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Research Protocol

Ayurveda Section

Pharmaceutico-analytical Evaluation of *Drakshadi Gutika* and a Novel Polyherbal Tablet with Comparative Assessment of Antioxidant Activity and Acid-neutralising Capacity: A Research Protocol

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ABSTRACT

Introduction: Polyherbal formulations are an essential element of traditional medicine systems, particularly Ayurveda, due to the synergistic effects produced by the combination of multiple plant-derived ingredients. *Drakshadi Gutika* is a well-known Ayurvedic formulation primarily used to enhance digestion and address gastrointestinal disorders. In contrast, the Novel Polyherbal Tablet (NPT) will be a contemporary multi-herb-based formulation designed to address similar therapeutic indications. Both formulations are believed to possess antioxidant and acid-neutralising properties, which will be crucial for managing oxidative stress and gastric acidity, respectively.The study intends to provide a scientific basis for their quality control and therapeutic potential.

Need of the study: Stress is a major cause of hyperacidity, affecting 60–70% of individuals. This study introduces a Novel Polyherbal Tablet formulated with proven antioxidant and antiulcer herbs to evaluate its synergistic antioxidant and acid-neutralising effects compared to Drakshadi Gutika. Due to the impracticality of Drakshadi Gutika's classical 12 g dosage, a modified, formulation is proposed.

Aim: To evaluate and compare the pharmaceutico-analytical properties, antioxidant activity and acid-neutralising capacity of Drakshadi Gutika and the Novel Polyherbal Tablet. The study intends to provide a scientific basis for their quality control and therapeutic potential.

Materials and Methods: This experimental analytical study will take place from July 2025 to November 2025 at the Biocyte Research and Development Pvt Ltd., Sangli. Both Drakshadi Gutika and NPT will be procured from authenticated sources and their ingredients will be identified and analysed for Standardisation. The pharmaceutico-analytical assessment included evaluations of organoleptic properties (colour, taste, odour), moisture content, total ash and loss on drying, as well as dissolution profiles. For antioxidant activity, the 2, 2-diphenyl-1- picrylhydrazyl (DPPH) free radical scavenging assay will be employed to determine the antioxidant potential of both formulations. The acid-neutralising capacity of each formulation will be measured through titration with a standardised acid solution, calculating the buffering capacity against simulated gastric acid. Statistical analysis will be performed to compare the results of both formulations with respect to antioxidant activity and acid-neutralising capacity will be compared by using statistical analysis by applying Unpaired t-test.

Keywords: *Amlapitta*, Ayurvedic medicine, *Guduchi Sattva*, Polyherbal formulations, Standardisation

INTRODUCTION

Ayurveda is a holistic science that prioritises both healing and prevention. Its primary goal is to prevent illness and maintain good health [1]. Ayurveda gives a thorough understanding of herbal and mineral drugs, including their identification, preparation and preservation under various conditions. *Rasashastra* and *Bhaishajya Kalpana* are two sections.

The word *Kalpana* literal meaning is *Yojana* (plan or strategy), which refers to the systematic method developed for the preparation of medicines. *Kalpana,* as a result, refers to the process of converting a substance or drug into a therapeutic form [2].

Nowadays, everyone lives a very busy and stressful life. Most people are unaware of their balanced diets or what foods they should consume at any given time. There are many people who prefer street food. These minor mistakes in their eating habits altered their diet plan. *Amlapitta* is the result of an inappropriate dietary regimen or stress [3].

Amlapitta is a common disease of *Annavahasrotas* (gastrointestinal tract disorder) caused by vitiated *Agni*. *Amlaguna* (sour taste) of *Pachak pitta* (gastric juice) rises due to *Samata* in *Amlapitta* disorder. Acharya Kashyapa mentioned the contribution of three doshas in *Amlapitta*, whereas Madhavkara stated that *pitta* is most prevalent in this disease. Acharya Charaka didn't refer to *Amlapitta* as an individual disease, but rather as a symptom. They also stated *amlapitta* in *Granhi* (intermittent loose motions that are followed by constipation) as a form of its *Lakshana* [4].

In modern science, *Amlapitta* corresponds with hyperacidity. In this condition, acid formation or acid levels in the stomach increase. During the digestion process, the stomach secretes a limited amount of hydrochloric acid and digestive juices, which convert the food into small particles for easy and normal digestion; however, when hydrochloric acid levels rise above normal limits, this is known as hyperacidity.

Acidity is a medical condition whereby fluid in the stomach produces too much acid. The English word "ulcer" is derived from the Latin word ulcus (genitive: ulceris), indicating "sore, wound, or ulcer," so a peptic ulcer literally refers to tissue corrosion in the digestive tract. The English word "peptic" comes from the Latin word pepticus, which means "to digest" or "promoting digestion."

An ulcer represents a sore or destruction within the digestive system's surrounding caused by acidic digestive juices secreted by stomach cells. A peptic ulcer is a wound or gap in the stomach, duodenum, or oesophagus [5]. According to the survey conducted in India in 2021, approximately 32% of adults aged 30 years to 44 years reported acidity and indigestion problems. There are certain side-effects of other antacid drugs and hence there is need to find an efficient drug. In present drug novel polyherbal tablet, we are using stevia instead of sugar, so that it can be beneficial for patients with the history of DM.

Glycyrrhiza glabra L. has been utilized in traditional medicine to treat stomach-related conditions such as peptic ulcers. There are currently effective treatments for peptic ulcers. However, they are prohibitively expensive and have numerous side-effects, limiting their use. Plants with medicinal properties are one of the most appealing sources of new drugs with promising results in peptic ulcer management [6]. *G. glabra* extracts showed strong antioxidant and free radical scavenging properties and they could be used for protecting tissues from free radical and Reactive Oxygen Species (ROS) damage [7]. The extract of ethanol from the root of *T. cordifolia* was found to be highly protective towards stress-induced ulceration. Its effect was similar to the effect of diazepam [8].

The present formulation contains the ingredients – *Draksha, Haritaki*, Stevia, *Patola*, *Shweta Chandan,Guduchi sattva, Yashtimadhu*, the antiulcer and antioxidant activity of each individual drug is proven. In the present study the authors are proving the synergistic activity of novel polyherbal tablet and comparative study of antioxidant and acid neutralising capacity of Drakshadi Gutika and novel polyherbal tablet.

Aim: Pharmaceutico-analytical study of Drakshadi Gutika and novel polyherbal tablet and their comparative assessment of antioxidant activity and acid neutralising capacity.

Objectives:

- To prepare SOP of Novel Polyherbal Tablet and *Drakshadi Gutika*.
- To study the quality control parameters of Novel Polyherbal Tablet and *Drakshadi Gutika*.
- To evaluate anti-oxidant activity and acid neutralising capacity of Novel Polyherbal Tablet.

REVIEW OF LITERATURE

Study published by Gupta A et al., in 2010 states that, the plant of *Haritaki* has the potential of treating various kind of diseases and has got many medicinal activity like anti-oxidant, wound healing, anti-microbial, anti-fungal, anti-diabetes, anti-ulcer, antidermatophytic, Cardioprotective, Hypolipidemic and Hypocholesterolemic and manymore yet to be discovered or experimented upon. There is a need toexplore this plant very thoroughlyandresearchers areexploringthe therapeuticpotential ofthisplant[8].

Another study published in 2019 by Malav R et al., examined, *Draksha digutika* correct the vitiated state of *pitta* and correctsthe whole digestion process which results in proper functioning of *Agni*. It also helps in abolishing all themajorfactors involved in pathogenesisofdisease [9].

A study by Insanu M et al., in 2021 was published as, every part of Vitis vinifera L. was rich in phytochemical compounds, which differ from one component to another. Every part and compound contained therein hadbenefits for humans, as evidencedby the many pharmacological activities found. The pharmacological activity depends on the part of the grapevines and the type of extract used [10].

Amlapitta pathogenesis involves impaired digestive function, which leads to the formation of Ama, a substance that undergoes transformation before reaching its final form. *Haritaki's Vatanulomana* (downward movement of vayu) property aids in the elimination of excess *vidgdha pitta* from the body. *Haritaki is also Mridu Rechaka* which excessive *vidgdhapitta* pulls out of body. *Draksha* having following properties like *trishan anigrahana, snehana, anulomana* due to having *guna* of *snigadha, sheeta* and *madhura* [9].

Ingredients in Novel Polyherbal Tablet correct *pitta*'s vitiated state and the entire digestion process, resulting in the proper functioning of *Agni*. It also helps to eliminate all of the major factors involved in disease pathogenesis. As a result, it can be demonstrated as an effective treatment for *Amlapitta*. This study could lead to a significant achievement in the treatment of *Amlapitta* in the future.

Drug Review

The ingredients and properties of Novel Polyherbal Tablet are enlisted in [Table/Fig-1] [11-17].

Name (Material)	*Rasa* (Taste)	*Guna* (Quality)	*Virya* (Potency)	*Vipaka* (Bio-transformed *rasa*)	*Doshaghnata* (Regulatory functional factors of the body)
Haritaki (*Termineliache bula Retz.*) [11]	Kashaya pradhan pancharasa Lavanvarjit	Laghu, Ruksha	Ushna	Madhur	Tridosahara
Draksha (*Vitisvinifera Linn*) [12]	Madhur	Snigdha, Guru, Mridu	Sheeta	Madhur	Vata-pittahara
Stevia (*Steviare baudiana Bertoni*) [13]	Madhur	Laghu	Sheeta	Madhur	Vata-pittahara
Guduchi Satva (*Tinosporacardifolia (Willd.) Miers*) [14]	Tikta, Kashay	Laghu	Ushna	Madhur	Tridoshaghna
Shweta Chandan (*Santalum album* L.) [15]	Madhur, Tikta	Laghu, Ruksha	Sheeta	Katu	Pitta-kaphahar
Patola (*Trichosanthese Dioica Linn*) [16]	Tikta, Katu	Laghu, Ruksha	Ushna	Katu	Pitta-kaphahar
Yashtimadhu (*Glycyrrhiza glabra Linn*) [17]	Madhur	Guru, Snigdha	Sheeta	Madhur	Vata-pittahara

[Table/Fig-1]: Showing the ingredients and properties of polyherbal tablet [11-17].

MATERIALS AND METHODS

The experimental analytical study will be planned to take place from July 2025 to November 2025.The research drug will be procured from Vedpoorna Ayurveda *Rasashala* and Herbal Garden, MGACH & RC, Salod (H.), Wardha. Drug will be verified and authenticated by Taxonomist/*Dravyaguna* department. Drugs will best and ardized as per Ayurvedic Pharmacopoeia of India (API). Study will be conducted at Biocyte Research and Development Pvt Ltd., Sangli. The research has been approved by the Institutional Ethics Committee (IEC) of DattaMeghe Institute of Higher Education and Research under reference number MGACHRC/IEC/Jun-2024/855.

Study Procedure

Method of preparation: Time required for preparation of *Guduchi Sattva* will be 15 days.

- **Preparation of *Guduchi satva***: Thick-thumb-sized stems of *Guduchi* will be taken and cut into small pieces. These pieces will then be crushed into a fine pulp using a *Khalvayantra*. The resulting pulp will be mixed with four times the quantity of water and kept undisturbed overnight for soaking. The next morning, the mixture will be thoroughly rubbed and squeezed by hand to separate the fibrous matter, which will then be filtered. The obtained filtrate will be allowed to stand still so that the sediment settles at the bottom. Once settled, the clear supernatant liquid will be carefully decanted and the remaining sediment or paste will be collected. This paste will finally be sun-dried until all moisture is completely evaporated.

Preparation of *Drakshadi Gutika* [Table/Fig-2,3] [11-18]

Time required for preparation of *Drakshadi Gutika*: 8 days

Raw materials will be procured and subsequently verified by a qualified taxonomist. After verification, they will be authenticated in accordance with the standards prescribed in the API. All the selected drugs will be thoroughly cleaned. Each ingredient will then be pulverised individually and sieved through an appropriate mesh to obtain a fine powder. The powders of all drugs will be weighed separately as per the required formulation. These individual powders, along with *Sita* (sugar), will be mixed in the specified quantity and triturated using a *Khalvayantra* to ensure uniform blending. Tablets of the desired size will then be prepared. Finally, the prepared tablets will be properly dried and stored for further use.

S. No.	Drugs	Part used	Proportion
1.	*Draksha* (*Vitisvinifera Linn*) [12]	Fruit	1Part
2.	*Haritaki* (*Terminalia chebula Bert*) [11]	Fruit	1Part
3.	*Sita* (*Sugar candy*) [18]	-	2 Parts

[Table/Fig-2] List of ingredients used for *Drakshadi Gutika* [11,12,18].

S. No.	Drugs	Part used	Proportion
1.	*Draksha* (*Vitisvinifera Linn*) [12]	Fruit	1Part
2.	*Haritaki* (Terminaliachebula Bert) [11]	Fruit	1Part
3.	Stevia (*Steviare baudiana* Bert) [13]	Leaves	1Part
4.	*Patola* (Trichosanthesdioica) [16]	Patra	1Part
5.	*Guduchi* (Tinospora Cordifolia (Willd) Miers) [14]	Sattva	1Part
6.	*Shweta Chandan* (*Santalum Album* Linn) [15]	Stem	1Part
7.	*Yashtimadhu* (*Glycyrrhiza glabra Linn*) [17]	Stem	1Part

[Table/Fig-3]: List of ingredients used for Novel Polyherbal Tablet [11-17].

Preparation of Novel Polyherbal Tablet: Time required for preparation of Novel Polyherbal Tablet: 15 days

Raw materials will be procured, verified by a taxonomist and authenticated as per API standards. All drugs will be cleaned thoroughly to remove any foreign matter. Each ingredient will then be individually pulverised and sieved through a mesh. After weighing the powders separately, they will be mixed in the specified quantity along with *Guduchi Sattva*. The blended powders, along with gum acacia, will be taken and tablets of the desired size will be prepared through wet granulation process using a tablet punching machine, followed by proper drying and storage.

Composition of material:

Analytical Study (Physico-chemical Parameter)

Analytical Parameters of Novel Polyherbal Tablet

A. Organoleptic Parameters: It includes the evaluation of Touch (*Sparsha*), Appearance (*Rupa*), Taste (*Rasa*) and Odour (*Gandha*).

B. Physico-chemical Parameters: The physico-chemical parameters will be analysed to ensure the quality, purity, stability and uniformity of the formulation. It includes loss on drying at 105°C, total ash, acid-insolubleash, water-soluble extractive and alcohol-soluble extractive values, hardness, uniformity of weight, disintegration time, microbial contamination, friability, High-Performance Thin-Layer Chromatography (HPTLC).

Experimental study:

Anti-oxidant study:

By DPPH Method:

- The sample compounds' antioxidant activity will be assessed using DPPH free radicals.
- The micro titer plate contained 100 µL of test compound water. The samples will be treated with 100 µL of 0.1% methanolic DPPH and incubated for 30 minutes in the dark.
- The samples will be examined for discolouration, with purple to yellow and pale pink indicating strong and weak positive results, respectively. The plate will read at 490 nm using an Elisa plate reader.
- The equation for calculating radial scavenging activity is as follows:
- DPPH radical scavenging activity (%)=

  (Abs control – Abs sample)/Abs control]×100

Acid neutralising capacity:

- The formulation's acid Neutralising capacity (50 mg/mL) will be compared to the standard antacid (Aluminum hydroxide + Magnesium hydroxide, 500 mg).
- Water will be added to the 5 mL mixture to make a total volume of 70 mL, then mixed for one minute.
- After adding 30 mL of 1.0 N HCl to the standard and test preparations and stirring for 15 minutes, add drops of phenolphthalein solution and mix.
- To achieve a pink colour, titrate excess HCl with 0.5N sodium hydroxide solution drop by drop.

The moles of acid neutralised are calculated as follows: Moles of acid neutralised = (vol. of HCl x Normality of HCl) - (volume of NaOH x Normality of NaOH)

Outcomes

Primary outcome: Improvement in efficacy of Drakshadi Gutika and Novel Polyherbal Tablet in *Amlapitta* (Hyperacidity).

Secondary outcome: Improvement in Antioxidant activity and Acid-neutralising capacity.

Scope and implication: The positive outcome of the study will help to generate the antioxidant and antiulcer potential amongst the formulations.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) Software for the statistical analysis is used. Unpaired t-test will be used for analysis and p>0.001 will be considered as a statistical significance.

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