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Pharmaceutical Modification of *Kasisadi Churna* to *Varti* and its Physicochemical Analysis

Research Article

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Abstract

Background: *Kasisadi churna* is a *yoga* (formulation) mentioned for treatment of *kaphaja yoni vyapath* (vulvo vaginal candidiasis) which is applied as *lepa* along with honey. But the administration of the drug through vaginal route in this form is highly discomforting. Modification of a dosage form is essential for the enhancement of efficacy, acceptability of the product and shelf life. Materials and Methods: *Varti* is prepared from the drugs of *kasisadi churna* in three methods, *bhavana* method (KV1), *gudapaka* method (KV2) and modified method (KV3) with the addition of cocoa butter as base. The prepared samples were tested for analytical parameters. Result and Discussion: *Kasisadi churna* can be easily modified into *varti* form. Preparation of KV2 was easy, gives more yield in less time and better in organoleptic features and disintegration time compared to KV1 and KV3. Conclusion: The results of the pharmaceutical and analytical study can be considered as the preliminary standards for the preparation of *Kasisadi Varti.*

Key Words: *Kasisadi churna, Varti, Samskara, Modification, Analysis, Yoni vyapath.*

Introduction

Samskara (transformation) is the process of modification of *guna* (properties) of a given substance which is responsible for conversion of a raw material into medicine. There are several *samskara* mentioned in *ayurveda* like *toya sannikarsha* (processing with water), *agni sannikarsha (processing with fire), shoucha (cleansing), mantha* (churning), *desha* (place), *kala* (time), *vasana* (processing with proximity), *bhavana* (trituration)(1). The *panchavidha kashaya kalpana* known as primary preparations of *bhaishajya kalpana* are modified into secondary dosage forms like *vati* (tablet), *varti* (suppositories), *avaleha* (semisolid dosage form), *sneha kalpana* and other such dosage forms for better shelf life, easy administration and palatability.

Kasisadi churna is a *yoga* mentioned for treatment of *kaphaja yoni vyapath* which is applied as *lepa* along with honey(2). But the administration of the drug through vaginal route in this form is highly discomforting. Modification of a dosage form is essential for the enhancement of efficacy, acceptability of the product and shelf life. When compared to *churna kalpana*, *varti* are having more shelf life and are easily administered. Hence in this work, *kasisadi churna* was modified into *varti* form.

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Varti kalpana is derivative of *vati kalpana*(3). Among the 7 types of *varti*, *yoni varti* is that mentioned for gynecological problems. It is designed in such a way that after insertion into vaginal canal they will either dissolve or disintegrate to release the medicaments (4). *Varti* can be prepared by classical methods like *gudapaka* or *bhavana*. In this study it was prepared by classical methods and by modified method with addition of cocoa butter as base.

Materials and Methods

The work was carried out in two steps

Pharmaceutical study

Kasisadi varti was prepared in three methods - *Bhavana* (KV1), *Gudapaka* (KV2), Modified method (KV3)

Analytical study

The prepared samples were analyzed to develop preliminary standards

Pharmaceutical study includes:

A.Drug collection and authentication

B.*Shodhana* of *Kasisa* and *Sphatika*

C.Preparation of *varti* in three methods

Drug collection and authentication

Drugs required were collected from local vendor. The herbal drugs were authenticated from the experts of *Dravya Guna.* The mineral ingredients were authenticated from the experts of *Rasashastra* and *Bhaishajya Kalpana*. Table 1 gives the list of ingredients and quantity taken.

Table 1: **Ingredients and their proportions**

S.N	Name of drug	Botanical Name/ English name	Part used	Quantity KV1	Quantity KV2	Quantity KV3
1	*Kasisa*	*Ferrous sulphate*	Whole	50gm	15gm	50gm
2	*Haritaki*	*Terminalia chebula Retz.*	Fruit	50gm	15gm	50gm
3	*Vibhitaki*	*Terminalia bellerica Roxb.*	Fruit	50gm	15gm	50gm
4	*Amalaki*	*Emblica officinalis Gaertn.*	Fruit	50gm	15gm	50gm
5	*Sphatika*	*Potash alum*	Whole	50gm	15gm	50gm
6	*Jambu*	*Syzygium cumini Skeels.*	Seed coat	50gm	15gm	50gm
7	*Amra*	*Magnifera indica L.*	Seed coat	50gm	15gm	50gm
8	*Dhataki*	*Woodfordia fruticosa Kurz.*	Flower	50gm	15gm	50gm
9	*Jala*	*Water*	Whole	3150ml	100ml	1250ml
10	*Guda*	*Jaggery*	Whole	-	240gm	-
11	Cocoa butter	*Theobroma oil*	Whole	-	-	40gm

Shodhana

Prior to preparation of *Varti*, *Shodhana* of *Kasisa* (Ferrous sulphate) and *Sphatika* (Potash alum) were done.

***Kasisa Shodhana*(5)**

Ashuddha Kasisa was powdered in a *khalva yantra*(mortar and pestle). Then it was transferred into a tray and sufficient quantity of *Bhringaraja Swarasa* required to soak the powdered *Kasisa* was added. It was dried under sunlight till it became completely devoid of moisture.

***Sphatika Shodhana*(6)**

Ashuddha Sphatika was powdered in a *khalva yantra*. It was taken in an inert vessel and fried till the moisture content is evaporated and *Sphatika* became white, light and brittle.

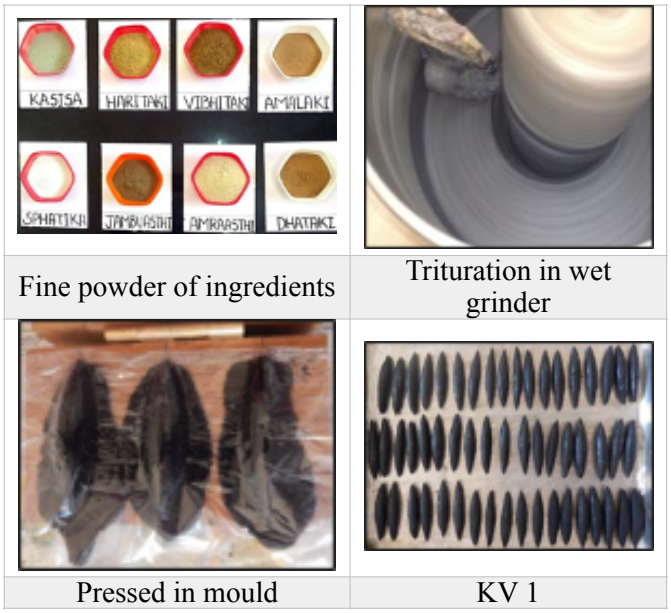
Preparation of Varti

Preparation of *Kasisadi varti* by *Bhavana* method (KV1)(7)

Ingredients of *Kasisadi Varti* (table 1) were taken in equal quantity and were pounded separately, sieved to obtain fine powders. They were mixed together and triturated along with water in a *wet grinder*. For *Bhavana*, the sufficient quantity of water to immerse the *Churna* was added. The mixture was subjected for continuous and cautious trituration. When the water was dried, it was considered as the completion of first *Bhavana*. As and when the contents dried, water was added and the quantity was noted. Total 7 days of *Bhavana* was given. The images of preparation are given in fig 1.

Preparation of *Kasisadi varti* by *Gudapaka* method (KV2)(7)

Ingredients of *Kasisadi Varti* (table 1) were taken in equal quantity and were pounded separately, sieved to obtain fine powders and all powders were mixed. *Guda* (jaggery) was dissolved in 100ml of water and heated on low flame. Once melted, it was filtered to remove impurities. The filtrate was reheated on low flame till 2 thread consistency. While heating was continued, *Churna* (powders) was added little by little and mixed well. The mixture was continuously stirred, till the *paka lakshana* was obtained. Later the gas stove was turned off. The mixture was taken out of stove and left for cooling. Initially the mixture was rolled into *Varti* form with approximate length and diameter of index finger. As it cooled and hardened it was again taken in the mould and was pressed to obtain *Varti* of uniform size and shape. It was dried in shade and stored. The images of preparation are given in fig 2.



Fine powder of ingredients | Trituration in wet grinder

Pressed in mould | KV 1

Fig 1: Preparation of Kasisadi Varti by Bhavana Method - KV 1

Gudapaka | *Tantumatvam* | Addition of fine powders

Homogenous mixture | Pressed in mould | KV 2

Fig 2: Preparation fo Kasisadi Varti by Gupaka Method - KV 2

Preparation of *Kasisadi varti* by modified method (KV3)

Ingredients of *Kasisadi Varti* (table 1) were taken in equal quantity. They were pounded separately, sieved to obtain fine powders. Cocoa butter was melted by indirect heating and mixed with the fine powders. Then the mixture was taken in wet grinder and water sufficient to immerse the *Churna* was added. The mixture was subjected for continuous and cautious trituration. As and when the contents dried, water was added and the quantity was noted. Two days *Bhavana* was given. After attaining *Subhavita Lakshana*, the mass was made into *Varti* form with the help of mould. Then it was dried and stored. The images of preparation are given in fig 3.

Fig 3: Preparation of Kasisadi Varti by Modified Methods - KV3

Addition of Cocoa Butter	Trituration in wet grinder	KV 3

Analytical Study

The prepared samples were subjected to following tests as per the standard protocol given in CCRAS.

1. Organoleptic characters: Colour, odour and texture of the samples were examined.

2. Physical parameters (8-10): Hardness, Uniformity of weight, Disintegration time, Friability

3. Physico-chemical parameters (11-15):

- Total Ash, Acid insoluble Ash, Alcohol soluble extractive, Water soluble extractive, Determination of pH, Volatile oil estimation
- High performance thin layer chromatography (HPTLC)(16) **:** 1g of powdered *Varti* was extracted with 10 ml of alcohol. 5 µl, and 10 µl of the extract were applied on a pre-coated silica gel F254 on aluminum plates to a band width of 7 mm using Linomat 5 TLC applicator. The plate was developed in Toluene: Ethyl acetate: Formic acid (8: 1: 0.2). The developed plates were visualized in UV 254, 366, after derivatisation with vanillin-sulphuric acid and scanned under UV 254 and 366. Rf (Retention factor), colour of the spots and densitometric scan were recorded.

Observations and Results

Result of *Kasisa Shodhana*

470gm of *ashuddha kasisa* was taken and 800ml of *bringaraja swarasa* was required for soaking of the drug. It took 52 hours for complete drying and final obtained *shuddha kasisa* was 373gm and greenish white in colour.

Result of *Sphatika Shodhana*

400gm of *ashuddha sphatika* was taken and time required for frying, till loss of moisture was 49 minutes. 197gm of *shuddha sphatika* was obtained which was white in colour.

Result of Pharmaceutical study

The results are tabulated in table 2.

Table 2: Result of pharmaceutical study

Parameters	**KV1**	**KV2**	**KV3**
Quantity of drug taken	400gm *churna*	120gm – *churna;* 240gm – *guda*	400gm *churna*
Total quantity of water used	3150ml	100ml	1250ml
Total time of *Bhavana*/ time for *paka*	26 ½ hrs	1hr 55mins	7 ½ hrs
Obtained quantity	760gm	330gm	892gm
Difference	360gm	30gm	452gm
Gain/loss	90%	8.33%	102.7%
Number of *Varti* obtained	74	29	94
Weight of all *Varti* after drying	438gm	330gm	512gm

Result of Analytical study

Organoleptic characters: All three samples were black in colour with characteristic odour. KV1 and KV3 were hard on touch, where as KV2 was soft.

The results of physical, physico chemical parameters are tabulated in table 3 and results of HPTLC are tabulated in tables 4 to 6 and photo documentation shown in fig 4.

Table 3: Results of standardization tests for KV1, KV2, KV3

Parameter	**Results n = 3 % w/w**		
	KV 1	**KV 2**	**KV 3**
Hardness	12	8	11.5
Uniformity of weight	6gm	12gm	5gm

Ph	2.32	2.83	2.43
Friability	0.83%	0.67%	0.61%
Disintegration time(min)	More than 45min	34min	More than 45min
Total Ash	12.97±0.17	6.26±0.01	11.45±0.23
Acid Insoluble Ash	5.52±0.00	1.95±0.00	4.48±0.01
Water soluble Ash	5.80±0.00	3.36±0.00	4.99±0.00
Alcohol soluble extractive value	10.01±0.01	23.10±0.00	17.46±0.00
Water soluble extractive value	39.36±0.01	82.50±0.00	40.13±0.00

Results of HPTLC

Table 4: R_f values of samples at short UV

Short UV (254nm)			**Long UV (366nm)**			**After derivatisation**		
KV1	**KV2**	**KV3**	**KV1**	**KV2**	**KV3**	**KV1**	**KV2**	**KV3**
-	0.06 (Green)	-	-	-	-	-	-	-
-	-	-	-	0.27 (F. blue)	-	-	-	-
-	-	-	-	-	-	-	-	0.33 (Purple)
-	0.38 (L. green)	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	0.42 (Purple)
-	-	-	0.44 (F. green)	-	0.44 (F. green)	-	-	-
-	-	-	0.52 (F. blue)	0.52 (F. blue)	0.52 (F. blue)	-	-	-
-	-	-	-	-	-	-	-	0.95 (Purple)

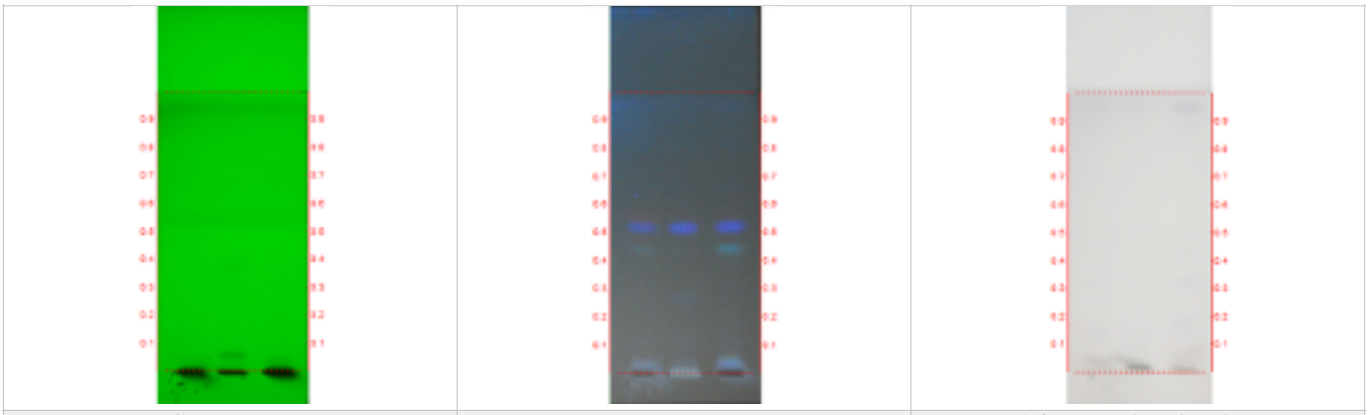
•L- light; D-dark; F – fluorescent

Table 5: HPTLC densitometric scan at 254 nm

KV1			**KV2**			**KV3**		
Peak	**Max position of Rf**	**% Area**	**Peak**	**Max position of Rf**	**% Area**	**Peak**	**Max Position of Rf**	**% Area**
1	0.04	90.25	1	0.04	60.08	1	0.04	88.22
2	0.09	1.53	2	0.10	19.83	2	0.09	2.15
Absent	3	0.19	4.24	Absent				
Absent	4	0.45	8.78	Absent				
3	0.66	8.22	5	0.64	7.06	3	0.65	9.63

Table 6: HPTLC densitometric scan at 366 nm

KV1			**KV2**			**KV3**		
Peak	**Max position of Rf**	**% Area**	**Peak**	**Max position of Rf**	**% Area**	**Peak**	**Max Position of Rf**	**% Area**
Absent	1	0.02	2.55	Absent				
1	0.04	5.73	2	0.05	11.49	1	0.05	30.13
2	0.07	2.19	3	0.08	8.35	2	0.08	4.42
Absent	4	0.34	5.12	Absent				
3	0.54	13.64	5	0.54	6.79	3	0.55	18.34
4	0.62	64.39	6	0.63	61.09	4	0.64	43.16
5	0.75	5.79	Absent	Absent				
6	0.79	4.82	7	0.79	4.61	5	0.81	3.94
7	0.89	3.43	Absent	Absent				



Short UV | **Long UV** | **After derivatisation**

Fig 4: HPTLC Analysis photo documentation of ethanol extract of KV1, KV2 and KV3

Discussion

The method of *Bhavana* was adopted in the preparation of KV1, since it is one of the common methods of preparation of *Vati*/*Varti*. Here, based on *anukta mana*, *bhavana dravya* is considered as *Jala*. Initially fine powders of drugs were mixed homogenously and water required for its complete immersion was added. It was taken in wet grinder and trituration was done. For every one hour the contents got dried and 100ml of water was added. For each subsequent drying the quantity of water required was decreased. This may be because, continuous grinding makes particles more fine, thereby increasing the surface area of each particle and facilitating the easy and fast absorption of liquid media. Softness and smoothness was developed in the material in the later process of trituration which may be due to application of force and pressure during trituration. Fineness of particles were assured before subjecting to *Bhavana* as otherwise the grinding would be difficult and gaining proper consistency would not be possible. The spilling of drug was avoided to assure the correct method of trituration and to prevent wastage of material.

Gudapaka method is another commonly employed method for *Varti* preparation. The second method KV2 involved the preparation of jaggery syrup. *Guda* used was blackish brown in colour. This would be reason for the dark brown colour when *Guda* was dissolved in water. On heating, thick syrup obtained was may be due to evaporation of water portion and concentrating of *Guda* into the solution. The characteristic odour of *Guda* was appreciable on heating may be due to hydrolysis of its sugar content. Constant stirring was required in the preparation to avoid charring and sticking of jaggery to the vessel. Hence, stirring as continuous precaution is justifiable. The *Gudapaka* method was found easier and less time consuming compared to *Bhavana* method. But giving the required shape was quite difficult as it needed to be rolled into *Varti* form while it was hot. After cooling, the content become hard and is difficult to give shape.

The modified method involved the addition of cocoa butter to the fine powders of drugs. The cocoa butter is used widely as base in suppositories due to its properties. Because of its easy melting it may act as disintegrating agent. It was observed that softness and smoothness was developed in the material which may be due to application of force and pressure by trituration. The softness was comparatively more than that in KV1 it may be due the unctuous nature of cocoa butter. *Subhavita Lakshana* was attained earlier, may be due to high fat content in cocoa butter.

While preparing the three samples of *Kasisadi Varti*, the average size and circumference of *Tarjani* (index finger - 7cm x 5cm) was considered to follow as '*Tarjani Pramana'* is specified for *Yoni Varti*. The quantity obtained from KV1 and KV3 method showed the gain of 9.5% and 16.3% respectively. It may be due to addition of water to ingredients for trituration. Whereas, in KV2, there was loss of 9.72%, it may be due to *Gudapaka* leading to evaporation of water portion.

Organoleptic characters

In all the three prepared samples, the colour after drying was noted as black. To assess why black color was imparted, the drugs were mixed individually in water and in combination. When *Kasisa* and *Amalaki* were mixed together with water, the colour turned to black indicating some chemical reaction. Characteristic odour of *Kasisa* and *Amalaki* was appreciated in all three samples. The presence of metallic odour of *Kasisa* might be the reason for this. Odour of *Guda* was also appreciated in KV2. Texture was seen as granular in KV1 and KV3 which might be because of the fibrous nature of the plant origin drugs, while the texture was smooth in the KV2 as *Guda* was added. Another reason would be that *Bhavana* with water does not add much smoothness to the product unlike *Guda*. *Guda* being unctuous in nature impart more smoothness to the product.

pH

pH of all the three samples was acidic. pH of KV1 was comparatively more acidic probably because of the Amla Rasa of *Kasisa*(17) and *Amalaki* (18). KV2 and KV3 had addition of *Guda* and Cocoa butter respectively which made the drug less acidic compared to KV1. pH as a measure of the hydrogen–ion activity is important from the standpoint of stability or physiological suitability. Since the pH of drug is almost near to the pH of vagina (3.8-4.5), it might help in better absorption.

Hardness

It is the resistance to attrition, abrasion, bending, breaking or crushing or impact strength. It is a property which is dependent on density and porosity of the material on one hand and pressure of the compression on the other. Hardness of three samples was within 12kg/sq/cm. While comparing the values, hardness of KV1 was found to be more, it may be due to the more number of *Bhavana* leading to more binding of particles of drug thereby resulting in more hardness, whereas in KV3 the percentage of cocoa butter in 10% and the *Bhavana* favored the binding and increase in intermolecular force. Hence the hardness is almost near to that of KV1 The percentage of *Guda* in KV2 is 66.66% and due to its soft nature the sample was less harder compared to other.

Uniformity of weight

The final product of each sample had different weight (KV1-6gm, KV2-12gm, KV3-6gm) which may be due to difference in ingredients like in KV2, addition of *Guda* and in KV1 more quantity of water added for *Bhavana* would have lead to gain in weight respectively.

Disintegration time

It is the measure of time required under a given set of conditions for a group of *Varti* to disintegrate into

particles. To determine the disintegration time of *Varti*, acidic pH was maintained to suit the vaginal pH. It was observed that only KV2 disintegrated in 34 minutes and the sample KV1 and KV3 did not disintegrate even after 45 minutes. In KV1 the incorporation of subsequent triturations increased the intermolecular force thus resulting in delayed disintegration. In KV2 the presence of *Guda* showed the better disintegrating effect. In KV3 the presence of cocoa butter may be was not sufficient and the trituration has resulted in delayed disintegration. These values are not of much importance as it is not for oral medication.

Friability

This test is intended to determine the physical strength of drug. The friability of all the samples was within 1% (permissible limit).

Total Ash

The residue remaining after incineration is the ash content of the drug. It is used as a criterion for purity and identity of crude drugs. It showed that the KV1 (12.97 % w/w), had more inorganic salts present in it. It was probably because it contained more percentage of *Kasisa* and *Sphatika* which are inorganic in nature. While KV2 (6.26 % w/w) and KV3(11.45 % w/w contained *Guda* and cocoa butter respectively which were more organic in nature, thus reducing the percentage of *Kasisa* and *Sphatika* resulting in less inorganic component compared to KV1.

Acid Insoluble Ash

It is a part of total ash which is insoluble in dilute HCL. The acid insoluble of three samples being KV1- 5.52%, KV2- 1.95%, KV3- 4.48% shows the constituents which are insoluble in acid were more in KV1 and least in KV2.

Alcohol soluble extractive

This value is applied for the drugs which contain alcohol soluble constituents such as tannins, resins and alkaloids, thus helps to know active principles. The extractive value of KV2 (KV1–10.01% w/w, KV2-23.10 % w/w, KV3-17.46% w/w) is more may be due to presence of more of *Guda* which would have added bulk to the value. The KV3 contained Cocoa butter which is insoluble in alcohol, the content of KV1 included organic material and inorganic material like *Kasisa* and *Sphatika* which are insoluble in alcohol.

Water soluble extractive

The samples showed extractive value as KV1-39.36%, KV2-82.50%, KV3-40.13%. The reason for this value would be same as above. Water soluble extractives indicate water soluble constituents such as tannins, sugars, plant acids and mucilage.

HPTLC photo documentation

HPTLC is a qualitative analysis method with major advancement of TLC principle with short time duration and better resolution. The prepared drugs were subjected to HPTLC fingerprinting at different wavelengths (254nm & 366 nm). This study reveals the chemical fingerprint profile of the test samples.

The Rf, is related to the retention of the components and their consequent separation. It is defined as the ratio of time of an analyte is retained in the stationary phase to the time it is retained in the mobile phase. Hence, Rf = distance traveled by the component / distance traveled by solvent front. Rf value is characteristic for a particular compound in a particular solvent system and environmental conditions. In the present study three different samples of *Kasisadi Varti* (KV) were assessed at selected UV regions wavelength (at 254 nm and 366 nm). The spots/peaks due to different components were documented. It acts as fingerprint of the used sample, which can be used as reference for the preparation of same kind of *Varti*.

At 254 nm: There were 3, 5 and 3 peaks in KV1, KV2 and KV3 respectively. It was observed that compounds with Rf 0.19 (4.24%) and 0.45 (8.78%) were absent in KV1 and KV3. The bands at different Rf value indicate the presence of particular active compounds.
Though KV2 had more percentage of *Guda* than other drugs, it has shown presence of more components.

At 366 nm : There were 7, 7 and 5 peaks in KV1, KV2 and KV3 respectively. Compound with Rf 0.02(2.55%) and 0.34(5.12%)was not detected in KV1 and KV3. Compound with Rf 0.75(5.79%) was absent in KV2 and KV3. Compound with Rf 0.89(3.43%) was absent in KV2 and KV3. More number of components are seen in KV1 and KV2, than in KV3.

Conclusion

Kasisadi Churna can be easily modified into *Varti* form. Preparation of *Kasisadi Varti* with *Gudapaka* (KV2) method is easy and gives more yield in less time. Analytical studies and HPTLC conducted on the study drug have helped to develop preliminary standards for *Kasisadi Varti*. *Kasisadi Varti* prepared by *Gudapaka* (KV2) method showed better organoleptic features and disintegration time.

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