FORMULATION AND EVALUATION OF *AGNIMUKHA CHURNA* TABLET

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ABSTRACT

*The aim of the study was to formulate **Agnimukha Churna tablets** with standardized plant material, to evaluate its pharmaceutical parameters and to develop its analytical parameters. For this, ingredients were collected from natural sources and authenticated. The macroscopical and microscopical features were studied and found same as given in monograph of Ayurvedic Pharmacopoeia for individual herbs. Physicochemical parameters were evaluated and found within the standard limits for the herbs. After this, the herbs were dried, powdered and mixed in the given ratio to prepare Agnimukha churna. The prepared churna was then formulated into tablet by direct compression and wet granulation methods. Different batches of formulated tablets were evaluated for weight variation, friability, disintegration time and hardness. On the basis of these parameters, best batch was selected.*

Keywords: **Agnimukha Churna (**AC**), Tablet formulation, Starch**

7836

1 INTRODUCTION
Ayurveda

Ayurveda is considered one of the world's oldest healing sciences, originating in India at least 5,000 years ago. Its name is a Sanskrit word that literally translates as "the wisdom of life" or "the knowledge of longevity" (it is a compound of *ãyus,* meaning life or longevity, and *veda,* meaning deep knowledge or wisdom). In accordance with this definition, Ayurveda views health as much more than the absence of disease.

Ayurveda or Ayurvedic medicineis an ancient system of health carethat is native to the Indian subcontinent. It ispresently in daily use by millions of people inIndia, Nepal, Sri Lanka,China, Tibet, andPakistan . It is now in practice for health care inEuropian countries.[1]

According to Charaka Samhita, "life" itself is defined as the "combination of the body, sense organs, mind and soul, the factor responsible for preventing decay and death." According to this perspective, Ayurveda is concerned with measures to protect "ayus", which includes healthy living along with therapeutic measures that relate to physical, mental, social and spiritual harmony. [2]

1.1.1 Eight Branches (Ashthanga) of Ayurveda [3]
The eight branches of Ayurveda are:
1. Internal medicine - Kayachikitsa Tantra
2. Surgery - Shalya Tantra
3. Ears, eyes, nose and throat - Shalakya Tantra
4. Pediatrics - Kaumarabhritya Tantra
5. Toxicology - Agada Tantra

6. Purification of the genetic organs – Bajikarana (or Vajikarana) Tantra

7. Health and Longevity - Rasayana Tantra

8. Spiritual Healing/Psychiatry - Bhuta Vidya

Agnimukha Churna

Churna¸ a is a fine powder of drug or drugs. Drugs mentioned in the Yoga are cleaned and dried properly. They are finely powdered and sieved. Where there are a number of drugs in yoga, the drugs are separately powdered and sieved. Each one of them (powder) is weighed separately, and well mixed together. As some of the drugs contain more fibrous matter than other, this method of powdering and weighing them separately them, according to the Yoga, and then mixing them together, is preferred.

In industry, however, all the drugs are cleaned, dried and powdered together by disintegrators. Mechanical sifters are also used. Salt, sugar, camphor etc., when mentioned are separately powdered and mixed with the rest at the end. Asafoetida and salt may also be roasted, powdered and then added. Drugs likeSatavari, Guduchi etc., which are to be taken fresh, is made into a paste, dried, and then added.

The powder is fine of at least 80 mesh sieves. It should not adhere together or become moist. The finer the powder, the better is its therapeutic value. They retain potency for one year and should be kept in air tight containers.

2 MATERIAL & METHOD

Material:

Collection of herb:

Hinga (Asafoetida), Vacha (*Acorus calamus* Linn.), Pipali (*Piper longum* Linn.), Shringavera (*Zingiber officinale* Roxb.), Vavani (*Trachyspermum ammi* Linn.), Haritaki (*Terminalia chebula* Retz.), Chitraka (*Plumbago zeylanica* Linn.) and Kushta (*Saussurea lappa* C.B. Clarke) were purchased from Ayurvedic Pharmacy, Meerut.

Chemical:

All the chemicals were procedure from CDH (New Delhi), Hi media.

Authentication:

The ingredients were then authenticated by Dr. Vijay kumar, Department of Botany, CCS university meerut.

Macroscopy:

Macroscopical features, like shape, size, color, odor and taste of ingredients were evaluated.

Microscopy:

The sample of the drug was boiled and treated with chloral hydrate. T.S. was prepared, stained, mounted in glycerine and observed under microscope. For powder microscopy, the drug was powdered and small amount of it was spreaded on the slide and observed under the microscope. [4]

Physicochemical evaluation of herbs: [5]

The parameters studied were loss on drying, total ash, acid-insoluble ash, alcohol and water-soluble extractive values, petroleum ether soluble extractive value, according to the methods outlined by Khandelwal.

a. Foreign matter:

Herbal drugs should be made from the stated part of the plant and be devoid of other parts of the same plant or other plants. They should be entirely free from moulds or insects, including excreta and visible contaminant such as sand and stones, poisonous and harmful foreign matter and chemical residues. Animal matter such as insects and "invisible" microbial contaminants, which can produce toxins, are also among the potential contaminants of herbal medicines . Macroscopic examination can easily be employed to determine the presence of foreign matter, although microscopy is indispensable in certain special cases (for example, starch deliberately added to "dilute" the plant material). Furthermore, when foreign matter consists, for example, of a chemical residue, TLC is often needed to detect the contaminants[6]

b. Determination of Total Ash:

Incinerate about 2 to 3 g accurately weighed, of the ground drug in a tarred platinum or silica dish at a temperature not exceeding 450º until free from carbon, cool and weigh. If a carbon free ash cannot be obtained in this way, exhaust the charred mass with hot water, collect the residue on an ashless filter paper, incinerate the residue and filter paper,

7837

add the filtrate, evaporate to dryness, and ignite at a temperature not exceeding 450º. Calculate the percentage of ash with reference to the air-dried drug. Ash value can be calculated by using formula:[7].

Ash value = Initial Weight – Final Weight ₓ₁₀₀
Initial Weight

c. Determination of Acid Insoluble Ash:
Boil the ash obtained in b for 5 minutes with 25 ml of dilute hydrochloric acid; collect the insoluble matter in a Gooch crucible, or on an ashless filter paper, wash with hot water and ignite to constant weight. Calculate the percentage of acid-insoluble ash with reference to the air dried drug [8].

d. Determination of Water Soluble Ash[8].
Boil the ash for 5 minutes with 25 ml of water; collect insoluble matter in a Gooch crucible, or on an ashless filter paper, wash with hot water, and ignite for 15 minutes at a temprature not exceeding 450º. Substract the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water soluble ash. Calculate the percentage of water-soluble ash with reference to the air dried drug.

e. Determination of Alcohol Soluble Extractive:

Macerate 5 g of the air dried drug, coarsely powdered, with 100 ml of Alcohol of the specified strength in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105º, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug [9].

f. Determination of Water Soluble Extractive:
Proceed as directed for the determination of Alcohol-soluble extractive, using chloroform water instead of ethanol.

g. Determination of petroleum ether soluble extract:
Proceed as directed for the determination of Alcohol-soluble extractive, usingpetroleum ether instead of ethanol

Preparation of *Agnimukh Churna*
Asafoetida was cleaned and roasted. Herbs were washed and dried in shade. All the ingredients were powdered individually and mixed in the ratio mentioned (Table 1). The powder was then passed through sieve no. 80 to get a fine powder. The prepared AC was stored in air tight container for further use.

7838

Formulation of *Agnimukh Churna*tablets

S.No	Ingredients (mg)	F1	F2	F3	F4	F5	F6
	Agnimukh Churna	450	450	450	450	450	450
	Lactose	10	20	30	10	20	30
	Starch (binder)	30	20	10	-	-	-
	Acacia gum	-	-	-	30	20	10
	Mg stearate	5	5	5	5	5	5
	Talc (mg)	5	5	5	5	5	5
Tablet weight 500mg							

Evaluation of tablets [10,11]
Appearance
Appearance is the first most required quality for the acceptance of tablet. General elegance and its identity play a major role for the consumer acceptance. Acceptance of the appearance of batches of the tablet has been done based on the measurement of the following factors like size, color, shape, presence or absence of odor, taste etc.
Size and shape

Size and shape of a tablet has been determined by its thickness. Size and shape of a tables plays an important role in its patient compliance as the size of the tablet increases it is not much easier for its administration. Micrometer is the devise which is used to determine the thickness of a tablet. It can be acceptable if the batch falls within the ±5% of standard deviation.
Organoleptic properties

Color should be distributed uniformly without appearance of any signs of mottling. Colour of the tablet should be compared with the standard colour for comparison.

Uniformity of thickness

To determine the uniformity of thickness random selection of tablets has to be done from each and every batch and need to measure its thickness independently. If the thickness of any single tablet varies then the batch containing that batch will not be dispatched into market.

Hardness

The ability of a tablet to withstand for mechanical shocks is known as hardness. Pfizer hardness tester is the instrument which is used to determine the hardness of tablet. It is expressed in kg/cm2 . Take three tablets from each batch and hardness should be determined and the selection of tabled should be done randomly. Then the mean and standard devialtion values should be determined.

Friability

Roche friabilator is the equipment which is used for the determination of friability. It is expressed in percentage. Note down the initial weight of the tablets individually (W initial). Tablets are placed in a plastic chamber which revolves at 25 rpm and they are subjected to fall from a height of 6 inches in the friabilator for about 100 revolutions. Then measure the weight of the tablet (W final) and observe any weight difference before tablet and after the friabilator processing (Figure 2). Limits: loss in weight less than 0.5 to 1% of the initial weight of the tablet should be considered as acceptable limits. Percentage of friability is calculated as: $F = \{(W\ initial) - (W\ final)/(W\ initial)\} \times 100$.

Drug content uniformity

Initially weigh the tablet and then powder it. Now the powdered tablet is transferred into a 100 ml volumetric flask and add 0.1 N HCl upto mark. Now filter the solution and discard first few ml of filtrate. Take 10 ml of filtrate should be taken into a 50 ml volumetric flask and add 0.1 N HCl up to the mark and analysed spectrophotometrically at 274 nm and 234.5 nm. The concentration of the content of the drug (μg/ml) was calculated by using the standard calibration curve of the respective drug [51-75]. Drug content is calculated by using the below formula Concentration of the drug in (μg/ml) × 100 × 50/10 × 1000.

Weight variation test

Random selection of 20 tablets from each batch should be done and note down the weight of the tablet individually and check for any variation in its weight. According to US Pharmacopies small variations in the weight is negligible and can be accepted. Below is the acceptable limit of percentage deviation in weight variation.

Average weight of the tablet	Percentage deviation
130 mg or less	10.0
More than 130 mg and less than 324 mg	07.5

In vitro dispersion time

Dispersion time of a tablet is determined by placing a tablet in 6 ml of 6.8 pH phosphate buffer and note down the time taken for complete dispersion of tablet. Following procedure should be done for three tablets from each batch and in vitro dispersion time is calculated. Standard deviation time is also determined from the obtained results. It is expressed in seconds.

In vitro disintegration test

Disintegration is defined as the process of breakdown of tablet into small particles. Disintegration time of a tablet is determined by using disintegration test apparatus as per IP specifications. Place each tablet in each 6 tubes of the disintegration apparatus a then add a disc to each tube containing 6.8 pH phosphate buffer. The temperature of the buffer should maintain at 37 ± 2°C and run the apparatus raised and lowered for 30 cycles per minute. Note down the time taken for the complete disintegration of the tablet without any remitants.

Stability studies:

The stability studies of optimised formulation were carried out according to ICH guideline. The correct formulation was subjected to stability at 40±2°C/75±5% RH for 180 days. After then duration the product was

evaluated for Colour, Disintegration time & In-vitro release

3 RESULT AND DISCUSSION

Authentication :

The nuts was then authenticated by Dr. Vijay Kumar, Head Department of Botany, CCS University Meerut.

Macroscopy:

A

B

C

D

E

F

7840

G   H

Fig. no. 5.1 a. Vacha (*Acorus calamus* Linn.), b. Hinga (Asafoetida), c. Haritaki (*Terminalia chebula* Retz.), d. Shringavera (*Zingiber officinale* Roxb.), e. Kushta (*Saussurea lappa* C.B. Clarke), f. Vavani (*Trachyspermum ammi* Linn.), g. Pipali (*Piper longum* Linn.), h. Chitraka (*Plumbago zeylanica* Linn.).

5.4:- *Agnimukh Churna* Microscopy: - The diagnostic characters like stone cells, fragments of scalariform pitted vessels and simple pitted vessels were obseved.
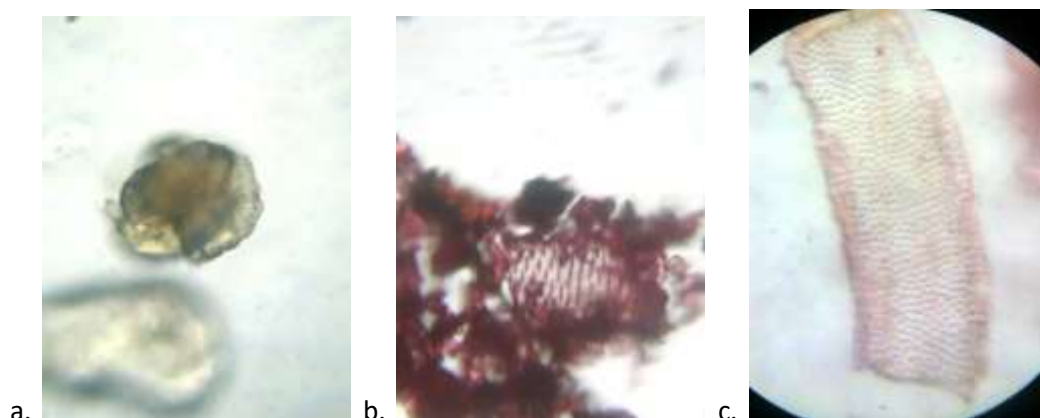

a.   b.   c.

Fig. – 5.2 Power Microscopy of *Agnimukh Churna*
a- stone cells, b- fragments of scalariform pitted vessels, c- simple pitted vessels

Physicochemical evaluation of individual herbs and *Agnimukh Churna*:-
The results of physicochemical evaluation were compared with the monograph of this drug given in The Ayurvedic Pharmacopoeia of India and were found within the limit. These value ensures the purity and strength of the herb.

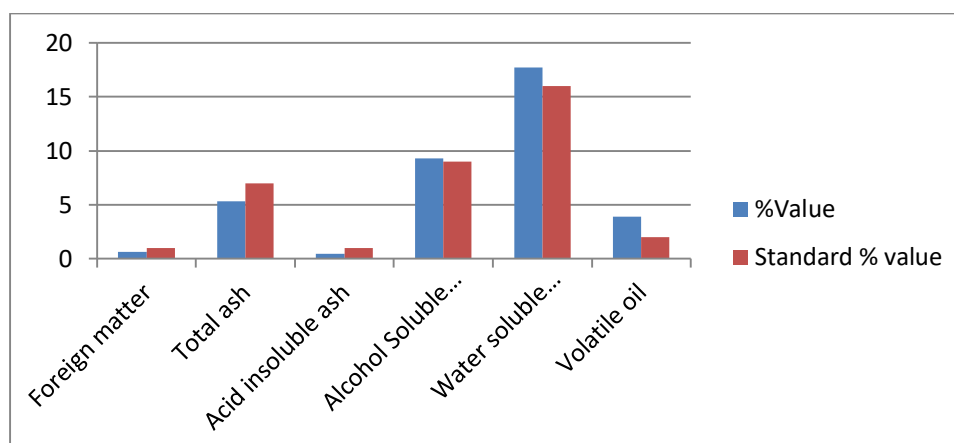 **Physicochemical evaluation results of Vacha (*Acorus calamus* Linn.)**

Figure Physicochemical evaluation results of Vacha (*Acorus calamus* Linn.)

Table. 5.1.1.: Physicochemical evaluation results of Hinga (Asafoetida)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	1.22±0.03	Not more than 2%
2	Total ash	13.11±0.24	Not more than 15%
3	Acid insoluble ash	2.49 ±0.36	Not more than 3 %
4	Alcohol Soluble Extractive	51.20±2.56	Not less than 50 %
5	Water soluble extractive	53.55±3.35	Not less than 50%

Table. 5.2: Physicochemical evaluation results of Haritaki (*Terminalia chebula* Retz.)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	0.22±0.02	Not more than 1%
2	Total ash	3.21±0.29	Not more than 5%
3	Acid insoluble ash	3.48 ±0.55	Not more than 5 %
4	Alcohol Soluble Extractive	42.10±3.33	Not less than40%
5	Water soluble extractive	64.40±4.55	Not less than 60%

Table. 5.3: Physicochemical evaluation results of Shringavera (*Zingiber officinale* Roxb.)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	0.58±0.10	Not more than 1%
2	Total ash	4.34±0.58	Not more than 6%

3	Acid insoluble ash	1.43±0.35	Not more than 1.5 %
4	Alcohol Soluble Extractive	5.20±0.32	Not less than3%
5	Water soluble extractive	15.10±2.35	Not less than 10%

Table. 5.4: Physicochemical evaluation results of Kushta (*Saussurea lappa* C.B. Clarke)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	1.76±0.54	Not more than 2%
2	Total ash	3.44±0.45	Not more than 4%
3	Acid insoluble ash	0.78±0.08	Not more than 1%
4	Alcohol Soluble Extractive	15.22±1.23	Not less than12%
5	Water soluble extractive	23.40±1.89	Not less than 20%

7843

Table. 5.5: Physicochemical evaluation results of Vavani (*Trachyspermum ammi* Linn.)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	3.99±0.59	Not more than 5%
2	Total ash	5.89±0.47	Not more than 9%
3	Acid insoluble ash	0.23±0.01	Not more than 0.2%
4	Alcohol Soluble Extractive	4.36±0.34	Not less than2%
5	Water soluble extractive	14.67±1.30	Not less than 13%
6	Volatile oil content	2.89±0.37	Not less than 2.5%

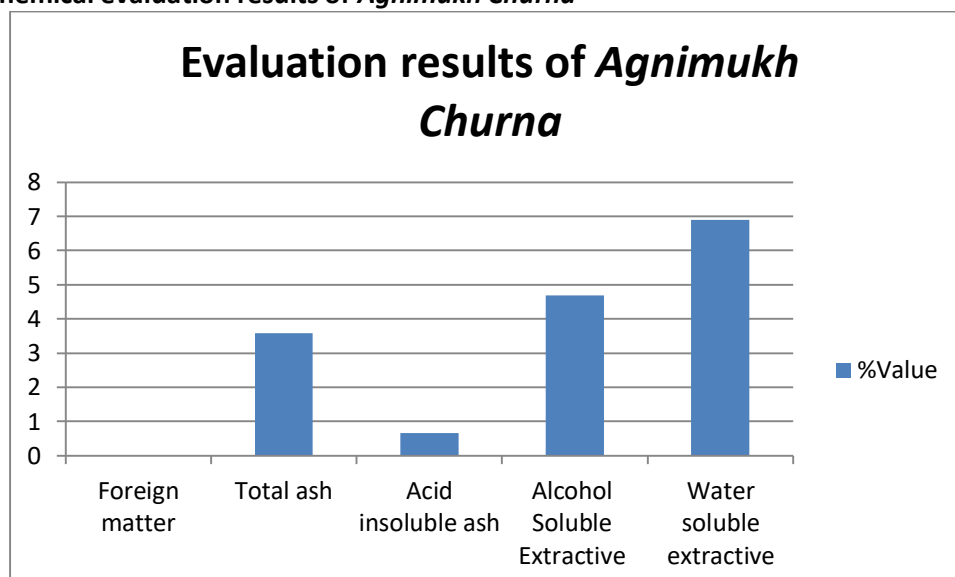### Table. 5.6: Physicochemical evaluation results of Pipali (*Piper longum* Linn.)

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	1.33±0.21	Not more than 2%
2	Total ash	5.49±0.78	Not more than 7%
3	Acid insoluble ash	0.38±0.05	Not more than 0.5%
4	Alcohol Soluble Extractive	7.43±1.03	Not less than5%
5	Water soluble extractive	7.75±0.89	Not less than 7%

Table. 5.7: Physicochemical evaluation results of Chitraka (*Plumbago zeylanica* Linn.).

S. No	Parameter	%Value (Mean ± SEM)	Standard % value (As per The Ayurvedic Pharmacopoeia of India)
1	Foreign matter	2.44±0.12	Not more than 3%
2	Total ash	2.14±0.35	Not more than 3%
3	Acid insoluble ash	0.67±0.02	Not more than 1%
4	Alcohol Soluble Extractive	10.02±1.05	Not less than12%
5	Water soluble extractive	11.14±1.75	Not less than 12%

Physicochemical evaluation results of *Agnimukh Churna*

Figure Physicochemical **evaluation results of *Agnimukh Churna***

All values of herbs were found in standard limit given in Ayurvedic Pharmacopoeia. This **Formulation of *Agnimukh Churna* tablets** ensures the quality of raw materials used in preparation of powder. The values of prepared powdered may be used in further research work.

Six batches of tablets were formulated.
Analytical evaluation of *Agnimukh Churna* tablets
Appearance, shape, color, odour and taste:

The tablets of all batches were found to be smooth, spherical, brown in colour and pungent in taste. The pungent taste and brown colour is due to the presence of dried plant material.

Table no. 5.10

Formulation	Appearance	Shape	Colour	Odour	Taste
F1	Smooth	Discoid	Brown	Characteristic	Pungent
F2	Smooth	Discoid	Brown	Characteristic	Pungent
F3	Smooth	Discoid	Brown	Characteristic	Pungent
F4	Smooth	Discoid	Brown	Characteristic	Pungent
F5	Smooth	Discoid	Brown	Characteristic	Pungent
F6	Smooth	Discoid	Brown	Characteristic	Pungent

Evaluation parameter

Table No. 5.11

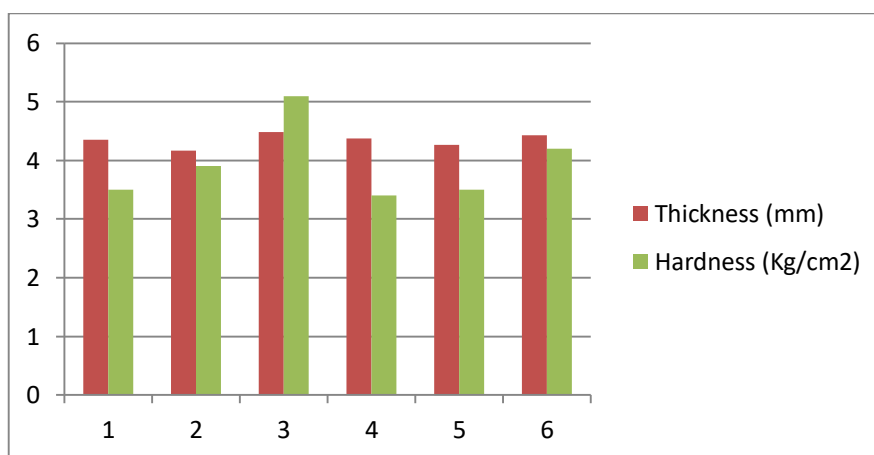| Formulation	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm2)	Friability (%)
F1	4.35±0.30	6.79±0.45	3.5±0.40	0.98
F2	4.17±0.24	6.68±0.41	3.9±0.25	0.86
F3	4.48±0.34	6.80±0.30	5.1±0.33	0.14
F4	4.38±0.18	6.78±0.36	3.4±0.32	1.30
F5	4.27±0.33	6.65±0.28	3.5±0.47	0.88
F6	4.43±0.25	6.75±0.25	4.2±0.43	0.58

Figure Hardness and thickness found in different batches

The hardenss of batch F3 was found to be appropriate when compared to other batches. Low hardenss of tablet may lead to physical loss of tablets during transport. Friability of the same batch was found minimum in comparison to the other batches, which should be less than 1 %.

And the thickness found between 4.17±0.24 to 4.48±0.34.

Table No. 5.12

S no	Formulation	Weight variation(in mg)	Dispersion Time (Sec)	Disintegration time (in min.)
01	F1	487(±10.34)	69±1	1.02±0.40
02	F2	498(±19.22	63±1	1.33±0.37
03	F3	492(±13.89)	36±1	6.00±0.28
04	F4	488(±17.67)	68±1	0.45±0.08
05	F5	466(±10.55)	50±1	2.49±0.10
06	F6	480 (±13.54)	71±1	3.22±0.20

The weight variation of all formulation found to be 466(±10.55) to 498(±19.22, there is a no major variation found in each batch.

The disintegration time of batch F3 was found to be 6 min. Very short disintegration time may lead to breakdown of tablet in mouth and very long disintegration time may lead to passing the GI tract without breaking.
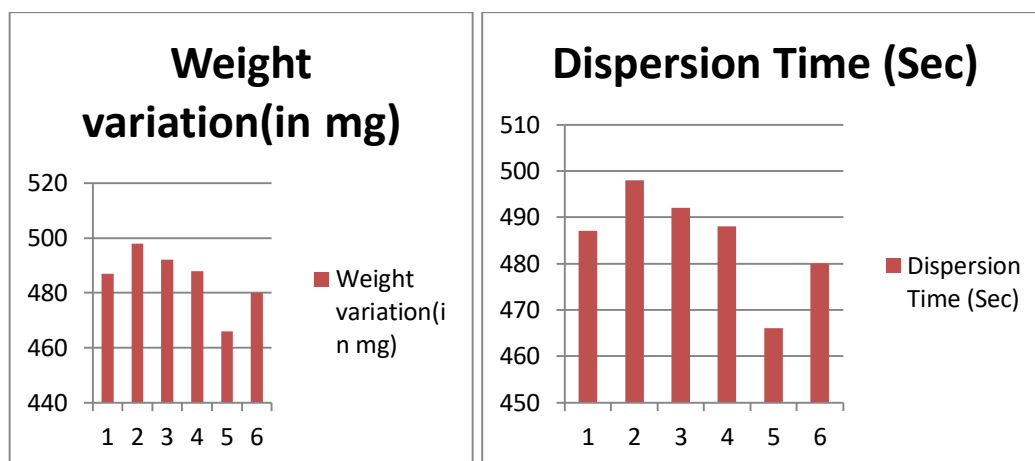

Figure weight variation of prepared tablet

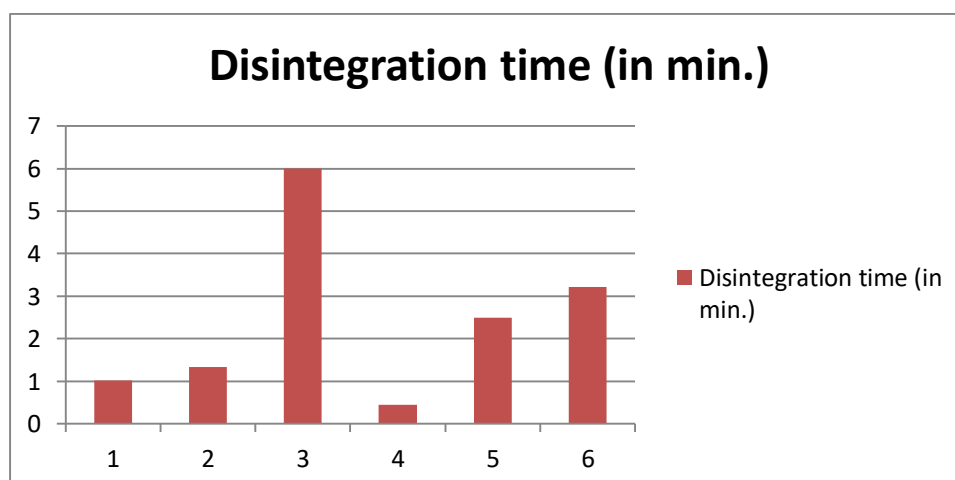Figure Dispersion time prepared tablet

7846

Figure Disintegration of prepared tablet

In vitro Dissolution study of formulated *Agnimukh Churna tablet*

Time/Min	% Release drug					
Formulation	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	51.75±2.4	50.3±0.28	58.42±1.30	50.04±0.96	53.4±0.72	51.65±0.24
10	56.56±2.2	55.55±0.99	67.78±1.25	59.52±1.33	56.85±0.88	56.46±0.48
20	61.78±2.3	58.04±0.90	73.47±1.20	63.13±1.28	57.58±1.24	59.52±0.76
30	69.25±0.9	70.56±0.36	85.89±1.18	69.49±1.22	61.44±1.45	65.32±0.82
60	76.52±0.5	78.78±1.25	96.45±0.97	72.21±0.98	72.98±1.30	79.7±0.91

In vitro Dissolution study of Marketed Agnimukh *Churna tablet*

Time/Min	% Release drug MKT
0	
5	55.12±1.30
10	63.52±1.25
20	78.41±1.20
30	84.47±1.18
60	98.12±0.99

MKT*(Marketed Product)

. Stability study

Table stability study

S.No.	Parameters	Initial	1 Month	2Month	3Month
1	Colour	Brown	No Change	No Change	No Change
3	Disintegration time (sec)	6.00±0.28(Min)	6.00±0.25(Min)	5.85±0.21(Min)	5.74±0.20(Min)
4	In-Vitro Drug Release	97.45±0.97	97.02±0.97	96.85±0.070	96±1.05

One of the objectives of the work was to carry out the stability studies on the tablets of The stability studies were carried out for F3 batch which have showed the promising results with disintegration test and dissolution

The results indicate that there was no significant change in disintegration time and In vitro dissolution after stability studies. Thus, it can be concluded that, the Agnimukha Churna tablets prepared in this study are stable.

Conclusion

The aim of the study was to prepare *Agnimukh Churna* and to formulate its tablet form with standardized plant material. The Churna was prepared by authenticated and standardized materials. The tablets were

formulated by using different percentage of starch and acacia gum as binder. The prepared six batches tablets were evaluated on quality parameters. On the basis of the results, we can conclude that AS3 was the best batch formulated.

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