

# Comparative Standardization Study of Three Marketed Amala Churna Formulations

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## ABSTRACT

India is a land mark for the traditional system of medicine from the past few centuries. Most of the traditional system of medicine is effective but only one major drawback is lack of standardization. So, there is a need to develop standardization technique to mingle this system of medicine in the main stream of health sciences. Centre council for research in Ayurveda and siddha has given the preliminary guideline for standardizing these conventional formulations. The present paper reports standardization of Amla churna an Ayurvedic formulation, from three different companies. Three marketed samples were subjected to organoleptic study, physical characterization and chromatographic study. It was observed that all the formulations are similar with their organoleptic properties and to some extent to their physical characters. This study ready reference for selection of an appropriate formulation in the clinical practice and hence effective rational therapy, the overall theme of health science. The physical data obtained from various samples shows different values as they are claimed to be of same plant material in same quantities. The qualitative estimation of volatile oil shows the presence in all the formulations.

**Keywords :** Standardization, Ayurvedic Formulation, Herbal Medicine, Quantitative Analysis

## I. INTRODUCTION

Nature always stands as a golden mark to exemplify the outstanding phenomena of symbiosis. Today about 80% of people in developing countries still relay on traditional medicine based largely on the different species of plants for their primary health care. About 500% of plants with medicinal uses are mentioned in ancient literature and 800 plants have been used in indigenous system of medicine. The various indigenous system such as ayurveda, siddha, unani use several plant species to treat different ailments.<sup>1,2,3</sup> Herbal medicines make up an important component of the trend toward alternative Medicine. A Harvard study recently found that one in three respondents acknowledged use of at least one alternative therapy within the past year. Extrapolated, these findings suggest that up to \$13.7 billion were spent in 1990 alone for these treatments.<sup>4</sup> Tyler defines herbal medicines as "crude drugs of vegetable origin utilized for the treatment of disease states, often of a chronic nature, or to attain or maintain a condition of improved health."<sup>5</sup> Current demands for herbal medicines have resulted in an annual market of \$1.5 billion and increasingly widespread availability.

## II. METHODS AND MATERIAL

### A. Potential Benefits of Herbal Drugs

Historically, herbal medicines have played a significant role in the management of both minor and major medical illnesses. One example is foxglove, which contains cardiac glycosides, and serves as a classic treatment for congestive heart failure. Even now, physicians still use many drugs that possess botanical origins.





- Safe
- Healthy
- Secure
- High quality
- Flexible

Standardization brings important benefits to business including a solid foundation upon which to develop new technologies and an opportunity to share and enhance existing practices.

#### Advantages of Herbal Medicine<sup>4</sup>

- ✓ They have large amount of use.
- ✓ They have better patient tolerance as well as acceptance.
- ✓ The medicinal plants have renewable source of cheaper medicines.
- ✓ Improvements in the quality, efficacy and safety of herbal medicines with the development of science and technology.
- ✓ Prolong and apparently uneventful use of herbal medicines may offer testimony of their
- ✓ Safety and efficacy.
- ✓ They are cheap in cost.
- ✓ They are not harmful.
- ✓ They are more effective than any synthetic drug.
- ✓ Throughout the world herbal medicines have provided many of the most potent medicines to the vast arsenal of drugs available to modern medical science, both in crude form as well as.

#### NEED OF STANDARDIZATIONS<sup>5</sup>

The quality control of herbal crude drug & formulation is important in justifying their acceptability in modern system of medicines. Standardization of synthetic drugs offers no problem with very well defined parameters of analysis. It is not uncommon to have as many as five or more different herbal ingredients in one single formulation. The batch to batch variation starts from the collection of the raw materials itself in absence of any reference standard for identification. WHO has emphasized the need to ensure quality control of medicinal plants products by using modern techniques and by applying suitable standards and parameters. Standardized products and services are valuable. User confidence builder's being perceived as

Standardization also plays a pivotal role in assisting Governments, Administrations, Regulators and the legal profession as legislation, regulation and policy initiatives are all support by standerdisation.

#### INTRODUCTION OF THE SAMPLE

- ✓ Amla churna of Divya
- ✓ Amla churna of Yogesh
- ✓ Amla churna of Madhuraj



Sample (1) Divya



Sample(2) Yogesh



Sample(3) Madhuraj

**Sample name**

*Amla* churna

**Biological name**

*Emblica Officinalis*

**Family**

Phyllanthaceae

**Vernacular name**

Sanskrit- Amalika

Marathi- Avala

Hindi- Amla

**Main Constituents**

- Emblicanin A and B
- Ellagi tannins
- Pedunculagin
- Punigluconin

**Use**

1. Popularly used in inks, Shampoos and hair oils.
2. Amla is effective for lightning the skin because of vit. C.
3. It has been used to reduce pigmentation.
4. Amla oil is effective treatment for lice which helps to prevent graying of hairs.

**Standardization parameter of Amla churna:**

**Study of organoleptic characters-**

- Colour
- Odor
- Taste

**Determination of phytochemical parameter:**

- Thin plate chromatography
- Loss of drying
- Photochemical test
- Heavy metal test
- Total ash value
- Water soluble ash value
- Acid insoluble ash value
- Alcoholic extract value
- Water soluble extract value
- Determination of ph

**Evaluation of Churna<sup>7-8</sup>**

- Hauser ratio
- Bulk density
- Tap density
- Angle of repose
- Compressibility
- Carr's index

**Study of Organoleptic Characters:**

The polyherbal formulation is studied for organoleptic characters like color, odour and taste using the sensory organ of the body.

**Determination of Loss on drying:**

Weigh about 1.5gm of the powdered drug into a weighed flat and thin porcelain dish. Dry in the oven at 100<sup>0</sup> c, until two consecutive weighing does not differ by more than 0.5gm. Cool in a desiccators and weigh. The loss in weigh is weight is usually recorded as moisture.

**Determination of Total ash value:<sup>7-8</sup>**

- Weigh and ignite flat, thin , porcelain dish or a tared silica crucible.
- Weigh about 2gm of the powdered drug into the dish/crucible.
- Support the dish on a pipe-clay triangle placed on a ring of retort stand.
- Heat with a burner, using a flame about 2cm high and supporting the dish about 7cm above the flame, heat till vapors almost cease to be evolved; then

lower the dish and heat more strongly until all the carbon is burnt off.

- Cool in desiccators.
- Weigh the ash and calculate the percentage of total ash with reference to the air dried sample of the crude drug.
- If a carbon free ash cannot be obtained in this way then any one of the following methods can be used.
- Exhaust the charred mass with hot water, collect the residue on an ashless filter paper, incinerate the residue and filter paper, add the filter, evaporate to dryness and ignite at a temp. not exceeding 450°C.
- Cool the crucible; add 15ml of alcohol, break up the ash with glass-rod, burn off the alcohol and again heat the whole to a dull red heat. Cool, weigh the ash.

#### **Determination of Acid insoluble ash:**

The total ash obtained was boiled for 5 minutes with 25 ml of dilute hydrochloric acid; the insoluble matter obtained was collected on an ashless filter paper, washed with hot water and ignited to constant weight. The percentage of acid insoluble ash was calculated with reference to the air dried drug.

#### **Water-soluble Ash**

The ash obtained in the determination of total ash was boiled for 5 minutes with 25 ml of water. The insoluble matter was collected on an ashless filter paper and washed with hot water. The insoluble ash was transferred into a tarred silica crucible and ignited for 15 minutes at a temperature not exceeding 450°C. The weight of the insoluble matter was subtracted from the weight of the total ash. The difference in weight was considered as the water-soluble ash and was calculated with reference to the air dried drug.

#### **Determination of Alcohol-soluble extractives**

- Weigh about 4gm of the coarsely powdered drug in a weighing bottle and transfer it to dry 250ml conical flask.
- Fill a 100 ml graduated flask to the delivery mark with the solvent (90% alcohol). Wash out the weighing bottle and pour the washing, together with the remainder of the solvent into the conical flask.

- Cork the flask and set aside for 24 hours, shaking frequently.
- Filter into a 50 ml cylinder. When sufficient filtrate has collected, transfer 25ml of the filtrate to a weighed, thin porcelain dish, as used for the ash value determinations.
- Evaporate to dryness on a water bath and complete the drying in an oven at 105°C for 6 hrs.
- Cool in a desiccator for 30min and weigh immediately.
- Calculate the percentage w/w of extractive with reference to the air dried drug.

#### **Determination of water-soluble extractive**

Procedure for alcohol soluble extractive was followed for the determination of water soluble extractive but chloroform water was used instead of 90% alcohol.

#### **Determination of Physical Characteristics**

##### **Bulk density:**

It is the ratio of given mass of powder and its bulk volume. It is determined by transferring an accurately weighed amount of powder sample to the graduated cylinder with the aid of a funnel. The initial volume was noted. The ratio of weight of the volume it occupied was calculated. As shown in fig no- 1

$$\text{Bulk density} = W/V_0 \text{ g/ml}$$

Where, W = mass of the powder, V<sub>0</sub> = untapped volume



**Figure 1.**

##### **Tapped density:**

It is measured by transferring a known quantity

(25g) of powder into a bulk density apparatus and tapping it for 100 times. The initial volume was noted. The graduated cylinder was tapped continuously for a period of 10-15 min. The density can be determined as the ratio of mass of the powder to the tapped volume. As shown in fig no 2

$$\text{Tapped volume} = W/V_f \text{ g/ml}$$

Where, W = mass of the powder,  $V_f$  = tapped volume



Figure 2.

### Compressibility Index

It is the propensity of the powder to be compressed. Based on the apparent bulk density and tapped density the percentage compressibility of the powder can be determined using the following formula

$$\text{Compressibility index} = [(v_0 - v_f)/v_0] \times 100$$

$$\% \text{ compressibility index} = [(\text{tapped density} - \text{bulk density}) / \text{tapped density}] \times 100$$

### Hausner's ratio:

It indicates the flow properties of the powder. The ratio of tapped density to the bulk density of the powder is called Hausner ratio.

$$\text{Hausner ratio} = \text{Tapped density} / \text{bulk density}$$

### Angle of repose

The internal angle between the surface of the pile of powder and the horizontal surface is known as the angle of repose. The powder is passed through funnel fixed to a burette at a height of 4 cm. A graph paper is placed below the funnel on the table. The height and the radius of the pile were measured. Angle of repose of the powder was calculated using the formula; as shown in fig no 3

$$\text{Angle of repose} = \tan^{-1}(h/r)$$

Where, h = height of the pile, r = radius of the



Figure 3.

### Determination of pH range:

The powder sample of Amla Churna was weighed to about 5g and immersed in 100 ml of water in a beaker. The beaker was closed with aluminum foil and left behind for 24 hours in room temperature. Later the supernatant solution was decanted into another beaker and the pH of the formulation was determined using a calibrated pH meter. Calibration by using buffer capsule pH meter. Adjustment of reading unto 7. After calibration determine the pH of amla churna. For determination of pH waterproof pen type pH meter is used.

### Determination of Rf value of Amla churna:

Mobile phase: Toluene: Ethyl acetate: Acetic acid (5:4:1) as shown in fig no 4

## Performance of TLC



Figure 4.

### Procedure:

- i. Prepare mobile phase and saturate the chamber.
- ii. Prepare TLC plate with silica gel which acts as an adsorbent.
- iii. Activate TLC plate by keeping it in hot air oven at 110<sup>o</sup>c for 30 min.
- iv. Prepare solution of a sample.
- v. Remove TLC plate from oven.
- vi. Dip the capillary tube into the solution and then gently touch the end of it onto the proper location on the TLC plate.
- vii. Place the prepared TLC plate in the developing beaker, cover the beaker with the petri plate, and leave it undisturbed. The solvent will rise up the TLC plate by capillary action..
- viii. Allow the plate to develop until the solvent is about half a centimeter below the top of the plate. Remove the plate from the beaker and immediately mark the solvent front with a pencil. Allow the plate to dry.
- ix. Prepare iodine chamber for visualization of the spot. Keep TLC plate in iodine chamber for visualization of the spot.
- x. If there are any colored spots, circle them lightly with a pencil.
- xi. Most samples are not colored and need to be visualized with a UV lamp. Hold a UV lamp over the plate and circle any spots you see.
- xii. Calculate and report R<sub>f</sub> value of a compound.

## III. RESULTS AND DISCUSSION

### 1. Determination of Organoleptic Characters

Table 1. Color, odor and taste are mentioned below

	Divya	Yogesh	Madhuraj
Color	Greenish brown	Greenish brown	Greenish brown
Odor	Indistinct	Indistinct	Indistinct
Taste	Slightly Sour	Slightly Sour	Slightly Sour

### 2. Physio-chemical standard

Table 2. Total ash value, Acid insoluble ash value, Water insoluble ash values are mentioned below

Sr. no.	Types of Ash Value	Divya	Yogesh	Madhuraj
1.	Total ash value	6.6 %	6.6 %	6.7 %
2.	Acid insoluble Ash Value	1.49 %	1.1 %	1.68 %
3.	Water soluble Ash value	3.3 %	3.3 %	6.6 %

### 3. Moisture content/Loss on drying:

Table 3. loss on drying are mentioned below

Sr.no.	Test	Divya	Yogesh	Madhuraj
1.	Loss on Drying	95.9 %	99.6 %	99 %

### 4. Extractive value

Table 4. Water and alcohol extractive values are mentioned below

Sr. no.	Types of solvent	% Extractive value (w/w)		
		Divya	Yogesh	Madhuraj
1.	Water	40 %	36 %	32 %
2.	Alcohol	32 %	24.8 %	23.2 %

### 5 .Determination of physical characteristics of powder:

Table 5. Bulk density, Tap density, carr's index % compressibility , Hausner's ratio ,Angle of repose are mentioned below

Sr. no.	Parameter	Divya	Yogesh	Madhuraj
1.	Bulk Density	0.657	0.510	0.625
2.	Tap density	0.961	0.735	0.892
3.	Carr's index	0.684	0.693	0.700
4.	% compressibility	31.58 %	30.6 %	29.99 %
5.	Hausner's ratio	1.461	1.441	1.428
6.	Angle of repose	0.0261	0.017	0.026

### 6. Determination of pH:

Table 6. pH ranges are mentioned below

Sr.no.	Test	Divya	Yogesh	Madhuraj
1.	pH	6.7	6.8	6.9

## IV. CONCLUSION

From the present investigation various standardization parameters such as physicochemical standards like total ash, acid insoluble ash, water & alcohol soluble extractive values, loss on drying, flow properties and safety evaluation were carried out, it can be concluded that the formulation of divya , Yogesh churna and Madhuraj churna was contains all good characters of an ideal churna and it was found to be non harmless, more effective,

and economic. The three marketed samples have been evaluated as above mentioned parameters which shows satisfactory results, but the efficacy of the products can only be judged by doing the pharmacology of which is suggested as future scope of R & D. The study shows that the contents of formulation presents within the permissible limits as per WHO.

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