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Comparative Quality Assessment of Three Different Marketed Brands of Indian Polyherbal Formulation – Avipattikar Churna

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Introduction

1. Amlapitta (Hyperacidity):

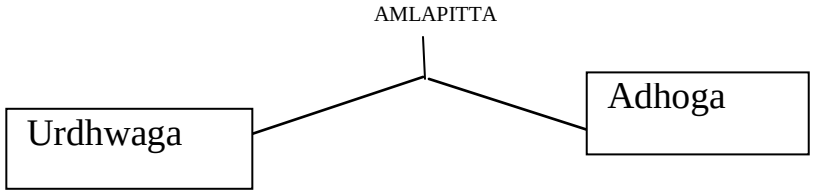
Amlapitta (Hyperacidity) is becoming common nowadays due to changing lifestyle, variation in sleeping patterns, improper diet and stress. The main cause of Amlapitta is not following Ahara vihara vishshaayatanaetc [1]. According to Sushrut in Sutrasthana, the quality of pitta is ordinarily katu and becomes amla when it vidagdha. [1]. When pitta is inflamed, it produces excessive acidity in the stomach, a burning feeling, and colic discomfort when combined with vata [1]. Amla-pitta cannot be linked to a single Acid Reflux Syndrome, which includes GERD, Gastritis, Dyspepsia, Peptic Ulcer, and Hyperacidity [3]. It is also caused by the side effects of some allopathic medicines, using over the counter drugs which mostly include analgesics, antibiotics, and gastric acid lowering drugs. These drugs have too many prove side effects from minute to life-threatening [3]. People having tendency of irregular pitta (acid) secretion are at higher risk of acidity when they do not follow proper diet, regular eating times, exercise, proper sleep, stress, etc.

Physiological properties (Guna) of Amlapitta:

- Kattu
- Amla Rasatmak
- Tikshana
- Ushana
- Visra
- Drava

Classification of Amlapitta:

Amlapitta can be classified based on sansarg (contagion)



Different dosh sansarga:

- Vatanubandhi
- Kaphanubandhi,
- Vatkaphanubandhi

2. Peptic ulcer:

Peptic ulcer is the lesion in the lining of stomach, small intestine and oesophagus. The ulcer that develops on the lining of stomach is called gastric ulcer, ulcer on the duodenum (part of small intestine) is called duodenal ulcer and the ulcer on the oesophagus is called oesophageal ulcer. Ulcer is caused due to rupture of mucous- bicarbonate barrier by various reasons like the bacteria H. pylori and anti-inflammatory agents, etc. The mucous membrane on the digestive tract protects it from hydrochloric acid and noxious gases by maintain a neutral pH.

When this barrier is ruptured the acid in the stomach damages the lining of the digestive tract causing open sores called ulcer. They can be serious and fatal if there are complications like bleeding at the site of ulcer or perforation of the ulcer.

Symptoms: Symptoms are similar to various acid reflux syndromes like GERD, Gastritis, Dyspepsia, and Hyperacidity.

Typical symptoms include:

- Upper abdominal pain
- Nausea
- Belching
- Heartburn
- Fatigue
- Loss of apetite

3. **AvipattikarChurna**:

AvipattikarChurna is a polyherbal formulation which comprises of 14 ingredients which are enlisted in Table no.1 with their ratios. AvipattikarChurna is an Ayurvedic medication used to treat problems that disrupt the digestive and excretory systems's natural functioning. It reduces acid secretion in the gastrointestinal system and increases the formation of digestive enzymes, which help in nutritional absorption [13].

Avipattikarchurna has potent carminative, antioxidant, and anti-inflammatory qualities that assist in the treatment of pitta dosha imbalances. It can help with digestive issues such as diarrhoea, constipation, gastritis, heartburn, indigestion, and ulcers. Avipatti means to cure a digestive ailment in Ayurveda [13]. It is used for the treatment of acid reflux syndromes like GERD, dyspepsia, hyperacidity, ulcers, etc.

Table No.1: Ingredients of Avipattikarchurna with their ratios

Sr No.	Ingredients	Ratio
1.	Shunthi	1
2.	Maricha	1
3.	Pippali	1
4.	Amalaki	1
5.	Vibhitaki	1
6.	Haritaki	1
7.	Vida lavana	1
8.	Vidang	1
9.	Nagarmotha	1
10.	Ela	1
11.	Tejapatara	1
12.	Launga	11
13.	Nishotha	44
14.	Sarkara	66

The physicocgemal properties of the drug are necessary to discover the best medicine composition and delivery strategy. In this study we have compared some of the physicochemical properties of various marketed preparations of the Indian polyherbal medication-Avipattikarchurna namely BaidyanathAvipattikarchurna, ZanduAvipattikarchurna and Dr. Shri Balaji Tambe'sAvipattikarchurna purchased rom a local pharmacy

Literature Review:

1. **D. Chamundeeswari et al (2007)**

   Evaluation and formulation of churna for digestive property

   Created the digestive churna using normal techniques and tested using physical and analytical methods. They also tested the physical parameters, microbial load and the efficacy of formulated churna was found by finding the amylolytic and lipolytic activity and comparing it with a marketed formulation called GASTRAP. The results obtained showed considerable amylolytic and mild lipolytic action, demonstrating the churna's efficacy for digestive problems.

2. **Aswatha Ram HN et al (2009)**

   Standardisation of AvipattikarChurna- A Polyherbal Formulation

   Standardized the Avipattikarchurna that was prepared in house and two other marketed preparations were used. The standardization was done on the basis of organoleptic characters, physical parameters and physicochemical characteristics according to API. The data obtained was found to be enough to use as reference standards for quality control laboratories.

3. **Aswatha Ram H.N et al (2009)**

   Antiulcer Activity of Aqueous Extract of Avipattikarchurna

   Evaluated the anti- ulcer activity of aqueous extract of Avipattikarchurna on ibuprofen, ethanol and pyloric ligation rats. They assessed the evaluation by mean ulcer size, ulcer number and gastric irritancy index. Aqueous extract of Avipattikarchurna was

found to be effective against gastric lesions.

4. **K. Jayaram Kumar et al (2012)**

Energy dispersive X-ray spectroscopy in quality control of powdered herbal formulation- Avipattikarchurna

In this investigation, flame photometry and EDX were used to quantify distinct trace elements in two different commercial formulations, an in-house formulation, and a formulation without salt of Avipattikarchurna. The presence of sodium, potassium, chlorine, calcium, copper, and zinc is shown by the results. Although flame photometry was used to quantify sodium and potassium, the findings obtained by EDX demonstrated greater sensitivity, precision, and accuracy.

5. **Sudesh Gyawali et al (2013)**

Evaluation of Anti-Secretory and Anti-Ulcerogenic Activities of AvipattikarChurna on The Peptic Ulcers in Experimental Rats.

Carried out a study to test the anti-secretory and anti-ulcerogenic activities of Avipattikarchurna and it with Ranitidine in pyloric ligated rats. They selected 4 groups of rats and each was given vehicle, low dose of Avipattikarchurna, high dose of Avipattikarchurna and Ranitidine respectively. Results showed that the effects of churna were comparable to ranitidine which was supported by histopathological studies of gastric tissues. This concluded that Avipattikarchurna had anti-secretory and anti-ulcerogenic activities.

6. **Rohit Kumar Ravte et al (2015)**

Evaluation of the efficacy of Avipattikarchurna in the management of Amlapitta.

Selected the condition was for clinical testing in order to evaluate the efficacy of a regularly used Ayurvedic medicine, Avipattikarchurna. The selection was done on the basis of signs and symptoms of Amlapitta. They selected 10 patients suffering from from OPD from National Institute of Ayurveda, Jaipur. These patients were treated for 21 days with AvipattikarChurna and scored arbitrarily. The results showed that AvipattikarChurna was effective in the treatment of Amlapitta without any side effects.

7. **Saini Malvika et al (2016)**

Rationality behind Ayurveda compound formulatons- A bird's eye view

Conducted a study to investigate the basic logic underpinning Ayurvedic remedies found in numerous ancient transcripts. Literary evidence on the evolution of a formulation was examined using examples of significant formulations described in diverse literature. According to the findings of this study, creating a specific formulation, aspects such as availability, palatability, potency, safety, effectiveness, and so on should be considered.

8. **Dr. Yadevendra Yadav et al (2019)**

An Updated Review on Recent In-Vitro, In-Vivo and Clinical Researches of AvipattikarChurna.

Did a review on in-vitro, in-vivo and clinical researches of Avipattikarchurna.They described its use in treating Amlapitta (hyperacidity) by relieving the signs and causing no side effects and addiction, even after giving 20 times its normal dose to rats they should no toxicity. They showed that many ingredients in the churna have anti- ulcerogenic and anti- oxidant properties which requires 21-45 days to show the effect. Results give the possible substitution of today's acid lowering drugs with Avipattikarchurna due to its efficacy and lower side effects.

9. **Sonali Patil et al (2019)**

Preparation, Quality Control and Stability Studies of Avipattikarchurna

Prepared the Avipattikarchurna and standardized it by using various quality control parameters. They carried out tests like,biochemical test, ash value, HPLC, IR spectroscopy according to pharmacopoeia. They prepared the churna in order to fulfill the increased demand for alternative medicines especially in traditional system of medicine.

10. **Ajay Kumar Meena et al (2020)**

Standardisation and HPTLC finger print profile of poly herbal churna, An Ayurvedic Formulation

Evaluated the standardization and HPTLC finger print profile of Avipattikarchurna. This evaluation was done on the basis of organoleptic characteristics, physical characteristics and physicochemical parameters like pH, total ash, acid soluble ash, loss on drying, extractive values, etc. and microbial load was evaluated as per API.

11. **Alpana Kulkarni et al (2021)**

Evaluation of Antacid Potential of Ayurvedic Poly-Herbal Formulation for Functional Dyspepsia

Prepared a stable and palatable Avipattikar suspension for the treatment of GERD and dyspepsia. The ingredients used were

sodium carboxymethylcellulose (CMC) as the suspending agent, sodium citrate as the flocculating agent, mannitol as a taste masking agent. The formulated suspension had similar acid neutralizing capacity to that of marketed antacid suspensions.

12. **Sowmya Binu (2021)**

    Avipattikarchurna: 5 ways this ayurvedic wonder improves gut health.

    Described 5 different ways how Avipattikarchurna increases the gut health. It also describes the usage, health benefits and methods of preparation of Avipattikarchurna.

13. **Dr Rajeev Singh (2022)**

    AvipattikarChurna: Uses, Benefits, Side Effects & More

    Wrote the article which highlights the uses, benefits and side effects of Avipattikarchurna along with its therapeutic uses. He has also answered some of the frequently asked questions regarding Avipattikarchurna. The article was written by him for educational purposes only.

Need of work:

Due to today's changing lifestyle various non-communicable diseases like cardiac disorders, Hypertension, Acid reflux syndromes, etc are growing at a faster rate. Acid reflux syndromes like GERD, dyspepsia, hyperacidity, peptic ulcers, etc are some of the most common non-communicable diseases that the people face almost daily. Nearly 15 million Americans suffer from acid indigestion daily [15]. Changing lifestyle include improper sleep, improper eating times, less exercise, obesity, stress, eating unhealthy food (junk food), etc. Also, the working pattern now a days includes sitting at one place for a long period of time which promotes indigestion leading to acidity. Extensive use of electronic gadgets like mobile phones, laptops, computers are also one of the causes.

For the treatment of acidity people tend to use over the counter which mostly include the antibiotics, analgesics and gastric acid lowering drugs. These drugs have many proven adverse effects. Hence, the demand for alternate medicines is increasing with a special demand to traditional system of medicines. Avipattikarchurna is one such medicine from the Ayurvedic medicinal system that is used to treat acid reflux syndromes, it is also used in the treatment of constipation, ulcers and is proven to have lesser side effects. It comprises of 14 different ingredients, The main component is Indian jalap, while the second most important element is clove.Candy sugar is used to hide the pungent and bitter flavour of the other ingredients in the recipe. Madhur Rasa (Sweet Taste) contains Pitta-samak (Pitta Dosha suppressing property) [3].

Ayurvedic, Siddha, and Unani pharmacopeial norms are insufficient to assure the quality of formulations. The analysis of marker chemicals is required to ensure the formulations' quality and identity [7]. The quality assessment tests of these drugs are required to assess the quality standards by determining the physicochemical properties like loss on drying, alcohol soluble extractive value and thin layer chromatography (TLC). These parameters are analysed by performing tests as per the API. This can help the pharmaceutical companies, laboratories, researchers, etc to evaluate and compare the quality standards of different marketed preparations of Avipattikarchurna.

Objective:

"To carry out comparative quality assessment of marketed preparations of Avipattikarchurna".

This would be achieved by

- Comparing the physicochemical parameters like:
- Loss on drying
- Alcohol soluble extractive value
- Thin layer chromatography

Plan of work:

For thereduction of Acid reflux diseases by the use of one of the Traditional systems of medicine i.e., Ayurveda the study was carried out. The compares 3 different marketed formulations of Avipattikarchurna by their quality assessment. Avipattikarchurna is proven to be effective in treating Hyperacidity, Ulcers, Dyspepsia, etc. The comparison can help to determine the quality standards and also the resultant values can be used as reference values. The plan of work is divided into phases to make it easy and understandable. Each phase gives an idea about how the particular work was carried out.

Phase 1

- **Literature review:** Acomprehensive literature review was conducted using journals, the internet, and books.
- **Marketed survey:** Marketed survey was done from internet and from Hadapsar locality in Pune and the marketed formulations were purchased from a local pharmacy shop.
- **Procurement of Raw materials:** Raw materials used were
    1. Baidyanath'sAvipattikarchurna
    2. ZanduAvipattikarchurna
    3. Dr Balaji Tambe'sAvipattikarchurna

Phase 2

It comprises of the study design which is further divided into three parts

1. Characterization of drugs
2. Selection of suitable instruments
3. Quality assessment tests.

Phase 3

Consists of compilation and interpretation of data collected from phase 1&2

Phase 4

It is the final step of study consisting of conclusion.

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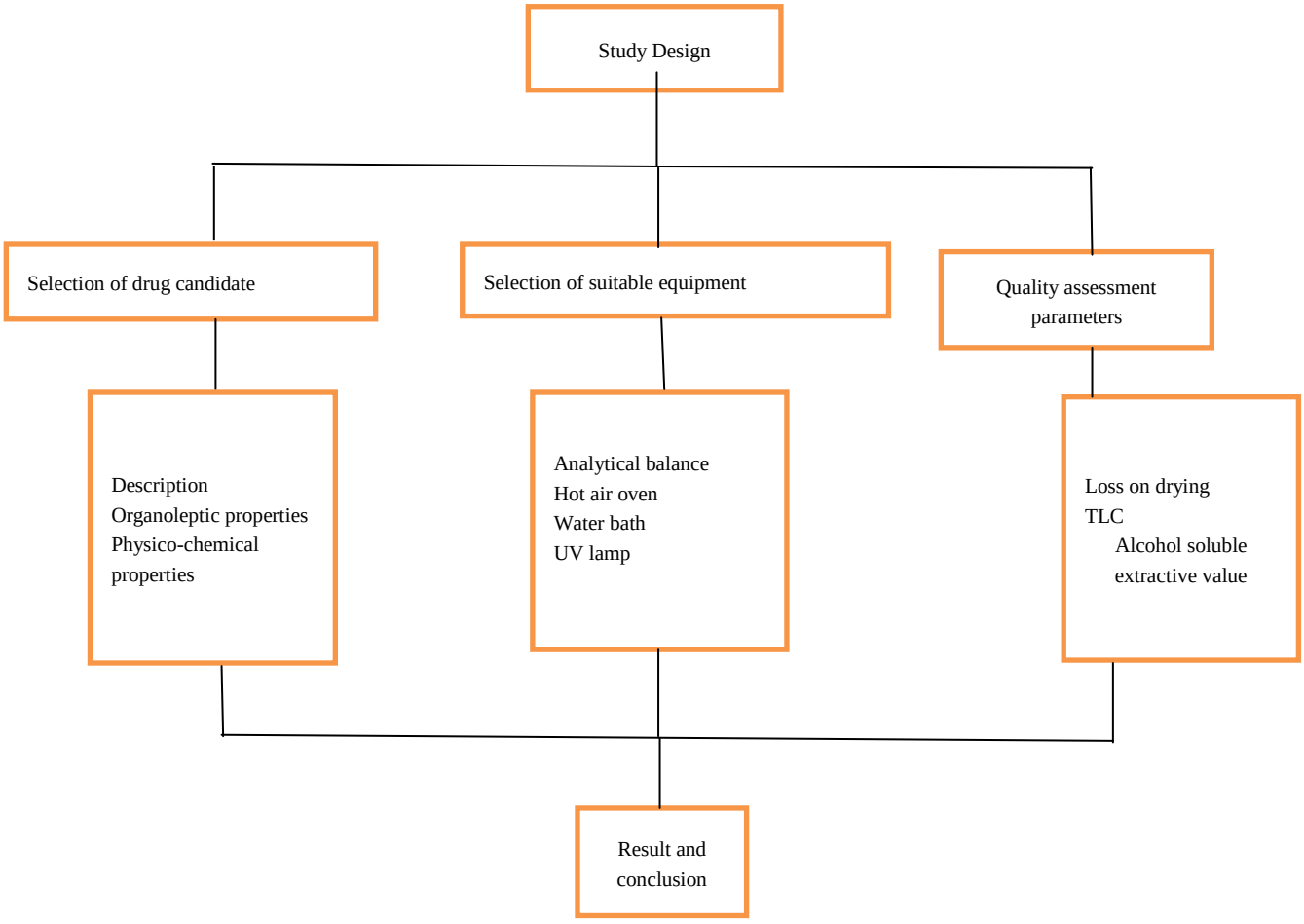
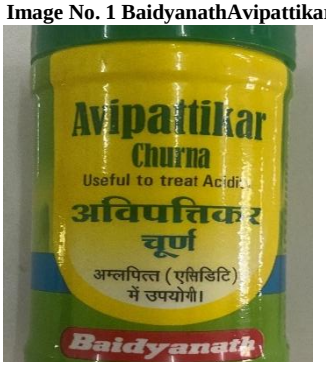


Churna Profile:

1. **Baidyanath**

Churna name: BaidyanathAvipattikarchurna
Brand: Baidyanath
Item form: Churna
Manufactured by: Siddh:ayu
Dosage: 1 to 2 tea spoonsful twice a day with water or as advised by the physician.
Ingredients: Sunthi, Pippali, Marica, Haritaki, Bibhitaka, Amlaki, Musta, Vida-lavana, Vidanga, Suksmaila, Tejpatra, Lavanga, Trivrt, Sarkara
Usage: Helps to relieve the problems of acidity like headache, nausea, sour taste, vomiting, etc. Helps to relieve constipation and to increase apitite.
Price:₹ 120.60

Image No. 1 BaidyanathAvipattikarchurna



2. **Zandu**

Churna name: ZanduAvipattiakarchurna
Brand: Zandu
Item form: Churna
Manufactured by: Emami limited
Doasge: 3gm to 6gm with water or coconut water in a day.
Ingredients: Sunthi, Pippali, Marica, Haritaki, Bibhitaka, Amlaki, Musta, Vida-lavana, Vidanga, Sthulaila, Tvakpatra, Lavanga, Trivrt, Sarkara, Nausader, Sarkara,
Usage: Useful in case of vomiting, hyperacidity, indigestion and constipation.
Price:₹ 116.00

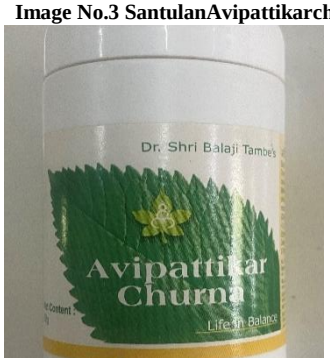
Image No. 2 ZanduAvipattikarchurna

3. **Santulan**

Churna name: Dr. Shri Balaji Tambe'sAvipattikarchurna

Brand: Santulan
Item form: Churna
Manufactured by: Atmasantulana therapy centre
Dosage: 1 tea spoon after food with ghee, milk or water 2-3 times a day, or as directed by the physician.
Ingredients: Sunthi, Pippali, Marica, Haritaki, Bibhitaka, Amlaki, Musta, Vida-lavana, Vidanga, Suksmaila, Tejpatra, Lavanga, Trivrt, Sharkara, Marich,
Usage: Hyperacidity, indigestion, headache due to excessive pitta.
Price:₹130

Image No.3 SantulanAvipattikarchurna



Company profile

1. Baidyanath

Table No. 2 Baidyanath Company profile

Name	Baidyanath
Year of establishment	Since 1917
CEO	Ram Narayan Sharma and Ram Dayal Joshi
Industry type	Medicine healthcare
Headquarters	India
No. of employees	5000
Address of company	Lakhandur road, Desaiganj, Wadsa- 441207, Dist.Gadchiroli(M.S.), Regd:404, Dr CawasjiHormosji street, Mumbai-02
Type of organization	Public
Name of founder	Pt. Ram Narayan Sharma and Pt. Ram Dayal Joshi
Name of current CEO	Vikram Baidyanath
Major areas of operation of company	Ayurvedic medicines Herbal skin care Health supplement
Top five products of company	Kaminividrawanras Chyawanprash Diab support kit Glowing skin combo Mahabhringrajtel

2. Zandu

Table No. 3 Zandu company profile

Name	**Zandu Realty Limited**
Year of Establishment	1910
CEO	Zandu Bhatt and Pattani
Industry type	Pharmaceutical, Real estate
Headquarters	Mumbai, India
No. of employees	2000
Address of company	Emami limited.687, Anandpur, Kolkata-107

Type of organization	Public
Name of founder	Sandeep Jhunjhuwala
Name of current CEO	Anand Mudra
Major areas of operation of company	Formulation and bulk drugs
Top five products of company	Bam, Kesarijivan, NityamVati, Ortho vedic oil, Chyawanprash

3. Santulan

Table No. 4 Santulan Company Profile

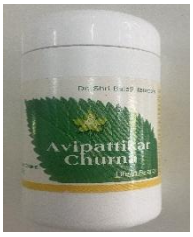
Name	**Santulan Ayurveda**
Year of establishment	1995
CEO	Shri Guru Balaji Tambe
Industry type	Ayurvedic
Headquarters	Pune, India
No. of employees	27
Address of company	Atmasantulan village, near MTDC holiday resort, off. Old Pune-Mumbai highway, Maharastra, India
Type of organization	Public
Name of founder	Shri Guru Balaji Tambe
Name of current CEO	Sunil Tambe
Major areas of operation of company	Immunity boosters Stess busters Pregnancy Acidity, Digestion and Liver Heart care
Top five products	Formula K2 Anant kalpa Brahmaleen oil Abhyanga(C) oil Arjunarishta

Material and Method:

Materials:

- Avipattikarchurna from three different companies were bought from a local Pharmacy shop in Hadapsar, Pune. The selected types included BaidyanathAvipattikarchurna, ZanduAvipattikarchurna and SantulanAvipattikarchurna.
- Comparative quality assessment was done using chemicals like Ethanol, Toluene, Ethyl acetate, etc.
  Glassware includes Beaker, Measuring cylinder, Conical flask, Funnel, Petri dish, Stirrer
  While instruments include weighing balance, Hot air oven, water bath, UV light.

Image No. 4 Different churnas used in study



Methods:

- Loss on drying
- Alcohol soluble extractive value
- Thin layer Chromatography

A. Loss on drying:

The process of loss on drying was carried as per procedure given in practical book. 1.5gm of sample from each marketed product was taken and dried in hot air oven at 100-105ºC till the consecutive weight of each sample was found to be 0.5gm. The sample was removed from hot air oven, cooled and weighed. [18]

Image No.5 Sample taken in porcelain dish for loss on drying

B. Alcohol soluble extractive value:

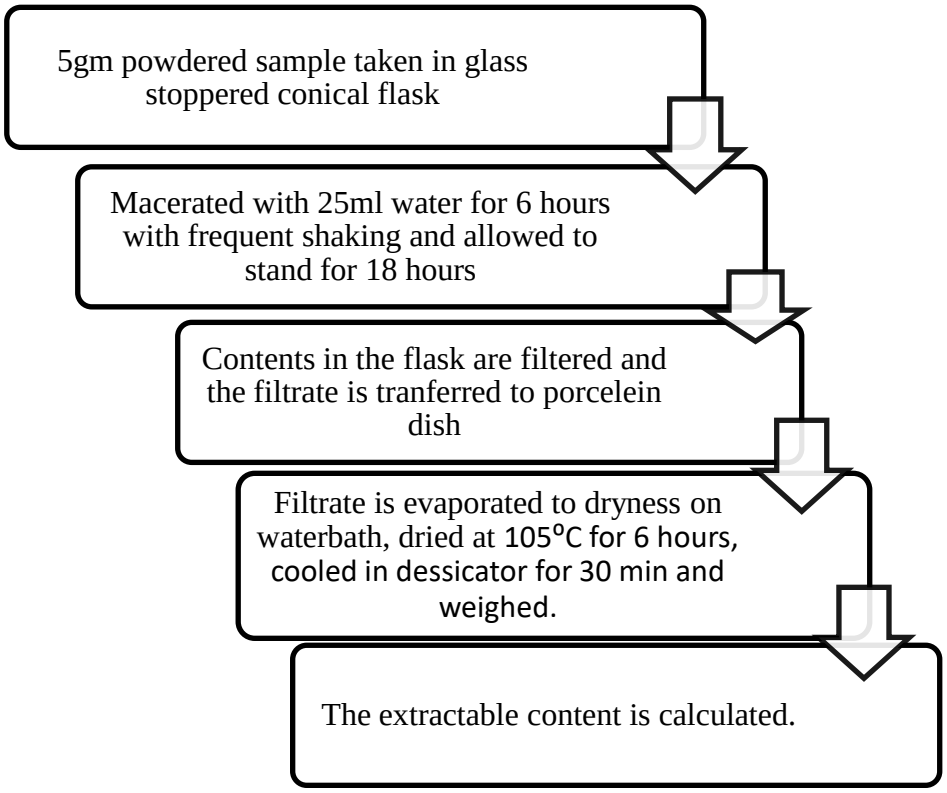


Image No.6 Filtration process in alcohol soluble extractive value

C. Thin layer chromatography:

1. 4gm of each sample was extracted under reflux on water bath for 30 min, filtered, concentrated to 10 ml for TLC.
2. Three TLC plates were prepared using silica and water and the slurry was applied on the plate uniformly.
3. Extract was applied on each of the plates using toluene: ethyl acetate in 5:2 proportion and the TLC plates were developed.
4. The Rf values for each sample was calculated.[19].

Image No. 7 Filtrate kept on water bath for extraction

Result:

After the selection of three different marketed formulations of Avipattikarchurna, the quality assessment parameters like loss on drying, Alcohol soluble extractive value and thin layer chromatography was carried out as per the procedures given in S. B. Gokhale et al Pharmacognosy and Phytochemistry-1 practical book and The Ayurvedic Pharmacopoeia of India.

1. **Organoleptic characteristics:**

   All the organoleptic characteristics were tested by physical method.

Table No. 5 Organoleptic characteristics of Avipattikarchurna of differentbrands

2. **Physicochemical parameters:**

a) Loss on drying: It was calculated as per the formula given in API [19].

%Loss on drying = Weight of sample before drying – Weight of sample after drying × 100
Weight of sample before drying

Weight after Loss on drying (Baidyanath) = 1.44gm
Weight after Loss on drying (Zandu) = 1.45 gm
Weight after Loss on drying (Santulan) = 1.43 gm

Sr No.	Name	Colour	Texture	Odour	Taste	Touch
1	Baidyanath	Yellowish green	Fine and smooth	Spicy	Sweet and bitter	Soft
2	Zandu	Yellowish white	Fine and smooth	Spicy	Bitter	Soft
3	Santulan	Yellowish white	Fine and smooth	Sweet and spicy	Very bitter	Soft

Table No. 6 Percent Loss on drying of each marketed product.

Sr No.	Name	% LOD
1	Baidyanath	3.91%
2	Zandu	3.33%
3	Santulan	4.66%

b) Alcohol soluble extractive value: It is calculated as per formula given in API.[19]

Alcohol soluble extractive value = Weight of dried extract × 100
Weight of sample taken

Table No. 7Alcohol soluble extractive value of each marketed product

Sr No.	Name	Alcohol soluble extractive value
1	Baidyanath	70%
2	Zandu	60%
3	Santulan	70%

c) Thin layer chromatography: Procedure carried out according to API [19]. The formula for Rf value is given below.

$$\text{Rf value} = \frac{\text{Distance travelled by solute}}{\text{Distance travelled by solvent}}$$

Table No. 8 Rf values of each marketed product

Sr No.	Name	Rf value
1	Baidyanath	0.28
2	Zandu	0.56
3	Santulan	0.46

Image No. 8 Thin layer chromatography

Conclusion:

Table No. 9 Conclusion of all tests performed

Sr No.	Brand	Loss on Drying	Alcohol soluble extractive value	TLC
1	Baidyanath	3.91%	70%	0.28
2	Zandu	3.33%	60%	0.56
3	Santulan	4.66%	70%	0.46

Hence, we can conclude the quality assessment of each marketed formulation of Indian polyherbal formulation- Avipattikarchurna was done

by testing Loss on drying, Alcohol soluble extractive values and TLC.\

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