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PHARMACEUTICAL DEVLOPMENT AND ANALYTICAL EVALUATION OF H.V.K.I.G COMPOUND IN TABLET AND SYRUP FORM

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ABSTRACT :

Aim & Objective:

1. To develop standard manufacturing process of tablet and syrup of HVKIG compound.
2. To develop possible analytical profile of table and syrup of HVKIG compound.

Materials and Methods: The study was carried out in following phases:

1) Conceptual study
2) Pharmaceutical study
3) Analytical study

Conclusion: This study is beneficial towards standard manufacturing process (SMP) of its tablet and syrup forms with possible analytical parameters which helps also in clinical documentation.

It will help to develop further suitable analytical parameters from of HVKIG compound (tablet and syrup).This study is first step towards developing SMP (standard manufacturing process) of HVKIG compound is said to be a standard for further study.

About topic: HVKIG tablet and syrup will prepared from five compound i.e *haritaki,vidang,kampillaka,indrayav,aragvadh*.those all are having *krimighna* properties,purgatives,*doshgna*.etc…its very beneficial pediatric worm infection. To devlop standard manufacturing process (SMP) of its tablet and syrup forms with possible analytical parameters.

Key words: H.V.K.I.G Compound

INTRODUCTION: *Rasashastra* and *BhaisajyaKalpana* is one of the important branch of *Ayurveda* mainly deals with pharmaceutical and pharmacological aspects of different formulations. It contains method of collection, purification preservation, standardization and therapeutically utilization of minerals and herbo-mineral preparations. In *BhaishajyaKalpana* mainly herbal drugs are used to prepare its decoctions, hot & cold infusions, distillations, and preparation like granules, syrup, *guggulu*, carbonizations, tablets and capsules. In recent era, modification and development of different forms of *aushadhi* take place. There are so many new dosages forms are available in market so for globalisation of *Ayurveda* and its formulations one should develop new way in the field of new drug dosage forms.

It is a well known formulation prepared in parulAyurvda pharmacy since long time. It has five drugs namely, *Haritaki (Termenaliyachebula), vidanga (Embeliaribes), Kampilaka (mallotusphilppinensis), Indrayava*

(holarrhenaantidysenterica), Aragvadgha (cassia fistula).

Despite being a renowned formulation no scientific documentation is available on it till date. Considering this, the study is planned to develop standard manufacturing process of tablet and syrup of HVKIG. It will help in future for further development and in clinical documentation.

AIM AND OBJECTIVE:

1. To develop standard manufacturing process of tablet and syrup of HVKIG compound.
2. To develop possible analytical profile of table and syrup of HVKIG compound.

MATERIALS AND METHODS:

- All the raw materials (*haritaki,vidang ,kampilak, indrayav, aragvadh*) used for this study were procured from local market of vadodara.
- Identification of all raw material of H.V.K.I.G Compound
- Authentication was done by senior expert as well on the basic of pharmacognostical study.

Preparation of H.V.K.I.G syrup:

preparation of HVKIG syrup

I. Collection of raw materials.
II. Purification of *kampillaka*.
III. Preparation of *yavkuta*(coarse) form.
IV. Preparation of *kwath*.
V. Preparation of syrup.

I. Collection of raw materials:-

- All the raw materials (*haritaki,vidang ,kampilak, indrayav, aragvadh*) used for this study were procured from local market of vadodara.

II. Purification of *kampilak:*

- Take 500 grm brick red powder ,spread on the water and soaking around 2 hours after *kampillaka* floating on the surface. Now collected and used for medicine preparation.

III. Test for purity of *kampillaka*:-

- The hair of the fruit is put in a bowl of water. The hair float in water whereas the brick powder sink in the water.
- If the hair of the fruit is rubbed over a white paper, it gives a yellow line.
- If the hair of the fruit is sprinkled over fire,it gives a crackling appearance.

- Preparation of *yavkut*(coarse) form:Take raw material of *Haritaki,Vidang,Indrayav,Aragvadh(garmado)*.all drug are separately triturated and filtered through sieve no 80.

IV. Preparation of *kwath* Table.1

S.NO.	Name of drug	Quantity
1	*Haritaki*	20 g.
2	*Vidanga*	20 g.
3	*Indrayava*	20 g.
4	*Aragvadha(garmado)*	20 g
5	*Kampilaka*	20 g

- One part each of above mentioned dravya are taken in coarse powder form in a clean stainless steel decoction vessel along with 1600 ML(16times) of clean and soft water.
- All drugs are mix properly and the vessel is kept undisturbed place for whole night.
- Next day the vessel is placed over mild fire, boiled and reduced to 1/8th part and later filtered.
- **Result:** After end of preparation total 200 ML *kwath* was obtain.

V. Preparation of syrup:-

- **Reference:***Anubhuta*

- **Room temperature:** 22℃
- **Batch code:** HVKIG Syrup
- **Equipment require:** weighing balance, gas stove, stainless steel vessels, measuring cylinder, cotton cloth, etc.
- **Vessel Specification:**

1.	Vessel type	stainless steel
2.	Diameter	22.7cm
3.	Depth	15cm
4.	Width of vessels	22.7cm
5.	Capacity	5 L
6.	Dimensions of cotton cloth	35×35cm

Table.2 Ingredients:

Sr. No.	Ingredients	Ratio	Quantity
1	HVKIG-*kwath*	1	200ml
2	Sugar(powder form)	2	400 g.

PROCEDURE:

- Needful equipment like gas stove, steel vessel, cotton cloth, measuring cylinder were procured before starting the experiment.
- HVKIG-*kwath*(200ml) was taken in stainless steel vessel.
- Now the double quantity of sugar is added.
- And boiled over mild fire until the liquid attains syrupy consistency (as that of honey).
- Low temperature should maintain to attend appropriate syrup consistency.
- It is letter on filtered to get rid of any impurities present in sugar.
- It is stored in dry and stopper bottles in a cool dark place with room temperature.

Precaution and confirmatory tests:

- Very mild fire is must to attain appropriate syrup consistency.
- More quantity of sugar if added, the sugar may remain as sediment in the end product.
- With less quantity of sugar, the consistency of syrup may not be obtained.
- The mixture should be boiled up to 1-2 thread consistency.
- During *sarkarapaka* a part of *paka* material should settle down without spreading when it is put in a bowl of water.

The product should posses the desired ‘odor’ and ‘colour’ of the liquid preparation used.

Table.3 RESULT OF FIRST BATCHES

1	**Weight of ingredients**	**100 g.**
2	**Quantity of water used**	**1600 ml.**
3	**Quantity of sugar used**	**400 g.**
4	**Total quantity of syrup**	**550ml.**

Table.4 RESULT OF SECOND BATCH

1	**Weight of ingredients**	**100 g.**
2	**Quantity of water used**	**1600 ml.**
3	**Quantity of sugar used**	**400 g.**
4	**Total quantity of syrup**	**545ml**

Table.5 RESULT OF THIRD BATCHES

1	**Weight of ingredients**	**100 g.**
2	**Quantity of water used**	**1600 ml.**
3	**Quantity of sugar used**	**400 g.**
4	**Total quantity of syrup**	**548 ml.**

PREPARATION OF HVKIG TABLETS:

I)RawDrugs:All the raw material used for this study were procured from local market of vadodara .

Authentication of was done by senior experts as well as on the basic of pharacognostical study.

II) Purification of *kampilak*:

- *Kampillak*(500g) being the fruit skin powder is very light in nature.
- It is put into water.
- All the impurities will settle down while the *kampillaka* floats.
- The floating particles are collected,dried and preserved.

Test for purity of *kampillaka*:-

Brick powder is used as adulterant for *kampillaka*.Hence to check the quality,the following test can be done-

- The hair of the fruit is put in a bowl of water.The hair float in water whereas the brick powder sink in the water.
- If the hair of the fruit is rubbed over a white paper,it gives a yellow line.
- If the hair of the fruit is sprinkled over fire,it gives a crackling appearance.

Table.6 III) Preparation of powder form *(curnaKalpana):*

Sieve no.	Size of aperture in mm	Diameter of wire in mm	Standard wire gauge	Approx % of screening area	%of aperture tolerance average
85	0.152	0.102	42	35	6.2

Table.7 Obtain quantity of powder of each drug:

Sr. No.	**Name of drug**	**Quantity of powder**
1	*Haritaki*	200 g
2	*Vidanga*	200 g
3	*Kampilaka*	200 g
4	*Indrayava*	200 g
5	*Aragvadha(Garmado)*	200 g

IV) Preparation of tablet: Ingredients: Table.8

Sr. No.	**Name of drug**	**Quantity of powder**
1	*Haritaki*	200 g
2	*Vidanga*	200 g
3	*Kampilaka*	200 g

4	*Indrayava*	200 g
5	*Aragvadha(Garmado)*	200 g

Table.9 For binding agent:

Gum accasia	10%	10 g

Table.10 For shining purpose:

Shankhajiru	As required

PROCESS:

- Desire quantity of base drugs like powder of HVKIG compound are taken.
- Now 10 g of gumaccasia was added for binding agent.
- *Shankhajiru* was added as a appearance of shining purpose.
- All are homogeneous mix and added require quantity of water.
- When all the medicinal drug powder is incorporated in to the base drug by thorough pounding, the mixture is further bounded to obtain a smoother and homogeneous drug mass.
- Kept bolous in to oven for drying purpose.
- After drying completely the bolous will be crush properly.
- All bolous are converted in to powder form.
- The powder was prepare all medicinal drug are kept in to tablet making machine.
- Total 850g weight of tablet out of 1kg of medicinal powder.
- Their sizes in the range of 500mg. as per present day scenario.

Table.11 HVKIG Tablet first batch

Sr. No.	Name of drug	Weight of drug Before preparation	Weight of drug After preparation
1	HVKIG Compound	**1000g**	**852g**

Table.12 HVKIG Tablet second batch

Sr. No.	Name of drug	Weight of drug Before preparation	Weight of drug After preparation
1	HVKIG Compound	**1000g**	**860g**

Table.13 HVKIG Tablet third batch

Sr. No.	Name of drug	Weight of drug Before preparation	Weight of drug After preparation
1	HVKIG Compound	**1000g**	**668g**

Table.14 Average result of three batches of HVKIG tablet

1	Weight of ingredients	1000g
2	End of preparation(total weight of material)	793.33g
3	Weight of single tablet	500mg

ANALYTICAL STUDY

INTRODUCTION:

- The important aims for analytical study of *ayurvedic* drugs are to know the particular chemical configuration and to point out the physic-chemical changes and effect of different

processing (*samskara e.g. shodhana, marana* etc.)

- It also helps to know the probable role of a media during the pharmaceutical processing.
- It provides some standards to judge the quality of raw material as well as finished product. Through analytical study one can interpret the probable pharmacokinetics and pharmacodynamics of the drug.
- *Ayurveda* has given parameters (*siddhi lakshna*) to access the quality of selected material and final product.
- Hence for better utilization of *ayurvedic* pharmaceutics, it is need of hour to analyze the drug through both classical and modern qualitative and quantitative parameters.

HARITAKI:

Table.15 Showing organoleptic characteristic of *Haritaki*

Characteristic	Observation
Color	Dark brown
Odor	Characteristic
Taste	Sweet,sour,bitter
Texture	Fine

Table.16 showing physicochemical parameters of *Haritaki*

Serial no	Parameters	Results
1	Foreign matter	0.68%
2	Loss on drying at 105°C	0.85%
3	Total Ash value	0.45%
4	Acid insoluble ash	0.031%
5	Water soluble extractive	56.10%
6	Alcohol soluble extractive	22.30%

VIDANG:*Table.17 Showing organoleptic characteristic of *Vidang

Characteristic	Observation
Color	Blackish brown
Odor	Distinct
Taste	Astringent
Texture	Wrinkled

Table.18 Showing physicochemical parameters of *Vidang*

Serial no	Parameters	Results
1	Foreign matter	1.03%
2	Loss on drying at 105°C	0.80%
3	Total Ash value	2.15%
4	Acid insoluble ash	2.89%
5	Water soluble extractive	5.9%
6	Alcohol soluble extractive	4.5%

KAMPILAKA:*Table.19 Showing organoleptic characteristic of*Kampilaka

Characteristic	Observation
Color	Deep reddish
Odor	Pleasant odor
Taste	Slightly bitter and astringent
Texture	Coarse powder

Table.20 Showing physicochemical parameters of *Kampilaka*

Serial no	Parameters	Results
1	Foreign matter	1.80%
2	Loss on drying at 105°C	1.28%
3	Total Ash value	7.02%
4	Acid insoluble ash	3.80%
5	Water soluble extractive	0.67%
6	Alcohol soluble extractive	44.50%

INDRAYAVA:*Table.21Showing organoleptic characteristic of *Indrayava

Characteristic	Observation
Color	Light yellow
Odor	Specific aromatic
Taste	Astringent
Texture	Fine powder

Table.22 Showing physicochemical parameters of *Indrayava*

Serial no	Parameters	Results
1	Foreign matter	0.70%
2	Loss on drying at 105°C	2.05%
3	Total Ash value	5.20%
4	Acid insoluble ash	2.05%
5	Water soluble extractive	08.70%
6	Alcohol soluble extractive	12%

ARAGVADHA(GARAMADO):*Table.23 Showing organoleptic characteristic of*Aragvadha

Characteristic	Observation
Color	Chocolaty Brown
Odor	Pleasant odor
Taste	Slightly bitter and astringent
Texture	Fine

Table.24 Showing physicochemical parameters of *Aragvadha*:-

Serial no	Parameters	Results
1	Foreign matter	0.03%
2	Loss on drying at 105°C	3.07%
3	Total Ash value	3.02%
4	Acid insoluble ash	1.07%
5	Water soluble extractive	49.05%
6	Alcohol soluble extractive	6.09%

7	Ph	

Table.25 Organoleptic test of Tablet /Syrup:

Organoleptic test	Tablet	Syrup
Colour	Yellowish black	Chocolate brown
Smell	characteristic	characteristic
Taste	Kashaya, tikta	kashaya, tikta
Touch	Soft	Soft

Table.26 HVKIG Syrup

S.N.	Parameters	Result B-I	Result B- II	Result B- III
1	PH	4.00	4.30	4.20
2	Viscosity	288cp	291 Cp	290 Cp
3	Total sugar content	56.58%	57.76%	57.58%
4	Total solid content	36.48%	38.79%	38.48%
5	Specific gravity	1.31 g/ml	1.31g/ml	1.31 g/ML

Table:27 HVKIG Tablet

S.N.	Parameters	Result B-1	Result B-II	Result B- III
1	Hardness	4.90kg	5.20kg	5.0kg
2	Friability	0.25%	0.28%	0.27%
3	Uniformity of weight	509 mg	512 mg	511mg
4	Disintegration time	50.0 min	56.12min	55.0min
5	Water Soluble extractive	20.1%	21.30%	21.03%
6	Alcohol soluble extractive	15.03%	15.23%	15.19%
7	Total ash	10.96%	11.80%	11.08%
8	Acid insoluble ash	6.12%	6.50%	6.45%

1. **High performance thin layer chromatography (HPTLC):**

- HPTLC is a sophisticated and automated from of TLC.
- HPTLC is an invaluable quality assessment tool for the evaluation of botanical materials. It allows for the analysis of a broad number of compounds both efficiently and cost effectively.
- Additionally, numerous samples can be run in a single analysis thereby dramatically reducing analytical time. With HPTLC, the analysis can be viewed using different wavelengths of light thereby providing a more complete picture of the plant than is typically observed with more specific types of analyses.

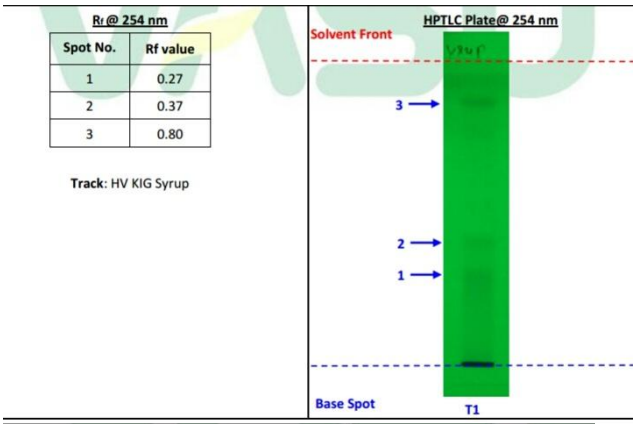
2. **Principle of HPTLC:**

- Principle remains the same as of TLC i.e. adsorption.
- One or more compounds are spotted on a thin layer of adsorbent coated on a chromatographic plate.
- The mobile phase solvent with more affinity towards stationary phase travels faster. Thus, the components are separated on a thin layer chromatographic plate based on the

affinity of the components towards the stationary phase.

STEPS INVOLVED IN HPTLC:

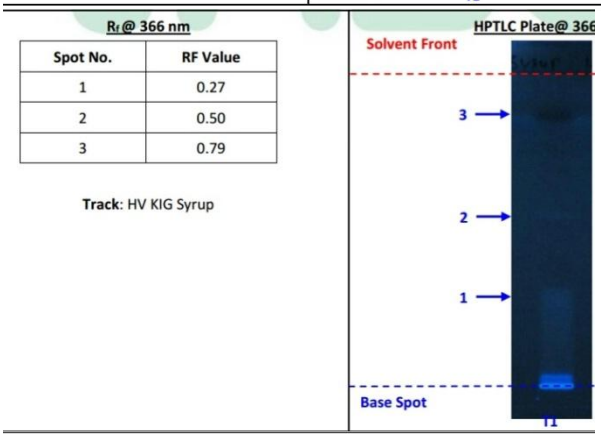
- Selection of chrometographic layer.
- Sample and standard preparation.
- Later pre-washing, layer pre-conditioning.
- Application of sample and standard.
- Chromatographic development.
- Detection of spots.
- Scanning.
- Documentation of chromatic plate.



Rf @ 254 nm

Spot No.	Rf value
1	0.27
2	0.37
3	0.80

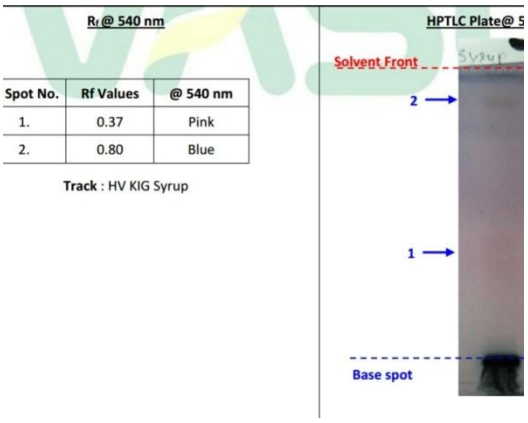
Track: HV KIG Syrup



Rf @ 366 nm

Spot No.	RF Value
1	0.27
2	0.50
3	0.79

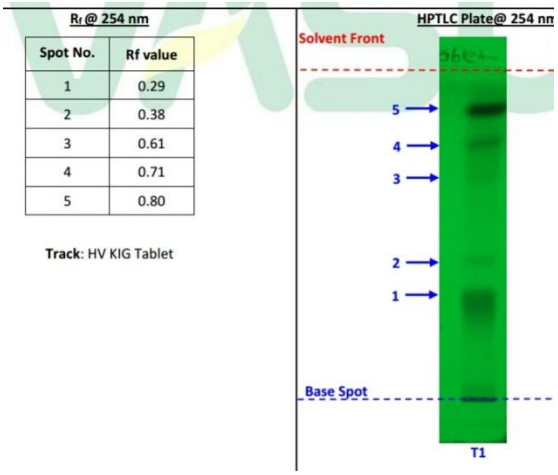
Track: HV KIG Syrup



Rf @ 540 nm

Spot No.	Rf Values	@ 540 nm
1.	0.37	Pink
2.	0.80	Blue

Track : HV KIG Syrup



Rf @ 254 nm

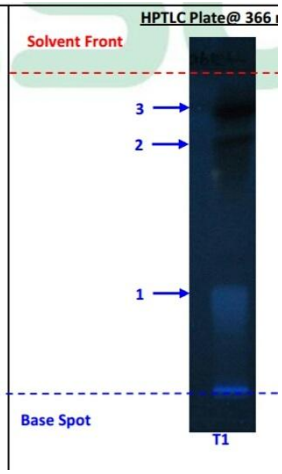
Spot No.	Rf value
1	0.29
2	0.38
3	0.61
4	0.71
5	0.80

Track: HV KIG Tablet

R_f @ 366 nm

Spot No.	RF Value
1	0.29
2	0.71
3	0.81

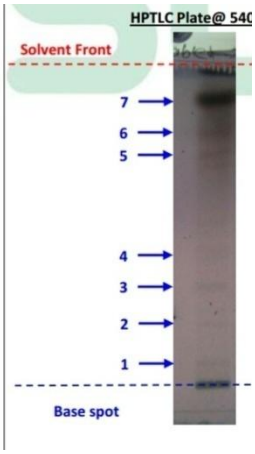
Track: HV KIG Tablet



R_f @ 540 nm

Spot No.	Rf Values	@ 540 nm
1.	0.23	Blue
2.	0.35	Blue
3.	0.51	Blue
4.	0.66	Pink
5.	0.70	Blue
6.	0.77	Blue
7.	0.82	Blue

Track: HV KIG Tablet



DISCUSSION: Discussion is a process of re-examination that forms a base for conclusion. Inspite of detail classical literary study and experimentation by various method, a theory is accepted only after proper reasoning of the observations. Hence, it forms a crucial part of any scientific research work. Discussion of present work has been carried out based on the result and observation from three segments viz. pharmaceutical and analytical studies.

It was found that the formulations meet required qualitative pharmaceutical standards for a tablet. The parameters observed in the present study will help for the reproducibility of the formulations in future the research prospects.

The quality of tablet is ascertained by a cascade of physico-chemical and phytochemical screening for the findings in accordance with the observations of the present study.

All the pharmaceutical parameters analyzed showed values permissible for a syrup.

It was found that the formulations meet required qualitative pharmaceutical standards for a syrup.

Suggestion for furture study:

- Future Clinical studies can be planned by considering *Apakarshana or PrakrithiVighantana* as an individualized line of treatment in children suffering from *Krimi* to analyze their efficacy.
- Study with Large sample size can be planned in future to collect more data regarding the efficacy of drug.

- Better palatable form of drug can be used in future studies.

The dissertation has begun with introducing the subject in brief, necessity of the study and method of presentation of the work.

Conceptual study consisted of review on disease (Vedic, Ayurvedic and Modern), origin of the word *Krimi* and its understanding from various literature of ancient and present era was analyzed and discussed. Concepts for the comprehension of the *Krimiroga* were studied in detail regarding its naming, types, features, classical signs and symptoms and management. Description of available modern literatures regarding worm was analyzed.

CONCLUSION: After a detailed observation and discussion on the observed data, the following conclusions may be drawn:-

comprehensive description on *sarkarakalpana* and *vatikalpana* are available in classics regarding their classification,types,method of preparation,advantages, disadvantages and precautions.HVKIG (tablet and syrup)is an Anubhut yoga which is used for the treatment of different worm infectious diseases. This study is first towards developing SMP(standard manufacturing process) of HVKIG compound which will be became a standards for further study and others remedies in future. It is noticed that recurrence rate is very high due to development of resistance towards routine antihelminthic drugs. Intestinal worm infections in humans is a silent epidemic that destroys the health, well being and learning potential of millions of children in many developing countries today and now documentation related to pharmaceutical, analytical and clinical of HVKIG compound are also available.

Hence, this study will be beneficial towards standard manufacturing process (SMP) of its tablet and syrup forms with possible analytical parameters which helps also in clinical documentation.

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