic acid
11.	Syzygium aromaticum	Myrtaceae	Monoterpene	p-Cymene
12.	Tephrosia purpurea	Fabaceae	Flavonoids	Flavones
13.	Cissampelos pareira	Menisperaceae	Alkaloids	Hayatine
14.	Zingiber officinale	Zingiberaceae	Volatile, phenolic acids	Zingiberene
15.	Hygrophilla auriculata	Acanthaceae	Phytosterols	β-sitosterol

Table 2: Organoleptic character of STD and sample of KSK

S. No	Name of the formulation	Colour	Odour	Appearance and texture	Taste
1.	Reference Standard	Brown	Pungent	Coarse and fibrous	Bitter
2.	Sample 1	Brown	Pungent	Coarse and fibrous	Bitter
3.	Sample 2	Brown	Pungent	Coarse and fibrous	Bitter
4.	Sample 3	Brown	Pungent	Fine and smooth	Bitter
5.	Sample 4	Brown	Pungent	Coarse and fibrous	Bitter

Table 3: Powder microscopic characters of STD and sample of KSK

S. No	Name of the formulation	Observation
1.	Reference standard	Presence of fiber, xylem, crystals, trichome, cork tissue, stomata, peridermal cell, stone cell etc.
2.	Sample 1	
3.	Sample 2	
4.	Sample 3	
5.	Sample 4	

Table 4: Ash value of STD and sample

S. No	Name of the formulation	Percentage of the Total ash(%w/w)
1.	Reference standard	7.7%
2.	Sample 1	8.35%
3.	Sample 2	8.25%
4.	Sample 3	8.45%
5.	Sample 4	8.52%

Table 5: Moisture content

Sl. No.	Name of the Formulation	Percentage of the Moisture Content
1	Reference Standard	6%
2	Sample 1	4.4%
3	Sample 2	9.2%
4	Sample 3	8.4%
5	Sample 4	9.4%

Table 6: Extractive value of ethanolic extract of STD and sample

S. No.	Name of the formulation	Percentage of the extract (w/w%
1.	Reference Standard	1.2%
2.	Sample 1	2.2%
3.	Sample 2	1.2%
4.	Sample 3	2.2%
5.	Sample 4	2.6%

Table 7: Extractive value of aqueous extract of STD and sample

S. No.	Name of the formulation	Percentage of the extract (w/w %)
1.	Reference standard	1.6%
2.	Sample 1	1.6%
3.	Sample 2	1.4%
4.	Sample 3	2.4%
5.	Sample 4	0.6%

Table 8: Preliminary phytochemical screening of STD and sample

S. No	PHYTOCHEMICAL SUBSTANCE	OBSERVATION				
		IMCOPS	SAM 1	SAM 2	SAM 3	SAM 4
1	**Carbohydrate**	Positive	Positive	Positive	Positive	Positive
2	**Alkaloids**	Positive	Positive	Positive	Positive	Positive
3	**Phenol**	Positive	Positive	Positive	Positive	Positive
4	**Tannin**	Positive	Positive	Positive	Positive	Positive
5	**Flavanoids**	Positive	Positive	Positive	Positive	Positive
6	**Saponins**	Positive	Positive	Positive	Positive	Positive
7.	**Protein and amino acid**	Negative	Negative	Negative	Negative	Negative

Table 9: Total phenolic content and Flavanoid content

S. No.	Samples	Phenolic Content (Gallic Acid Equivalent)	Flavanoid Content (Quercetin Equivalent)
1.	Reference Standard	**100 mg / g**	**246.6 mg / g**
2.	Sample 1	**160 mg / g**	**260 mg / g**
3.	Sample 2	**200 mg / g**	**264.4 mg / g**
4.	Sample 3	**140 mg / g**	**275.5 mg / g**
5.	Sample 4	**180 mg / g**	**275.5 mg / g**

Table 10: Rf and AUC With Anisaldehyde Sulphuric Acid @520nm

Peak	Track 1		Track 2		Track 3		Track 4		Track 5	
	Rf	Area	Rf	Area	Rf	Area	Rf	Area	Rf	Area
1	0.14	1017.4	0.06	108.7	0.06	143.8	0.13	698.2	0.31	1326.8
2	0.20	134.8	0.13	237.0	0.13	508.5	0.16	144.2	0.68	492.0
3	0.23	739.2	0.16	174.5	0.16	125.8	0.23	239.5	0.73	345.1
4	0.27	121.4	0.20	251.4	0.23	737.3	0.30	421.8	0.89	1058.7
5	0.34	903.6	0.23	852.9	0.29	441.1	0.39	601.0	0.96	1988.2
6	0.39	521.7	0.34	498.1	0.33	679.3	0.47	534.3	0.99	1023.8
7	0.51	2190.4	0.39	702.6	0.39	687.6	0.52	1044.8		
8	0.59	997.6	0.45	240.1	0.53	1140.4	0.59	1510.9		
9	0.63	1249.1	0.64	1236.2	0.60	1543.9	0.66	2839.7		
10	0.73	193.7	0.66	1234.6	0.65	3493.4	0.73	557.1		
11	0.77	295.2	0.73	223	0.73	1480	0.85	1147.9		
12	0.84	789.6	0.89	306.5	0.78	680.9	0.88	1882.5		
13	0.97	1920.3	0.96	275.1	0.84	1745.5	0.96	2586.0		
14	0.99	362.2	0.99	442.9	0.86	1284	0.99	636.4		
15					0.96	3082.7				

Table 11: Rf Value and AUC peaks after derivatization with 5% ferric chloride reagent @520nm

Peak	Track 1		Track 2		Track 3		Track 4		Track 5	
	Rf	Area	Rf	Area	Rf	Area	Rf	Area	Rf	Area
1	0.07	3181.5	0.07	1323.3	0.08	1959.4	0.08	1863.5	0.08	1379.0
2									0.26	3502.4
3									0.28	2101.4
4										

Table 12 - Rf Value and AUC peaks after derivatization with aluminum chloride @366nm

Peak	Track 1		Track 2		Track 3		Track 4		Track 5	
	Rf	Area	Rf	Area	Rf	Area	Rf	Area	Rf	Area
1	0.03	208.1	0.03	435.3	0.05	394.9	0.04	4539.8	0.03	2202.1
2	0.11	1071.7	0.12	838.7	0.12	1253.1	0.11	2693.5	0.12	3509.5
3	0.16	1259.6	0.17	1224.2	0.16	938.8	0.14	3690.3	0.18	1336.2
4	0.20	773.7	0.26	4476.4	0.24	2224	0.24	1910.5	0.24	1137.2
5	0.24	1797.7	0.35	5868.7	0.29	1130.1	0.29	1379.8	0.29	825.1
6	0.28	1557.5	0.39	4030.4	0.35	2083.5	0.35	2637.9	0.35	1806.4
7	0.30	1281.4	0.46	8867.9	0.39	1252.9	0.39	1412.2	0.39	1251.2
8	0.36	2333.6	0.51	2020.2	0.43	2792.2	0.43	2107.4	0.43	2269.4
9	0.40	1621.9	0.59	4483.3	0.57	1394.3	0.54	927.1	0.65	1340.6
10	0.45	1837.8	0.64	2299.4	0.65	3605.7	0.65	2876.3	0.67	887.8
11	0.60	1421.0	0.67	1358.0	0.72	236.1	0.68	493.8	0.85	19691.9
12	0.67	3637.4	0.76	2046.3	0.75	487.5	0.72	459.9	0.95	3163.0
13	0.76	900.9	0.83	10024.2	0.86	5440.7	0.74	477.1	0.99	739.2
14	0.84	17848.9	0.84	7906.0	0.94	8838.7	0.84	14614.3		
15	0.94	6494.5	0.88	4748.2	0.96	2630.8	0.89	4104.3		
16	0.96	496.2	0.93	5300.4	0.97	214.3	0.94	5524.3		
17	0.98	2002.4	0.96	764.2			0.99	1002.9		
18			0.98	504.0						
19			0.99	670.7						

Table 13: Rf Value and AUC peaks derivatization with Liebermann Burchard reagent @366nm

Peak	Track 1		Track 2		Track 3		Track 4		Track 5	
	Rf	Area	Rf	Area	Rf	Area	Rf	Area	Rf	Area
1	0.04	768.8	0.05	1495.3	0.06	3596.0	0.13	13301.5	0.09	6223.5
2	0.13	5408.3	0.12	8566.6	0.11	2406.0	0.24	28983.4	0.14	11885.8
3	0.17	6184.0	0.22	19207.5	0.13	3404.3	0.32	7132.9	0.19	17920.0
4	0.21	19319.0	0.26	8674.3	0.18	6198.9	0.37	19473.7	0.25	26169.9
5	0.31	9927.7	0.32	9299.4	0.23	14760.6	0.43	13974.7	0.3	7586.2
6	0.37	15057.2	0.37	11518.9	0.26	3267.0	0.53	20880.5	0.33	11773.1
7	0.41	10542.0	0.45	17524.8	0.31	6807.5	0.64	18302.5	0.38	30003.4
8	0.52	8990.4	0.52	6293.3	0.38	16978.4	0.72	13777.9	0.43	15385.7
9	0.62	10834.6	0.58	5890.0	0.42	3077.3	0.78	2634.7	0.47	7320.3
10	0.71	23220.5	0.63	10873.9	0.44	5678.4	0.81	2294.9	0.52	25437.3
11	0.92	2171.1	0.70	9675.8	0.5	5161.0	0.83	2914.0	0.65	20178.2
12	0.94	3665.0	0.79	1945.2	0.53	4552.0	0.96	13943.5	0.72	14525.3
13	0.98	333.9	0.82	2312.3	0.57	3870.0	0.98	1360.3	0.79	11770.0
14			0.94	10596.7	0.59	2749.4			0.89	4887.6
15			0.98	794.3	0.64	15193.2			0.95	5502.5
16					0.7	10514.4			0.98	816.2
17					0.74	2050.2				
18					0.8	5406.8				
19					0.95	13601.8				
20					0.98	1652.8				

Table 14: Rf Value and AUC derivatization with dragendroff's reagent @520nm

Peak	Track 1		Track 2		Track 3		Track 4		Track 5	
	Rf	Area	Rf	Area	Rf	Area	Rf	Area	Rf	Area
1	0.09	7142.1	0.08	3680.5	0.08	2421.7	0.09	3278	0.1	2721.6
2	0.28	1299.9	0.28	2373.9	0.17	3219.9	0.21	1633.3	0.33	3399.7
3	0.62	1748.8	0.44	3478.2	0.29	3924.5	0.29	3159.7	0.44	3047.6
4	0.86	3730.5	0.63	6276.7	0.86	1566.4	0.44	1987.2	0.47	3531.5
5			0.72	7950.1			0.57	3087.2	0.77	15633.0
6			0.86	2714.2			0.77	7531.2		
7										

Figure 1: Standard curve for gallic acid

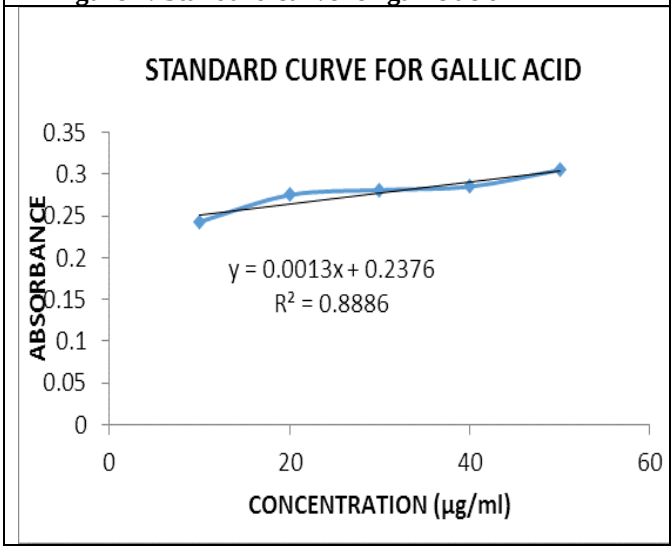


Figure 2: Standard curve for Quercetin

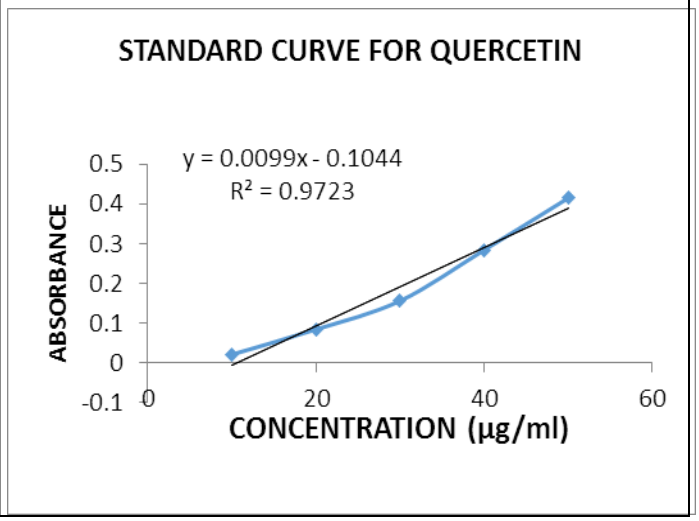
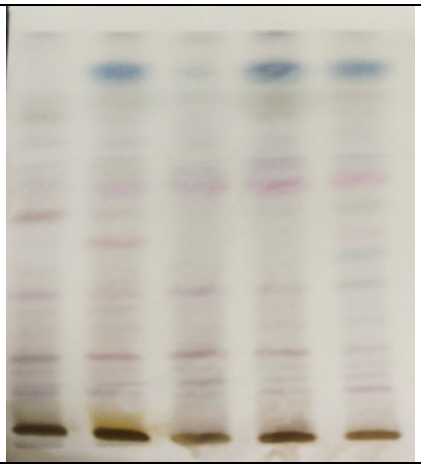
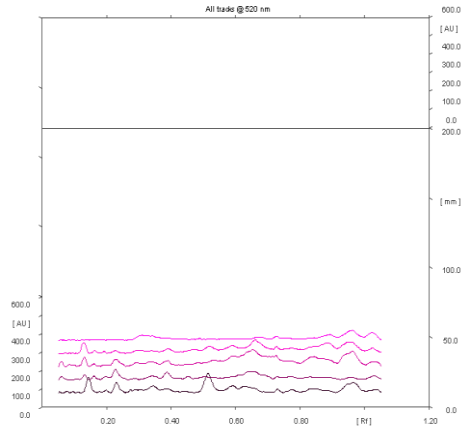
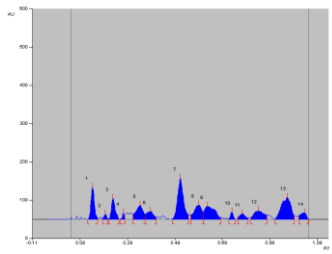
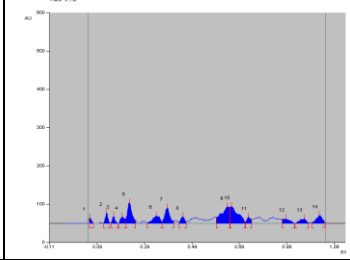
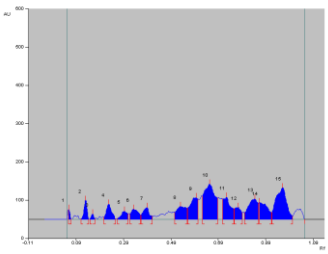


Figure 3: Derivatization with Anisaldehyde Sulphuric Acid @520nm

VISUALIZATION	FINGER PRINTING
	

PEAK DISPLAY

Track 1	Track 2	Track 3
		

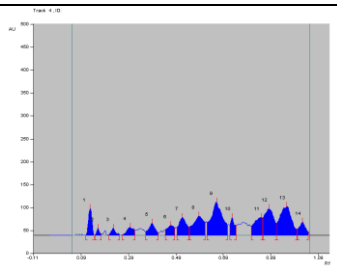
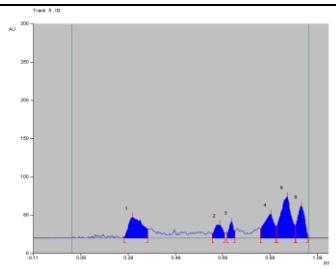
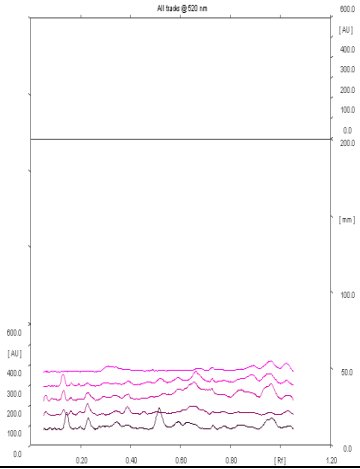
Track 4	Track 5
	

Figure 4 : Derivatization with 5% Ferric Chloride Reagent @520 nm

VISUALIZATION	FINGER PRINTING
	

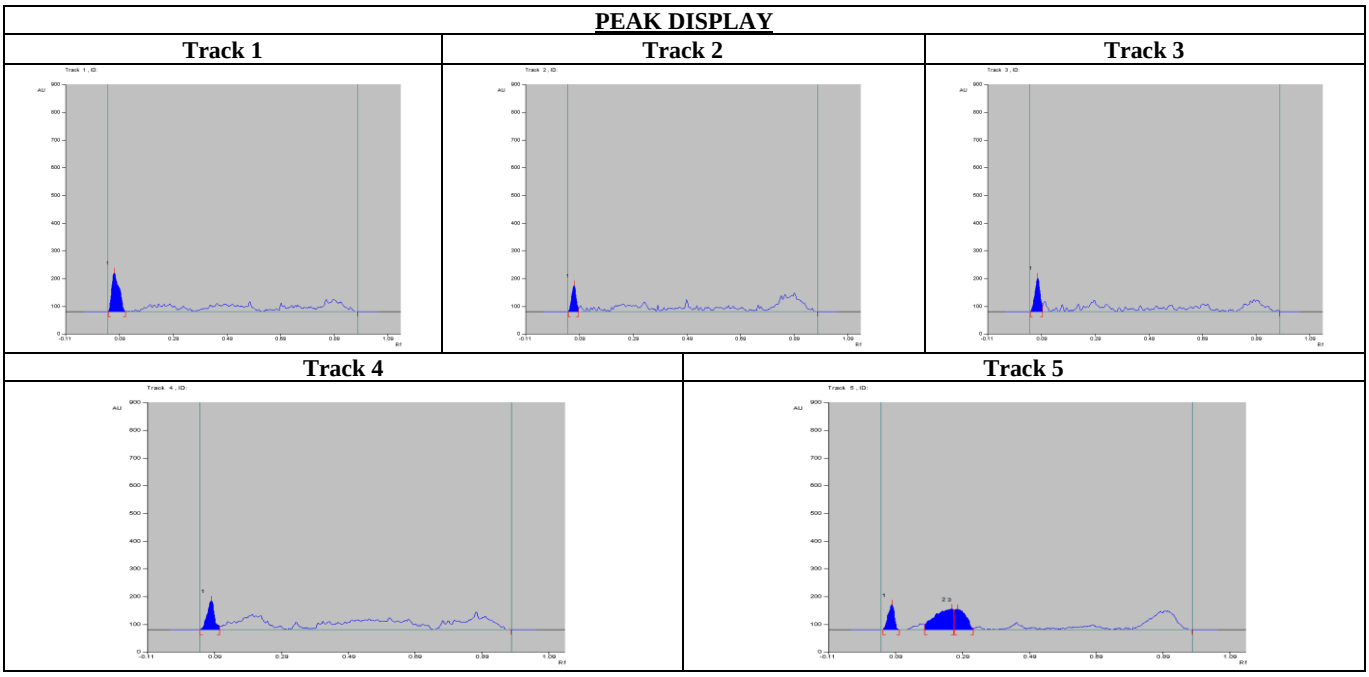
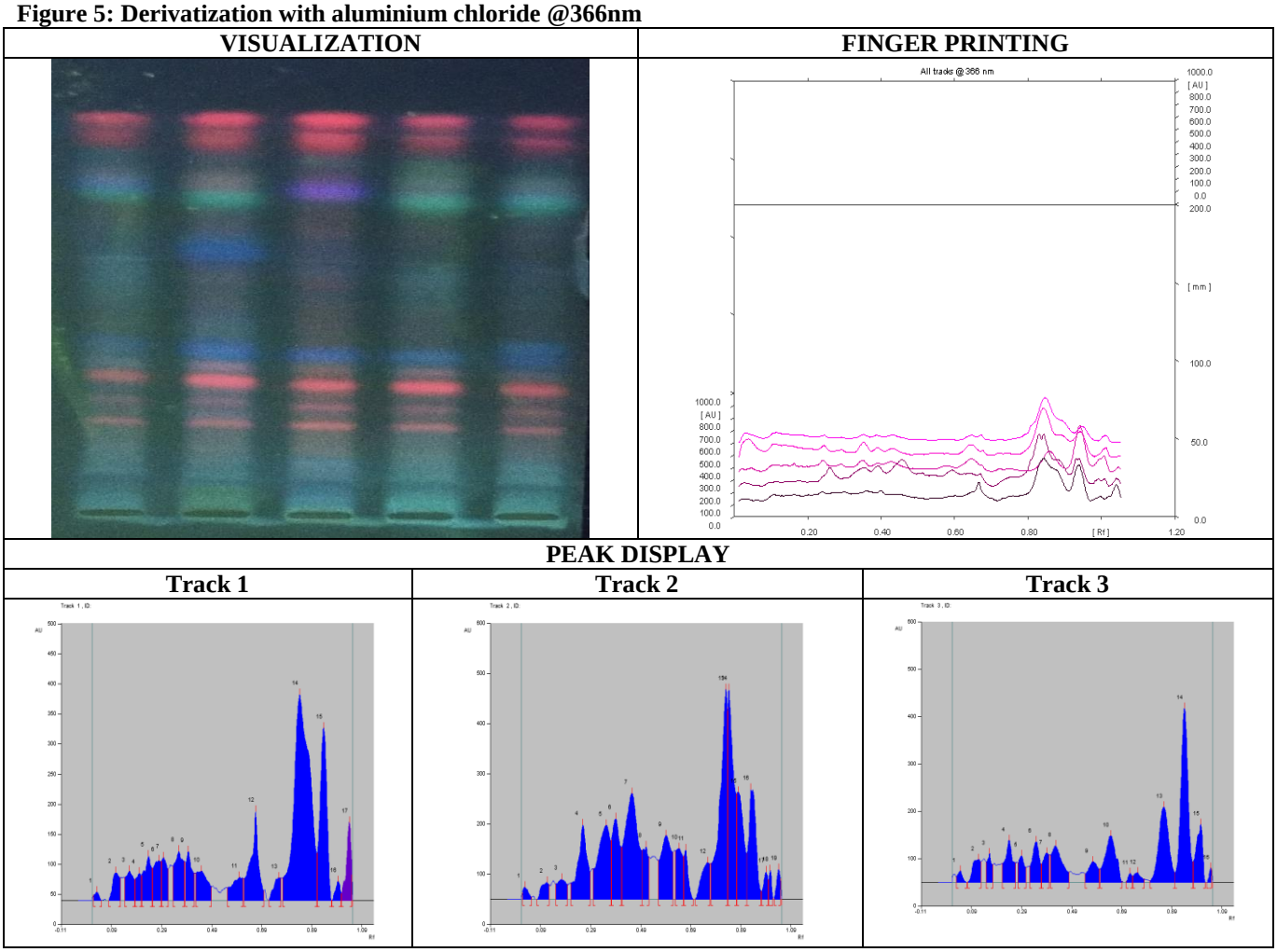


Figure 5: Derivatization with aluminium chloride @366nm



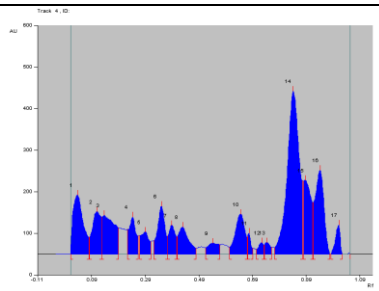
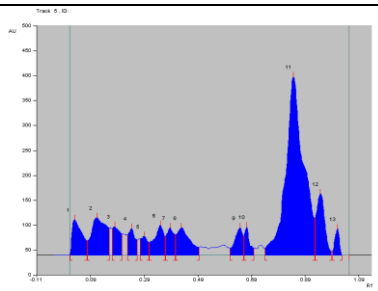
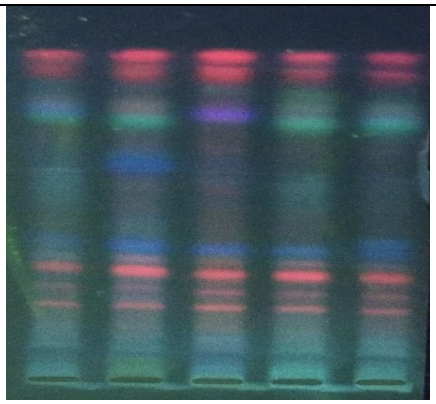
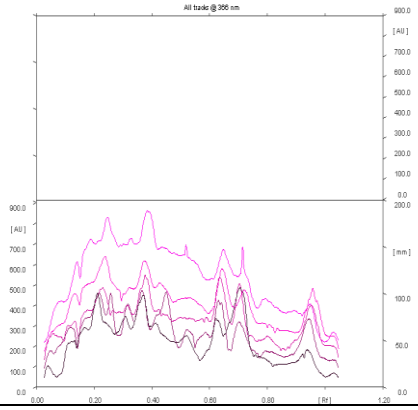
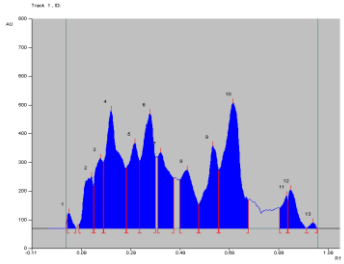
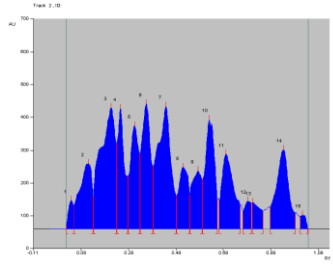
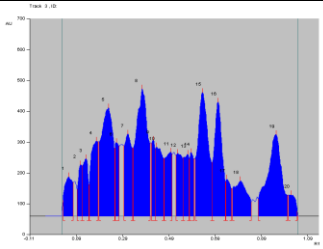
Track 4	Track 5
	

Figure 6: Derivatization with Lieberman Burchard Reagent @366nm

VISUALIZATION	FINGER PRINTING
	

PEAK DISPLAY

Track 1	Track 2	Track 3
		

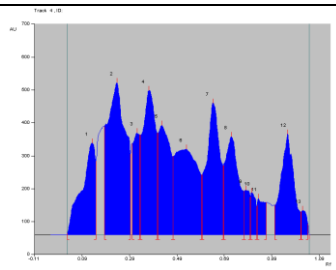
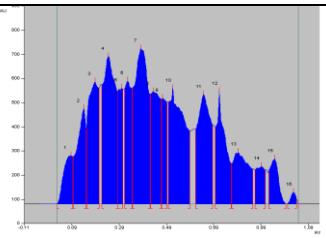
Track 4	Track 5
	

Figure 7: Derivatization with Dragendroff's reagent @520nm

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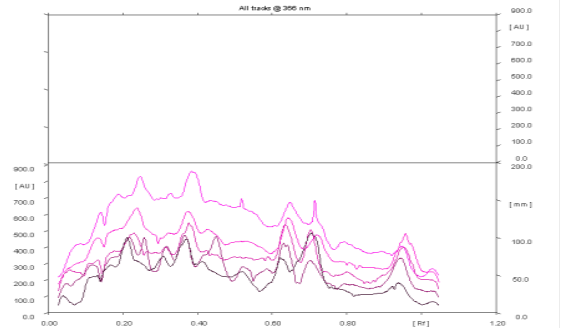
<tr><td>  </td><td>  </td></tr>
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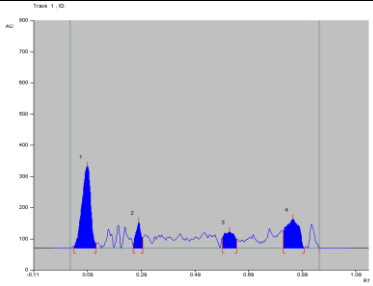
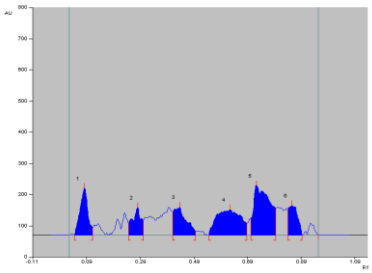
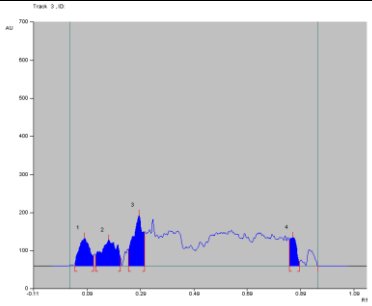
<tr><td>  </td><td>  </td><td>  </td></tr>
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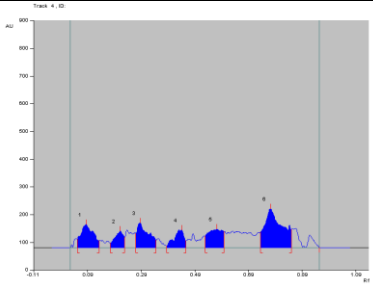
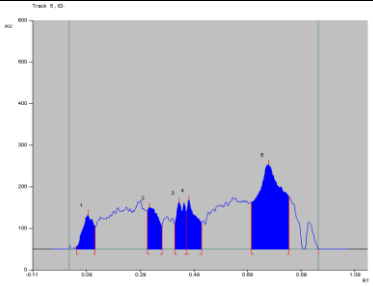
<tr><td>  </td><td colspan="2">  </td></tr>
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DISCUSSION

Indian systems of traditional medicine are known for the use of various polyherbal formulations and multi-ingredients therapeutics for the management of health and diseases. The Kabasura Kudineer Chooranam is a polyherbal Siddha medicine traditionally used in illness related to respiration and flu like symptoms in southern parts of India over past decade, presently this KSK chooranam is being practiced primarily in the management of COVID 19 pandemic to heave respiratory system. The current study deals with monograph analysis of different commercial brands of Kabasura kudineer by modern analytical techniques to evaluate KSK by different manufactures. The detailed evaluation of commercial preparations of as public interest is growing enormously towards traditional systems of medicine during current pandemic outbreak; both the marketed preparations were tested for relevant physicochemical and analytical properties for its quality and consistent efficacy through various quality control measures as per pharmacopoeial specifications. Organoleptic properties are the characteristics of herbs/food/supplements as experienced by the sensory organs, including taste, appearance, smell, and touch. Even slight variation in organoleptic properties gives a primary indication about quality variation. Hence, the characteristic organoleptic features of Kabasura Kudineer Chooranam formulations are reported in our work and a difference in appearance and texture was observed with reference. Physicochemical standards are crucial for assurance of uniformity of the quality of formulations and provide key information for further assessments and facilitate the identification of formulations in routine industrial production. The test for percentage of moisture content (loss on drying), one of the most widely used measurements in the processing and testing of foods and

herbs, measures both water content and amount of volatile matter present in sample because excess of water content facilitate the growth of microbes which impair the quality and purity of the formulations. Total ash denotes the number of materials remaining after ignition. Extractive values are useful in particular for assessing consistency of nature and amount and type of chemical constituents present in the herbal drug. Considering the importance of these physicochemical parameters, KSK was evaluated and reported. The results predict more or less similarities with official reference standard KSK.

The physicochemical properties stimulated us to perform further investigation. Crucially the phytochemical screening was performed along with quantitative estimations of Flavanoids and tannins. These phytochemical findings were correlated with the forementioned reports with the presence of secondary metabolities in the key ingredients of these polyherbal formulations. [4] HPTLC is an important tool by which the key quality control procedures including fingerprints of herbs/phytopharmaceuticals can be assessed. One of the main objectives of the HPTLC study of Kabasura Kudineer Chooranam was to develop a unique HPTLC chromatogram of its key ingredients in formulations. HPTLC chromatograms of all the selected herbal ingredients with respect to their standards are indicative of their presence in both the marketed Siddha formulations. Sample 1-4 with reference official standard, though the chemical composition of key ingredients more or less noticeable in sample 1-4 compared with reference to standard as implies the statement of [4]**.** Tests and analytical procedures adopted in this study are as specified in Indian Pharmacopoeia 2018 and addenda. Pharmacopoeias i.e., IP, Ayurvedic Pharmacopoeia of India, Siddha Pharmacopoeia of India etc. develop reliable standards for herbs, their products and formulations containing herbal/natural ingredients by providing standard specifications and test methods. Further, there is a scope for synchronization in analytical methods and stipulation adopted for herbs, their products and formulations containing herbal/natural ingredients as differences were observed in different pharmacopoeial requirements. There is slight variation in key ingredients of different polyherbal formulation. Here, we are in agreement that adoption of a harmonized monograph could increase further the interest of the global stakeholders in alternative systems of medicine.

CONCLUSION

Scrutinization of commercially available polyherbal formulations of KSK has been carried out with a vision to propose appraisal standards for its quality, purity and uniformity in official formulations. The analytical parameters along with physiochemical, preliminary phytochemical and HPTLC fingerprinting profile will be symptomatically salient features in secure its pharmacopoeial monograph standards.

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Cite this article:
DR. Sethuramani A, Raxshiya smily J, Balaji S, Manimaran S, Rajalakshmi H, DR. Venkata Rathina Kumar T, DR. Abdul Hasan Sathali A. Comparative Monograph Analysis Of Commercially Available Kabasura Kudineer. *International Journal of Pharmaceutical Research & Analysis*, 12(1), 2022, 30-40.