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A Comparative Pharmaco-Analytical Study of *Vyoshadi Gutika* and its Modified Dosage Form w.s.r. to Lozenges.

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ABSTRACT:

Ayurveda is the science of life and one of the world's oldest holistic healing system. Its aim is to prevent disease formation along with cure of diseased ones. For both of the purpose it advocates use of metal, minerals and herbal compounds in treatment of various Diseases. Ancient dosage forms are good but it needs some modification regarding its palatability, shelf life and marketing feasibility. The new dosage forms of herbal and herbo-mineral formulations in Ayurveda are – Tablets, Capsules, Lozenges, Ointment, gel, creams, Balms, Lotions, Granules etc. All these formulations have their Boons and Banes. *Vyoshadi Gutika* is used for *Pratishyay.* It is a chewable tablet, but its contents are *Ushna* and *tikshna* due to which it is difficult to take. Modification of *Vyoshadi Gutika* into Lozenges will make it easier to take and probably more effective due to keeping it for long time in mouth. Lozenges are the solid, unit dosage form that contains one or more medicaments, usually in a flavored, sweetened base, that are intended to dissolve or disintegrate slowly in the mouth. Development of lozenges dates back to 20th century and is still in commercial production. New dosage form has several benefits like easy to use, more effective, better presentation etc. On the other hand, they also have few demerits like expensive, change in formulas, added sugars etc.

Keywords: New dosage form, *Vyoshadi Gutika*, Granules, Lozenges.

INTRODUCTION

Rasa Shastra and *Bhaisajya kalpana* is the unique branch of Ayurveda. It is also called as Alchemy of Ayurveda. In this branch we find the use of different metal, minerals and herbs compounds in treatment of various Diseases. Thousands of formulations are explained in *Rasa Shastra* and *Bhaishajya kalpana* with number of dosage forms like, *Avaleha, Curna, Vati, Bhasma, Ghrita* and *Taila etc.* All

these dosage forms are used and prescribed as per the need of disease condition and convenience in hectic life now days. There is need of developing some traditional dosage forms into new, easy to take dosage forms. *Vyoshadi Gutika* is amongst the various preparations of Ayurveda. *Vyoshadi Gutika* is a chewable tablet, used in *Pratishya* but its contents are *Ushna* and *tikshna* due to which it is difficult to chew for very small children as well as for *Pitta Prakriti* individual. Keeping the same idea in mind, here *Vyoshadi vati* lozenges is developed. Lozenges are flavoured medicated dosage formulations used pharyngeal and other mouth problems. Their local action as well as systemic action helps to relieve the symptoms. It is absorbed by buccal epithelium. It is basically intended to use for prolong delivery of drugs in mouth which may alter the pH and will help to maintain healthy oral environment. It is useful for patients having dysphagia as well as it avoids first pass metabolism. This study is focused on modification of *Vyoshadi Gutika* into Lozenges Form. Modification of *Vyoshadi Gutika* into Lozenges will make it easier to take and probably more effective. Hard candy lozenges were made of *Vyoshadi Vati* ingredients. By putting the findings of this study into wider spectrum, researchers in this field will get a larger view to understand the use of *Vyoshadi Gutika* in the form of Lozenge.

AIM AND OBJECTIVE

1. Pharmaceutical preparation of *Vyoshadi Gutika* and its Lozenges.
2. Analytical study of *Vyoshadi Gutika* and its Lozenges.

MATERIAL AND METHOD

It is prepared as per textual reference of *Sharangdhar Samhita*[1] (**Table No. 1) (Table No. 2)**

Pharmaceutical Method implied for *Gutika* Preparation:-

- Preparation of Churna
- Preparation of Gudapaka
- Preparation of *Gutika*

Procedure (*Gutika*)[2]:

1. **Preparation of *Churna*:**
   All ingredients were separated from physical impurities like sand particles, stones etc. After cleaning all the raw drugs were powdered with the help of disintegrator in fine form.
2. **Preparation of *Gudapaka*:**
   Specified quantity of jaggery powder is taken in a clean, wide mouthed stainless steel vessel placed over mild fire. It is added with required quantity of water and cooked with frequent stirring till the *gudapaka lakshana* appears.
3. **Preparation of *Gutika*:**
   When gudapaka lakshana are attained, the fine powder of all the other drugs are added little by little and stirred well to get a homogenous drug mass. This drug mass is used to roll the pills of two grams, which are later dried in shade and stored suitable airtight container.

Pharmaceutical Methods implied for Lozenges preparation: In this practical hard candy form of lozenges is prepared. Sugar, starch and menthol were the excipients used. Heating and Congealing technique was adopted by slight modification[3].

- Preparation of Coarse powder.
- Preparation of *Kwath*.
- Preparation of *Vyoshadi* Lozenges.

Materials:

1. Kwath of Raw Drugs: 500ml
2. Water: 100ml
3. Sugar: 2 Kg
4. Corn Syrup: 250gm
5. Menthol: 1gm

Procedure:

1. **Preparation of Coarse Powder:**
   All ingredients were separated from physical impurities like sand particles, stones etc. All the raw drugs were powdered in the coarse form with the help of disintegrator. This coarse powder is basically known as *sthoola churna*. This coarse powder is ready to prepare *kwatha*.
2. **Preparation of *Kwatha*:**
   Kwatha is the liquid preparation obtained by boiling one part of ingredients in coarse powder form along with sixteen parts of water and reduced to 1\8th. The coarse powder of all the ingredients of *Vyoshadi* are taken together in a stainless-steel vessel. Add sixteen-time water in it. Put it on mild fire. When the 1\8th of the total mixture remains then filter the liquid. This filtrate is called *kwatha* and ready to make lozenges.
3. **Preparation of *Vyoshadi* Lozenges:**
   A wide mouthed stainless-steel vessel is taken and add water in given quantity into it. Add the sugar and corn syrup in given quantity into the water. Put it on mild fire and continue heating the water and mix it with the help of

spoon till the sugar completely dissolve in it. After that add the *kwatha* of raw drugs into it and continuous mix it on mild fire till all the water evaporates and the liquid starts thicken and 2 to 3 thread consistency starts appearing. When the water completely evaporates and the liquid becomes thick then remove the vessel from fire and add menthol into it. After that mould the lozenges into proper shape and 2 gm size when the mass is hot. **(Table No. 3)** Organoleptic Characters: (Table No. 4) showing organoleptic character of lozenges and *Gutika*. Analytical Study: (Table No. 5) showing analytical study of lozenges and *Gutika*. HPTLC FINGERPRINTING OF *VYOSHADI GUTIKA* AND *VYOSHADI* LOZENGES (Table No. 6) Showing HPTLC Chromatogram @254 nm

DISCUSSION

For the purpose of making *Gutika* under this research study, the reference of *Vyoshadi Gutika* has been taken from *Sharangdhar*. Although, many other different *acharyas* have given the references of same formulation in different classical text but some *acharya* like *Chakradutta, Rasa Ratnakar, Gada Nigraha* explains *Vyoshadi Gutika* as Vyoshantika *Gutika* with some of different ingredients but in same disorders *kasa, shwasa* etc. *Acharya Vagbhatta* explains *Vyoshadi Gutika* with different ingredients in *Arsha Roga* and *Twak Dosha*. The texts which explains the same formulations of *Vyoshadi Gutika* are: *Sharangdhar Samhita***,** *Brihat Nighantu Ratnakar***,** *Yog Chintamani.*

Analytical tests of both the formulations were done. Hardness of lozenges was more than *gutika*, it may be because of adding of corn syrup, binder. Total Ash of Lozenges is less than of *gutika*, it may be due to adding of *kwatha* rather than raw drugs. Water sol. ash is more in Lozenges compare *to gutika*, it may be due to amount of sugar is more in Lozenges than the *guda* in *gutika*. Friability of Lozenges is 0%. More sugar content makes more water soluble ash. Reducing sugar is more in Lozenges which is due to Corn syrup. High content of reducing sugar makes preferable[4]. Non-reducing sugar is more in Lozenges which is due to sucrose, a non-reducing sugar is used in more quantity.

Lozenges are Chewable tablets which are used for many disorders like *Pratishyaya, Kasa, Shwasa* and *swarbheda.* They act through a favored delivery system by dissolving slowly in the oral cavity or throat which is ideal for drugs meant for relieving sore throat and cold symptoms. *Vyoshadi Gutika* and *Vyoshadi* Lozenges were quite differing in the organoleptic characters like Odour, Colour, taste due to change of *kalpana*. In the slides of HPTLC chromatogram @ 254 nm 8 spots observed in *Gutika* and 4 spots were observed in lozenges. In the slide of HPTLC chromatogram @ 366 nm 11 spots observed in *Gutika* and 4 spots were observed in lozenges. In the slide of HPTLC chromatogram @ 540 nm 5 spots were observed in *Gutika* and 2 spots were observed in lozenges. It was found that all the results drawn out of the analytical analysis of both *Gutika* and Lozenges concluded that the active components of lozenges were more sensitive under 254 nm UV radiation.

CONCLUSION

The classical chewable tablets have bitter taste so less preferred and less palatable. Hence, lozenges are the new dosage form for those chewable tablets as it tastes far better with some extra sugar and menthol in it which sooths throat very effectively. As well as they pass the criteria of less friable, they can be easily marketed on large scale. The specific characters of some ingredients used in the preparation were analysed with the help of Phyto-chemical evaluation. The current observations drawn out of the study can be considered standard for future studies.

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Table No. 1 showing drugs and quantity for preparation of *Gutika*.

S. No.	Name of Drug	Latin Name	Part Used	Quantity
1.	*Sunthi*	*Zingiber officinale*	*Kanda*	36 gms
2.	*Marich*	*Piper nigrum*	*Phala*	36 gms
3.	*Pippali*	*Piper longum*	*Phala*	36 gms
4.	*Amalvetas*	*Garcinia pedunculata*	*Phala*	36 gms
5.	*Chavya*	*Piper retrofractum*	*Kaand*	36 gms
6.	*Talishpatra*	*Abies webbiana*	*Patra*	36 gms
7.	*Chitarak*	*Plumbago zeylanica*	*Mool*	36 gms
8.	*Jeerak*	*Cuminum cyminum*	*Phala*	36 gms
9.	*Tintidik*	*Rhus Parviflora*	*Phala*	36 gms
10.	*Dalcheeni*	*Cinnamomum zeylanicum*	*Twak*	9 gms
11.	*Tejpatra*	*namomum tamala*	*Patra*	9 gms
12.	*Ela*	*Elettaria cardamomum*	*Phala*	9 gms
13.	*Guda*			720 gms

Table No. 2 showing drugs and quantity for preparation of lozenges.

S. No.	Name of Drug	Latin Name	Part Used	Quantity
1.	*Sunthi*	*Zingiber officinale*	*Kanda*	36 gms
2.	*Marich*	*Piper nigrum*	*Phala*	36 gms
3.	*Pippali*	*Piper longum*	*Phala*	36 gms
4.	*Amalvetas*	*Garcinia pedunculata*	*Phala*	36 gms
5.	*Chavya*	*Piper retrofractum*	*Kaand*	36 gms
6.	*Talishpatra*	*Abies webbiana*	*Patra*	36 gms
7.	*Chitarak*	*Plumbago zeylanica*	*Mool*	36 gms
8.	*Jeerak*	*Cuminum cyminum*	*Phala*	36 gms
9.	*Tintidik*	*Rhus Parviflora*	*Phala*	36 gms
10.	*Dalcheeni*	*Cinnamomum zeylanicum*	*Twak*	9 gms
11.	*Tejpatra*	*namomum tamala*	*Patra*	9 gms
12.	*Ela*	*Elettaria cardamomum*	*Phala*	9 gms
13.	Sugar			1404 gms
14.	Corn Syrup			175.5 gm
15.	Menthol			5 gm
16.	Water			250 ml

Table No. 3 showing result of lozenges.

S. No.	Particulars	Results
1.	Weight of all ingredients	351 gms
2.	Weight of *Kwatha*	702 ml
3.	Weight of Sugar taken	1400 gms
4.	Weight of Corn Syrup taken	175 gms
5.	Weight of each Lozenges	2 gm
6.	Total No. of Lozenges	480

Organoleptic Characters:

Table No. 4 showing organoleptic character of lozenges and *Gutika*.

S. No.	Organoleptic Character	*Vyoshadi Gutika*	*Vyoshadi* Lozenges
1.	Colour	Brown	Chocolate Brown
2.	Odour	Characteristic	Aromatic
3.	Taste	Sweet, Sour	Sweet
4.	Touch	Solid	Solid

Analytical Study:

Table No. 5 showing analytical study of lozenges and *Gutika*.

S. No.	Test	Result (*Gutika*)	Result (Lozenges)
1.	pH (5% Aq. Solution)	5.5	5
2.	Loss on Dry (LOD)	4%	3%
3.	Water Soluble Ash	2.6%	3.95%
4.	Acid Insoluble	0.5 % w/w	0.81
5.	Ash Value	4%	1.5%w/w
6.	Hardness	3.8 kg/cm^2	6.2 kg/cm^2
7.	Friability	0.64 %	0.0 %
8.	Wt. Variation	2.05%	2.017%

HPTLC FINGERPRINTING OF *VYOSHADI GUTIKA* AND *VYOSHADI* LOZENGES

Table No. 6 Showing HPTLC Chromatogram @254 nm

Spot No.	Track 1	Track 2
1.	0.30	-
2.	0.37	-
3.	0.42	-
4.	0.52	0.52
5.	0.61	0.61
6.	0.69	0.69
7.	0.77	0.77
8.	0.85	-

Track T1: *Vyoshadi Gutika*, Track T2: *Vyoshadi* Lozenges

Table No. 7 showing HPTLC Chromatogram @366 nm

Spot No.	Track 1	Track 2
1.	0.33	-
2.	0.38	-
3.	0.42	-
4.	0.47	-
5.	0.50	-
6.	0.60	0.60
7.	0.68	-
8.	0.72	0.72
9.	0.78	-
10.	0.84	0.84
11.	0.92	0.92

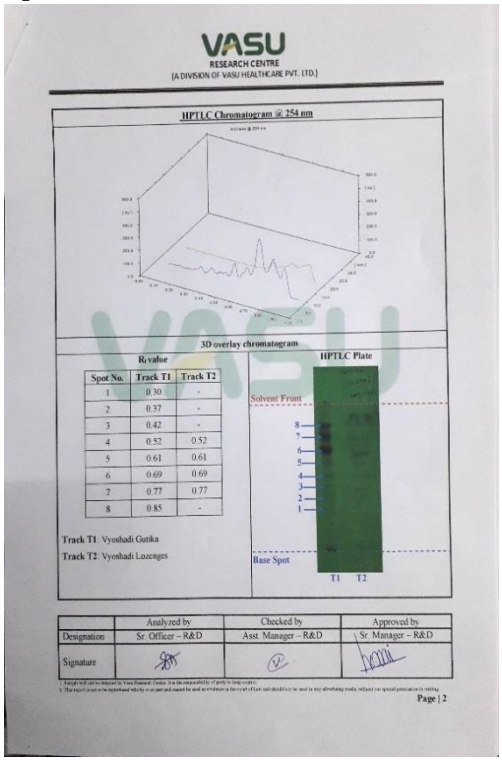
Track T1: *Vyoshadi Gutika*, Track T2: *Vyoshadi* Lozenges

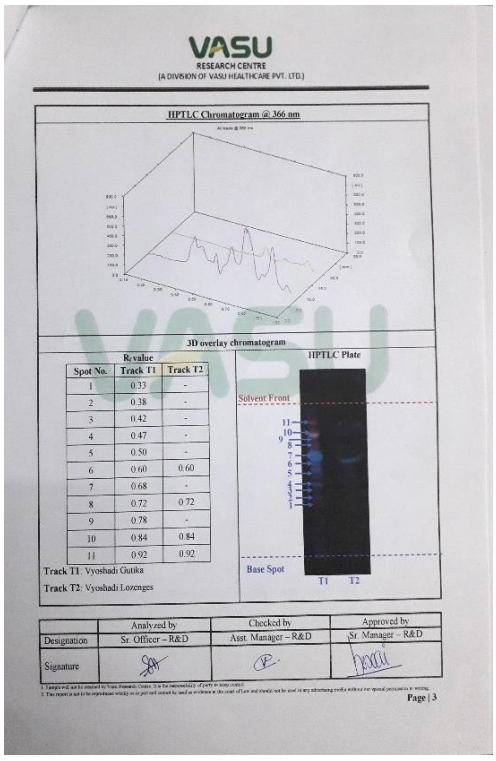
Spot No.	Track 1	Track 2
1.	0.17	-
2.	0.58	0.58
3.	0.70	0.70
4.	0.83	-
5.	0.93	-

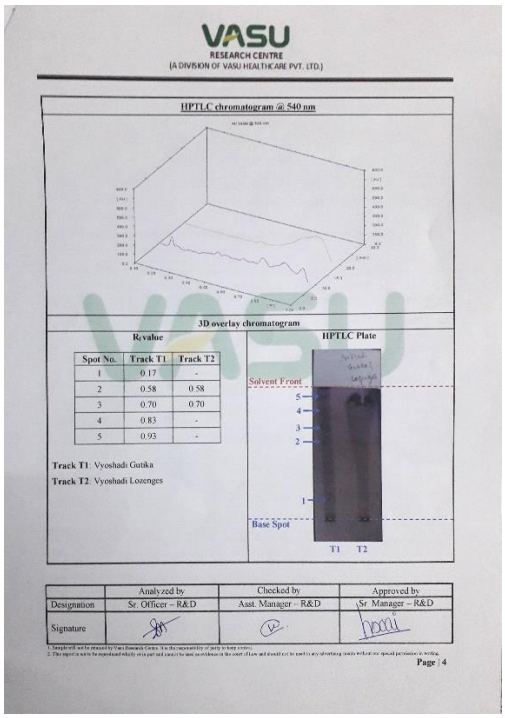
Table No. 8 showing HPTLC Chromatogram @540 nm

Track T1: *Vyoshadi Gutika*, Track T2: *Vyoshadi* Lozenges

Reports of HPTLC done at different wavelength:-







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HPTLC chromatogram @ 540 nm

3D overlay chromatogram

Rf value

Spot No.	Track T1	Track T2
1	0.17	-
2	0.58	0.58
3	0.70	0.70
4	0.83	-
5	0.93	-

Track T1: Vyoshadi Gutika
Track T2: Vyoshadi Lozenges

HPTLC Plate

Solvent Front
Base Spot
T1 T2

	Analyzed by	Checked by	Approved by
Designation	Sr. Officer – R&D	Asst. Manager – R&D	Sr. Manager – R&D
Signature			

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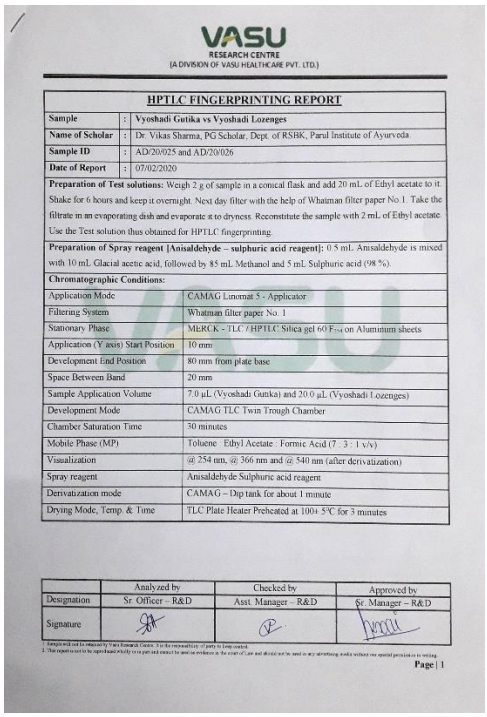

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HPTLC FINGERPRINTING REPORT

Sample	:	Vyoshadi Gutika vs Vyoshadi Lozenges
Name of Scholar	:	Dr. Vikas Sharma, PG Scholar, Dept. of RSBK, Parul Institute of Ayurveda
Sample ID	:	AD/20/025 and AD/20/026
Date of Report	:	07/02/2020

Preparation of Test solutions: Weigh 2 g of sample in a conical flask and add 20 mL of Ethyl acetate to it. Shake for 6 hours and keep it overnight. Next day filter with the help of Whatman filter paper No.1. Take the filtrate in an evaporating dish and evaporate it to dryness. Reconstitute the sample with 2 mL of Ethyl acetate. Use the Test solution thus obtained for HPTLC fingerprinting.

Preparation of Spray reagent [Anisaldehyde – sulphuric acid reagent]: 0.5 mL Anisaldehyde is mixed with 10 mL Glacial acetic acid, followed by 85 mL Methanol and 5 mL Sulphuric acid (98 %).

Chromatographic Conditions:

Application Mode	CAMAG Linomat 5 - Applicator
Filtering System	Whatman filter paper No. 1
Stationary Phase	MERCK - TLC / HPTLC Silica gel 60 F254 on Aluminium sheets
Application (Y axis) Start Position	10 mm
Development End Position	80 mm from plate base
Space Between Band	20 mm
Sample Application Volume	7.0 µL (Vyoshadi Gutika) and 20.0 µL (Vyoshadi Lozenges)
Development Mode	CAMAG TLC Twin Trough Chamber
Chamber Saturation Time	30 minutes
Mobile Phase (MP)	Toluene : Ethyl Acetate : Formic Acid (7 : 3 : 1 v/v)
Visualization	@ 254 nm, @ 366 nm and @ 540 nm (after derivatization)
Spray reagent	Anisaldehyde Sulphuric acid reagent
Derivatization mode	CAMAG – Dip tank for about 1 minute
Drying Mode, Temp. & Time	TLC Plate Heater Preheated at 100± 5°C for 3 minutes

	Analyzed by	Checked by	Approved by
Designation	Sr. Officer – R&D	Asst. Manager – R&D	Sr. Manager – R&D
Signature			

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Total Sugar :-

Table No. 9 showing Total sugar in lozenges and *Gutika*.

S. No.	Parameters	*Vyoshadi Gutika*	*Vyoshadi* Lozenges
1.	Total Sugar by UV (% w/w)	60.80%	72.68%

Reducing Sugar:-

Table No. 10 showing Reducing sugar in lozenges and *Gutika*.

S. No.	Parameters	*Vyoshadi Gutika*	*Vyoshadi* Lozenges
1.	Reducing Sugar (%w/w)	9.13%	15.21%

Non-Reducing Sugar:-

Table No. 11 showing Non- Reducing sugar in lozenges and *Gutika*.

S. No.	Parameters	*Vyoshadi Gutika*	*Vyoshadi* Lozenges
1.	Non-Reducing Sugar(%w/w)	51.67%	57.47%