



Research Article

FORMULATION AND EVALUATION OF *USIRADI YOGA* OINTMENT FOR DERMATOLOGICAL CONDITIONS

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ABSTRACT

The prevalence of skin and subcutaneous illnesses and the worldwide burden of skin disorders has increased significantly in recent times. In addition to physical health, these medical and cosmetic issues also affect mental health and self-esteem. In Ayurveda, skin conditions are mostly categorized under the spectrum of *Kushta*. Classical literature describes eighteen different forms of *Kushtas*, and their treatment. In the treatment of dermatological conditions, medicinal powders are utilized as external therapies in forms such as *Lepa*, *Udwartana*, and *Udsadana*. Nevertheless, using powder can cause discomfort and pain in certain skin conditions. Given today's fast-paced lifestyle, there is a need for a convenient dosage form made from easily available raw materials. The goal of this study is to formulate an ointment using *Usiradi Yoga churna*, mentioned in *Vaidyamanorama (Chikilsa krama)*, and to improve patient compliance without compromising its efficacy. This report includes the development and quality analysis of *Usiradi Yoga* ointment (USYO). Fine powders of *Vetiveria zizanioides*, Soot, *Plumbago zeylanica*, *Psoralea corylifolia*, *Pongamia pinnata*, *Piper longum* triturated with cow's urine distillate (3.16% each) were added to the liquid paraffin and bees wax mixture (6:1) as ointment base. In addition to physicochemical parameters, microbiological test and finger printing of phytochemical constituents of USYO was conducted. The Results showed that USYO was of good consistency and fair extrudability and successfully passed the microbiological test. HPTLC fingerprinting of USYO demonstrated the presence of several constituents.

INTRODUCTION

In recent years, skin and subcutaneous disorders have become more prevalent. China and India have recorded the highest number of skin and subcutaneous diseases.^[1] Dermatological conditions, which affect both physical health and mental well-being, significantly impact self-esteem. In Ayurveda, skin diseases are primarily categorized under the term *Kushta*.^[2, 3] Classical literature includes eighteen different forms of *Kushtas*, and their treatment.^[4,5] In addition to internal therapies, *Acharyas* emphasize the significance of external medicinal applications such *Lepa*, *Taila*, and *Kashaya* etc. In the treatment of

dermatological conditions, medicinal powders are utilized as external therapies in forms such as *Pradeha*, *Pralepa*, *Alepa*, *Udwartana*, and *Udsadana* etc.^[6, 7,8, 9] Nevertheless, using these powders can cause discomfort and pain in certain skin conditions, and the duration for which the medication remains in contact with the target area may vary or be insufficient. Given today's fast-paced lifestyle, there is a need for a convenient dosage form made from easily available raw materials.

Usiradi yoga is one such formulation mentioned in *Vaidyamanorama (Chikilsa krama)* intended for *udwarthana* type of external therapy in all types of *Kushta*^[10]. The yoga includes seven ingredients such as *Usira*, *Gruhadhuma*, *Citraka*, *Avalguja*, *Karanja beeja*, *Pippali* and *Gomutra*. *Udwarthana* with the powdered ingredients along with *Gomutra* is indicated to cure all types of *Kushtas*. Even though *Udwarthana* is said to be *Twak prasadakaram param*,^[11] in the case of skin diseases it may cause pain. All the ingredients

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of the selected yoga are used widely in skin diseases since ancient times.^[12,13] Thus, converting the dosage form into an ointment may be beneficial.

Ointments have longer-lasting therapeutic benefits and a sustained release of medication because of their semi-solid consistency.^[14] Additionally, they usually include mineral oil and petrolatum, which assist in preserving and hydrating the skin, making them perfect for dry and damaged skin types.^[15] Ointments also form an occlusive barrier that keeps moisture in and shields the skin from external factors.^[16] Among the various topical dosage forms, ointments are usually easier to use and require smaller amounts, making them more convenient for patients. Ointments are a common choice for treating a variety of skin disorders because of these properties, particularly those that call for long-term treatment and hydration. The goal of this study is to develop an ointment using *Usiradi Yoga churna*, mentioned in *Vaidyamanorama (Chikilsa krama)*, and to evaluate its properties.

MATERIALS AND METHODS

Procurement and processing of materials

Herbal ingredients such as *Usira (Vetiveria zizanioides)*, *Chitraka (Plumago zeylanica)*, *Avalguja (Psoralea corylifolia)*, *Karanja (Pongamia pinnata)* seed, and *Pippali (Piper longum)* were sourced from a reliable supplier. The plant materials were processed to remove any dirt or foreign substances. The processing of *Chitraka* was performed using *Churnodaka*. Subsequently, all herbal raw materials (except *Gruhadhuma*) were individually washed with water, and dried in the shade. *Gruhadhuma*, which can be considered plant soot, was collected from a household chimney in Kannur, Kerala. Visible foreign particles were manually removed, and all ingredients were then stored separately in airtight containers until needed. Beeswax was obtained from a trustworthy source in Wayanadu, Kerala. It was then scraped, and all visible foreign materials were removed by hand. Liquid paraffin heavy and vetiver essential oil were sourced from reputable suppliers. *Gomutra arka* was procured from Govigyan Anusandhan Kendra, Nagpur, Maharashtra. It was stored in amber-coloured plastic bottles in a dry place until it was used for the preparation.

Formulation of the *Usiradiyoga* ointment

After four trial preparations, we adopted the monophasic ointment preparation method according to the British Pharmacopoeia 1988 edition.^[17] Ingredients of USYO is given in Table 1.

Preparation of *Usiradi Yoga Churna*

200grams of each ingredient was taken separately in a tray. After ensuring that the drugs satisfied the quality and purity parameters through proper analytical methods, each one of them, along with the previously prepared *Shodhita Chitraka*, was powdered together in a disintegrator. After removing foreign bodies, 200g of *gruhadhuma* was added and mixed thoroughly with the obtained powder. This homogeneous mixture was then sieved through sieve No.85 to get a fine powder of *Usiradi Yoga churna*. After ensuring proper mixing and desired particle size, the powder was kept in an airtight container. 983 grams of fine powder of *Usiradi yoga* was obtained.

Preparation of active ingredient for USYO

Exactly 900grams of previously prepared fine powder of *Usiradi yoga churna* was taken in a wide-mouthed vessel. 1250ml of *Gomutra arka* was added to the powder gradually and mixed thoroughly until the powder was completely soaked. The mixture was transferred into an electric horizontal wet grinder and triturated well until the fine paste became completely dry. *Gomutra arka bhavita Usiradi churna* was collected carefully as it tends to fly off, and it was then kept in an airtight glass bottle.

Base Preparation

2764.12 grams of heavy liquid paraffin, accurately weighed, was heated over a water bath using the double boil method. 460.68 grams of scraped beeswax was added, and the mixture was stirred continuously until the wax flakes were completely melted and mixed with the paraffin to form a homogeneous blend. The temperature of the base was noted at this point with an industrial thermometer.

Preparation of *Usiradi Yoga* ointment

Just before preparing the base, 768 grams of the active ingredient was precisely weighed and placed in an ointment mixer vessel. As soon as the base was ready and the temperature reading fell between 70-80°C, it was added to the active ingredient that was still in the vessel, and then vigorously and thoroughly mixed to create a uniform mixture. 24.95grams of vetiver essential oil and an accurately measured 38.39 grams of preservative (Iscaguard PEG) were added during mixing. Once the mixture reached ambient temperature and formed a uniform mixture, it was put into 25-gram laminated tubes using a semi-automatic Lami/plastic tube/filling, sealing, coding, and cutting machine.

Table 1: Ingredients of Usiradi Yoga Ointment

S.no	Ingredients	Botanical name	Parts used
1	<i>Usira</i>	<i>Vetiveria zizanioides</i>	Root
2	<i>Gruhadhuma</i>	Soot	
3	<i>Chitraka</i>	<i>Plumbago zeylanica</i>	Root
4	<i>Avalguja phala</i>	<i>Psoralea corylifolia</i>	Seed
5	<i>Karanja beeja</i>	<i>Pongamia pinnata</i>	Seed
6	<i>Pippali</i>	<i>Piper longum</i>	Dried fruit
7	<i>Gomutra</i>		<i>Arka</i>
8	Bees wax		
9	Liquid paraffin heavy		
10	Isca guard PEG		
11	Vetiver essential oil		

Physical evaluation of the *Usiradi Yoga* ointment

The ointment was tested for homogeneity, phase separation, texture, colour, and odour. Visual observation was used to evaluate these characteristics. A small amount of the prepared ointment was placed between the thumb and index finger in order to examine homogeneity, Phase separation and texture.^[18,19]

Spreadability^[18,20]

The spreadability of the formulations was determined by measuring the spreading diameter of one gram of the sample between two horizontal glass plates after a specific time period. The standard weight applied to the upper plate was 500 grams.

pH value^[21]

One gram of formulated ointment was dispersed in 25ml of distilled water and pH was determined using a pH meter. The pH meter was each time calibrated with standard buffer solution before use.

Viscosity^[22,23]

The Brookfield viscometer [DV-I Prime (LV)] was used to measure the viscosity of the sample at room temperature, providing quantitative data on the flow behaviour of the ointment. The viscometer was turned on and allowed to stabilize by auto-zeroing. The ointment sample was placed in a beaker, and the spindle 64 was inserted in a tilted position until the immersion groove on the spindle's shaft touched the surface of the ointment to avoid air entrapment. The spindle was allowed to rotate at various rpm (5, 10, 20, 100), and the corresponding readings from the viscometer's screen were recorded.

Extrudability^[24]

Tube extrudability was assessed by measuring the amount of ointment extruded through the tip when pressure was applied on to the tube. The tube was weighed and the weight was recorded initially. Then

the tube was positioned in between two glass slides and clamped. An Iron block of 500 g was placed over the slides. After that the cap was removed. The ointment extruded was collected and weighed. The whole procedure was conducted at room temperature. The percent of the extruded ointment was calculated and compared with the standards. (>90% extrudability: Excellent, >80% extrudability: Good, and >70% extrudability: Fair).

Determination of Moisture Content (Loss on Drying)^[25]

Five grams of *Usiradi yoga* ointment, accurately weighed, were placed in a tared, previously dry evaporating plate. After three hours at 105°C in a drying chamber, it was weighed. The drying and weighing procedure was carried out every 30 minutes until the difference between two subsequent weigh-ins was no greater than 0.25 percent.

Determination of Total Ash:^[25]

Accurately weighed Two grams of the USYO was taken in a silica crucible and incinerated until the sample becomes free from carbon. The crucible was then placed in a desiccator for 30 minutes and allowed to cool and weighed without any delay. The percentage of ash with reference to the USYO was calculated.

Determination of Acid-insoluble Ash^[25]

Accurately measured 25ml of dilute hydrochloric acid was added drop wise into the crucible containing total ash. The insoluble matter was collected using filter paper (Whatman 41) and washed with hot water until the filtrate become neutral. The filter paper containing the insoluble matter was transferred into the original crucible. Dried it on hot plate and ignited to constant weight. The crucible was then placed in a desiccator for 30 minutes and weighed without delay. The content of acid insoluble ash with reference to initial weight of USYO was calculated.

Determination of Alcohol-soluble Extractive^[21]

Accurately weighed 5gm of USYO was macerated with 100ml of alcohol of specified strength in a closed flask for 24 hours shaking frequently during six hours and allowing to stand for 18 hours. After taking precaution to avoid solvent loss, filtered it. Evaporated 25ml of the filtrate to dryness in a tared shallow dish having flat bottom and dried at 105°C to constant weight and the weight was noted. The percentage of alcohol soluble extractive with reference to the initial amount of USYO was calculated.

Determination of Water-soluble Extractive^[21]

The same steps as mentioned above was followed after adding 100ml of chloroform water to accurately weighed 5g of USYO.

Heavy Metal Analysis^[26]

The analysis of heavy metals present in the ointment sample was carried out by using Inductively Coupled Plasma Mass Spectrometry (ICP-MS). Working standard used for calibration instrument for heavy metal As, Hg, Pb, Cd were 5ppb, 10ppb, 25 ppb, 50 ppb and 100 ppb.

Microbial Analysis^[27]

Enumeration of Colony Forming Units

The entire procedure was conducted under a Laminar Air Flow hood. A 20µL sample of the ointment was dropped onto a pre-labelled Petri plate and swabbed onto Mueller Hinton Agar. The plate was incubated in a microbiological incubator at 37°C for 24 hours. After incubation, the plate was observed for colony-forming units (CFUs), which were counted using a Digital Colony counter and expressed as CFUs/ml.

Rancidity test (Kreis test)^[28]

Two grams of USYO were accurately weighed and treated with concentrated hydrochloric acid and a solution of phloroglucinol in ether. The mixture was then observed for a colour reaction. The intensity of colour produced in Kreis test is roughly proportional to the degree of oxidative rancidity. And all oxidised fat responds to the Kreis test.

HPTLC finger printing of polyherbal ointment^[23]

In order to extract of USYO components for high performance thin-layer chromatography (HPTLC), 5gm of USYO was extracted with 50mL of methanol. The HPTLC analysis was conducted using stationary phase HPTLC plates with dimensions of 4.0 x 10.0cm. The plates, made of silica gel 60 F 254, were sourced from E. MERCK KGaA.

For the sample application, the CAMAG Linomat 5 instrument was used. The application parameters included the use of inert spray gas, methanol as the sample solvent, and a dosage speed of 150nl/s. The pre dosage volume was set at 0.2µl, with a syringe size of 100µl, and two tracks were applied at

an application position (Y) of 10.0mm with an 8.0mm band length. The development was carried out using a glass tank, specifically a Twin Trough Chamber (20 x 10cm). The pre-conditioning time was 30 minutes, and the mobile phase composition was toluene, chloroform, and methanol in an 8:3:1 ratio. The solvent front position was 85.0mm, and a volume of 10.0ml was used. The plates were dried in an oven at 60°C for 5 minutes. Post-chromatographic derivatization was performed using a methanolic sulphuric acid reagent, with an oven drying step at 120°C for 20 minutes. The detection was carried out using the CAMAG TLC Scanner ("Scanner_171019" S/N 171019). The application position was 10.0 mm, and the solvent front position was 85.0 mm. The scan parameters included a number of tracks set to 2, with the first track positioned at X = 13.0mm and a distance of 13.0 mm between tracks. The scan started at Y = 5.0mm and ended at Y = 85.0mm. The slit dimensions were 4.00 x 0.30mm (Micro), and the optical system was optimized for light with a scanning speed of 20 mm/s and data resolution of 100µm/step.

RESULT AND DISCUSSION

In present research work, attempt was made to prepare an ointment of *Usiradi yoga churna* mentioned in *Vaidyamanorama Chikilsakrama*.^[10] The name *Usiradi Yoga* was assigned from the synonymous name of *Vetiveria zizanioides*. The Yoga includes ingredients *Usira*, *Gruhadhuma*, *Chitraka*, *Avalgujaphala*, *Karanjabija* and *Pippali* which are advised to be applied externally after preparing a paste using *Gomutra*. All the ingredients are known for their effectiveness in treating skin diseases. Their efficacy in various types of skin diseases and wounds has been proven by previous studies.^[29,30,31, 32] Considering the great role of external treatments for skin diseases and the general reluctance to use powders (*Lepas*) externally, it would be beneficial to convert the dosage form into an ointment.

Sodhita Chitraka was used in the formulation. The ingredients in the formulation are not known to cause any side effects or adverse drug reactions. Urea present in *Gomutra* as a humectant, help to alleviate dryness and its keratolytic property may also attributed to cure skin diseases. Even though *Gomutra* is beneficial for several diseases, its unpleasant smell and potential for contamination have become major concerns. *Usiradi yoga* exclusively uses easily available ingredients that have a high potential for treating skin disorders. Developing this medication into an ointment form increases patient compliance and ensures proper contact time.

The preparation procedure of USYO was confirmed after five trial preparations. We chose to prepare the USYO in accordance with the British Pharmacopoea 1988 edition's monophasic ointment

formulation (17) after analyzing the sensory parameters of the trial preparations. Beeswax and liquid paraffin heavy (1:6) were used to prepare the ointment base. Additionally, vetiver essential oil was added, and cow's urine distillate was substituted for *Gomutra* to reduce its unpleasant smell. *Gomutra arka* (cow's urine distillate), beeswax, and vetiver essential oil have all been studied and documented for their antibacterial and wound-healing activities.^[33-36] Therefore, we decided to use this combination in a

dosage form that is patient-friendly without sacrificing its effectiveness in treating skin conditions.

Both qualitative (organoleptic/sensory) and quantitative (physicochemical) assessments were used to evaluate the manufactured USYO. An essential part of product quality assurance is sensory analysis. The product's colour, smell, and consistency were examined. The ointment has a smooth, uniform texture and a subtle, pleasant vetiver scent and black colour. (Table 2)

Table 2: Evaluation of Usiradi Yoga ointment

Characters	Observation
Colour	Black
Odour	Characteristic
Consistency	Good
Homogeneity	Homogeneous
Phase separation	Absent
Loss on drying	4.3%
Total ash	1.096%
Acid insoluble ash	0.34%
Water soluble extractive	2.996%
Alcohol soluble extractive	3.71%
pH	5.36
Extrudability	78.32%
Viscosity	14157cps at 05 rpm
	7798 cps at 10 rpm
	3329 cps at 20rpm
	1176 cps at 100 rpm
Spreadability	7.6gcm/s

The physicochemical properties like pH, viscosity, extrudability, spreadability, moisture content, and ash values of the formulation were evaluated. Loss on drying is an important factor in preservation and resistance to deterioration. The amount of moisture content can affect the appearance, smell, texture, and stability of formulation. The USYO has a 4.3 drying loss. The ointment is prepared using the monophasic method, and adding *Dravadravya* through *Bhavana* may help reduce moisture content. A product with a pH range comparable to that of skin will be helpful in topical formulations. The USYO's pH of 5.36 indicates that it is beneficial for lipid synthesis and skin barrier protection.^[37,38] Extrudability of the formulation was identified as 78.32%, which implies that the ointment falls within the fair range of extrudability. Viscosity can influence the appearance and texture of an ointment, as it indicates how the formulation resists motion when a force is applied. The viscosity measurements at various RPM levels reveal that the ointment has a thick texture and exhibits slight

resistance to flow, which positively aids in maintaining its consistency during application. The viscosity of the ointment was assessed using a Brookfield viscometer. The results indicate that the viscosity of the ointment is 14157 cps at 5 RPM, 7798 cps at 10 RPM, 3329 cps at 20 RPM, and 1176 cps at 100 RPM, suggesting that the ointment formulations possess good consistency and are appropriate for topical use. The ointment's spreadability was 7.6gcm/s. The findings also demonstrate that the USYO is well-suited for external application and possess a satisfactory consistency.

Heavy metal analysis of the formulation was done as per ICP-MS method. The result given in table no.3 shows that all values are under API limit.^[26] The colony-forming units in the ointment were examined (Fig 3), and the results show that the prepared ointment has no CFU, indicating that it is free from microbial contamination. Figure 4 reveals that the prepared ointment passed the rancidity test, showing no signs of oxidative degradation, which confirms its stability.

Table 3: Result of Heavy Metal Analysis

Heavy metal	Detected value	API limit
Total Arsenic (As)/(ppm)	0.089	3ppm
Total Plumbum (Pb)/(ppm)	4.8	10ppm
Cadmium (Cd)/ppm	0.015	0.3ppm
Mercury (Hg)/(ppm)	0.097	1ppm

The HPTLC Report of methanolic extract of ointment shows 13 peaks, (fig 5, 6) both in 254nm and 366nm, indicating the presence of 13 different compounds in the ointment. In 254nm wavelength light measurement, the highest peak obtained with a height of 612.7 with maximum Rf value of-0.01 (Table 6) And under 366nm, maximum height attained was 810.4 with maximum Rf value 0.06. (Table 5)

Table 4: in 100 g composition Ratio of Usiradi Yoga Ointment

Ingredients	Quantity (in gram)
Active ingredient	18.935g
Bees wax	11.358g
Liquid Paraffin (heavy)	68.149g
Preservative	0.9465g
Essential oil	0.61g

Table 5: Track of Methanolic Extract of USYO Values in UV of 366nm

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	-0.04	0.1	-0.01	177.8	5.93	0.04	43.9	4836.2	6.09
2	0.04	44.1	0.06	89.5	2.99	0.09	55.7	2319.2	2.92
3	0.09	55.8	0.10	61.4	2.05	0.11	50.0	911.7	1.15
4	0.11	50.2	0.12	66.8	2.23	0.13	59.0	1088.9	1.37
5	0.13	59.1	0.15	89.5	2.99	0.16	64.3	1563.0	1.97
6	0.16	65.8	0.20	616.2	20.56	0.22	65.4	11697.6	14.73
7	0.22	66.0	0.23	78.2	2.61	0.24	57.0	1259.9	1.59
8	0.25	57.8	0.26	182.9	6.10	0.31	26.6	3961.9	4.99
9	0.31	26.8	0.34	95.2	3.17	0.39	19.4	3028.1	3.81
10	0.48	16.2	0.53	61.7	2.06	0.56	41.9	2325.2	2.93
11	0.56	42.3	0.61	810.4	27.04	0.64	244.3	25060.3	31.55
12	0.64	247.4	0.67	622.1	20.75	0.77	3.2	19730.1	24.84
13	0.80	3.0	0.86	45.8	1.53	0.92	1.9	1652.5	2.08

Table 6: Track of methanolic extract of USYO values in UV of 254nm

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	-0.04	5.6	-0.01	612.7	35.39	0.03	88.4	12236.7	25.89
2	0.08	84.6	0.10	91.1	5.26	0.12	75.9	2590.4	5.48
3	0.13	76.7	0.15	107.3	6.20	0.17	86.2	2355.0	4.98
4	0.17	86.7	0.17	96.2	5.56	0.18	84.4	1182.7	2.50
5	0.19	84.6	0.19	91.9	5.31	0.21	60.7	1575.0	3.33
6	0.21	61.0	0.23	66.9	3.86	0.26	44.9	1931.0	4.09

7	0.26	45.3	0.29	86.8	5.01	0.33	31.6	3335.0	7.06
8	0.36	46.9	0.39	114.9	6.64	0.44	16.3	4051.0	8.57
9	0.47	16.6	0.52	207.7	12.00	0.57	35.6	8804.3	18.63
10	0.60	23.6	0.64	38.8	2.24	0.65	37.7	1076.2	2.28
11	0.65	38.1	0.68	87.5	5.05	0.71	63.4	3507.9	7.42
12	0.71	63.9	0.72	66.0	3.81	0.79	7.4	1952.0	4.13
13	0.82	12.7	0.87	63.6	3.67	0.90	39.2	2668.7	5.65



Figure 1: The ingredients of *Usiradi Yoga* Ointment a) *Usira* b) *Gruhadhuma* c) *Citraka* d) *Avalguja* e) *Karanja beeja* f) *Pippali* g) *Gomutra Arka* h) Beeswax i) Liquid Paraffin heavy j) Vetiver essential oil k) Isca guard PEG



Figure 2: Stages of preparation of *Usiradi Yoga Ointment* a) Powdering of Ingredients b) Sieving through Sieve No.85 c) *Bhavana* in *Gomutra arka* d) Fine powder of *Gomutra arka bhavita usiradi churna* e) Melting of liquid paraffin and bees wax in water bath f) Reading ambient temperature of mixture of bees wax and liquid Paraffin g) Transferring the warm mixture into active ingredient (*Usiradi Powder*) h) Stirring of the mixture i) Transferring the mixture into ointment Tube filling machine j) Tube filling of ointment k) *Usiradi Yoga Ointment*.



Figure 3: CFU in USYO



Figure 4: Test for Rancidity -USYO- Negative

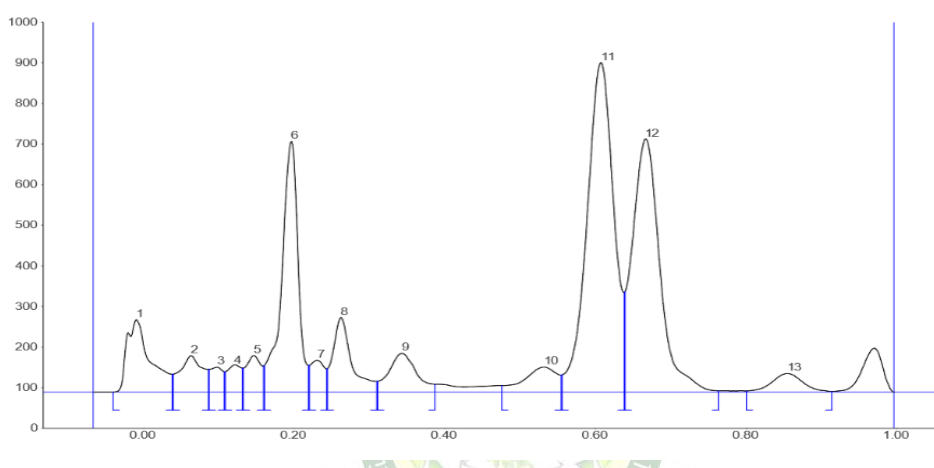


Figure 5: Track of Methanoilic extract of USYO at 366 nm

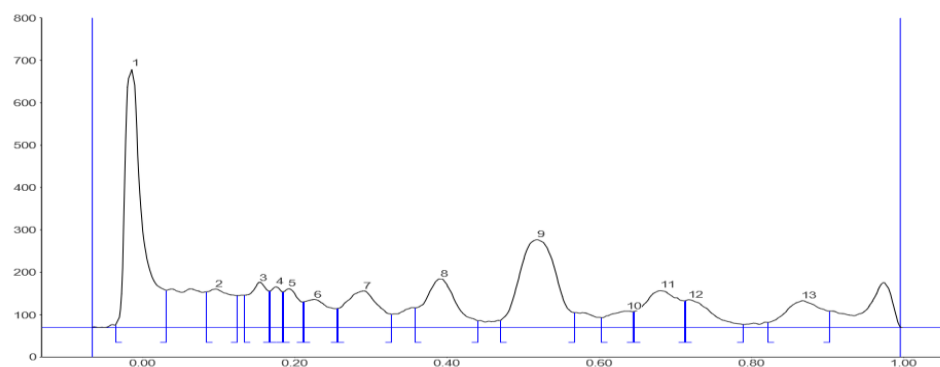


Figure 6: Track of Methanoilic extract of USYO at 254 nm

CONCLUSION

The present work was an attempt to develop and evaluate a polyherbal ointment, i.e., USYO with beeswax and liquid paraffin heavy as base. Since *Usiradiyoga* only includes readily accessible ingredients with a high potential for treating skin disorders, the addition of vetiver essential oil, *Gomutra arka*, and PEG to the dosage form may improve patient compliance. For the preparation of 100g ointment, the used ratio is given in Table 4. Homogeneous, smooth,

formulation of USYO is easier for topical application and will improve patient compliance.

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