



STANDARDIZATION OF TRIPHALA CHURNA: A POLYHERBAL FORMULATION

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ABSTRACT

Standardization of the herbal formulations is essential in order to assess the quality of drugs for their therapeutic values. Dabur Triphala Churna is used for immune system stimulation, improvement of digestion, relief of constipation, gastrointestinal tract cleansing, and treatment of diabetes and eye diseases. The present research study deals with the standardization of Dabur Triphala Churna [i.e. Emblica officinalis (Garetn.) (Amla), Terminalia bellerica (Gaertn.) Roxb. (Baheda) and Terminalia chebula (Retz.) (Harada)]. It was standardized in order to assess the quality of drugs, based on the concentration of their active principles according to the World health organization guidelines. The various parameters analyzed included organoleptic characteristics and physicochemical features. The set parameters were found to be sufficient to standardize the Triphala churna and can be used as reference standards for the quality control/ quality assurance study mostly on plant drugs for their primary health care needs. The results obtained may be considered as tools for assistance to the regulatory authorities, scientific organization and manufacturers for developing standard formulations of great efficacy.

KEYWORDS: Standardization, Triphala Churna, Traditional medicine, Physico-chemical parameters, Marketed formulation (MF), WHO guidelines.

1. INTRODUCTION

In the last few decades, there has been an exponential growth in the field of ayurvedic medicine. There is a great need of standardization and quality control of ayurvedic formulations.^[1] Standardization is a system to ensure that every packet of medicine that is being sold has the correct amount and will induce its therapeutic effect.^[2] WHO has also issued Guidelines for quality control methods for medicinal plant materials in 1992 with a clear objective to provide general test methods for correct botanical evaluation and identification of medicinal plants widely used in traditional and home remedies.^[3] Triphala is an age old commonly used Ayurvedic powdered preparation in Indian systems of medicine. This well known formulation is made by combining Terminalia chebula, Terminalia bellerica and Emblica officinalis, in equal proportions based on the observations of Ayurvedic Formulary of India (AFI). The formulation is prescribed in the first line treatment of many ailments and is used as laxative, detoxifying agent and rejuvenator.^[4] The preparation of Triphala churna is based on traditional methods in accordance with the procedures given in classical texts. This may not have the desired quality and batch to batch consistency. Hence this formulation required standardization according to guidelines given by WHO.^[5] 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 the 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. 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. Standardization also plays a pivotal role in assisting Governments, Administrations, Regulators and the legal profession as legislation, regulation and policy initiatives are all supported by standardization.^[6, 7, 8]

2. MATERIALS AND METHODS

Collection of material: A marketed Triphala Churna formulation was purchased from an authentic vendor of Kanpur. Marketed formulation was identified on the basis of standard

organoleptic characters in Pharmacognosy Research Lab, Kanpur. Formulation was kept in a safe dry place away from direct sunlight till used for further studies.

2.1 Organoleptic Evaluation:

Organoleptic evaluation refers to the evaluation of formulation by colour, odour, taste etc. The organoleptic characters of the samples were studied on the basis of the method described by Siddique *et al.*^[9]

Table 1: Organoleptic Properties of Triphala Churna.

| Parameters | Marketed formulation |
|------------|----------------------|
| Appearance | Powder |
| Colour | Yellowish |
| Odour | Characteristic |
| Taste | Salty |

2.2 Physicochemical Investigations

2.2.1 Determination of Total Ash

Total ash determination constitutes detecting the physiological ash (ash derived from plant (tissue) and nonphysiological ash (ash from extraneous matter, especially sand and soil adhering to the surface of the drug). For its detection 2g of powdered material of the formulation was placed separately in a suitable tared crucible of silica previously ignited and weighed. The powder was incinerated by gradually increasing the heat, not exceeding 450°C until free from carbon, cooled in a desiccators, weighed and percentage ash was calculated by taking in account the difference of empty weight of crucible & that of crucible with total ash.^[10]

2.2.2 Acid insoluble ash

The ash obtained as above was boiled for 5 min with 25ml of dilute hydrochloric acid; the insoluble matter was collected on an ash less filter paper, washed with hot water and ignited to constant weight. The percentage of acid-insoluble ash with reference to the air-dried drug was calculated.^[9]

2.2.3 Water Soluble Ash

The ash was boiled for 5 minutes with 25 ml of water; collected insoluble matter in an ash less filter paper, washed with hot water, and ignited for 15 minutes at a temperature not exceeding 450°C. Subtract the weight of the insoluble matter from the weight of the ash; the

difference in weight represents the water-soluble ash. The percentage of water soluble ash with reference to the air-dried drug was calculated.^[10]

2.2.4 Alcohol Soluble Extractive Value

5g of coarsely powdered air-dried drug was macerated with 100ml of alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowed to stand for eighteen hours. It was then filtered rapidly; taking precautions against loss of solvent. 25ml of the filtrate was evaporated to dryness in a tared flat-bottomed shallow dish at 105°C to constant weight and weighed. The percentage of alcohol-soluble extractive was calculated with reference to the air dried drug and is represented as % value.^[10]

2.2.5 Water Soluble Extractive Value

5g of coarsely powdered air-dried drug was macerated with 100 ml of water in a closed flask for twenty-four hours, shaking frequently during six hours and allowed to stand for eighteen hours. It was then filtered rapidly, taking precautions against loss of solvent. 25ml of the filtrate was evaporated to dryness in a tared flat bottomed shallow dish at 105°C to constant weight and weighed. The percentage of water-soluble extractive was calculated with reference to the air-dried drug and is represented as % value.^[10]

2.2.6 Loss on Drying

Loss on drying is the loss of mass expressed as percent w/w. About 10g of dug samples of each formulation was accurately weighed in a dried and tared flat weighing bottle and dried at 105 C for 5hrs. The percentage was calculated with reference to initial weight.

Table 2: Physicochemical Parameters: Triphala Churna Quantitative standards.

| Parameters | Result in % w/w |
|-----------------------------|-----------------|
| Total Ash Value | 9.60% |
| Acid insoluble ash | 3.20% |
| Aqueous soluble ash | 5.20% |
| Moisture content | 13% |
| Alcohol soluble extractives | 11.50% |
| Aqueous soluble extractives | 41.50% |

2.2.7 Bulk Density and Tap Density

The term bulk density refers to a measure used to describe the packing of particles or granules. The equation for determining bulk density (D), $D_b = M/V_b$. Where, M is the mass of the particles and V is the total volume of the packing. The volume of the packing can be

determined in an apparatus consisting of a graduated cylinder mounted on a mechanical tapping device (Jolting Volumeter) that has a specially cut rotating can. 100gm of weighing formulation powder was taken and carefully added to the cylinder with the aid of a funnel. Typically the initial volume was noted and the sample was then tapped until no further reduction in volume was noted. The initial volume gave the Bulk density value and after tapping the volume reduced, giving the value of tapping density.^[10, 11]

2.2.8 Angle of Repose

Angle of Repose has been used as an indirect method of quantifying powder flow ability because of its relationship with interparticle cohesion. As per general guidelines, powders with the angle of repose greater than 50 degrees have unsatisfactory flow properties, whereas minimal angle close to 25 degrees correspond to very good flow properties. The fixed funnel and the free standing cone method employs a funnel that is secured with its tip at a given height, which was taken 2.5 cm (H), above the graph paper that is placed on a flat horizontal surface. Powder or granulation was carefully poured through the funnel until the apex of the conical pile just touched the tip of the funnel.^[7,8] $\tan = H/ R$ or $= \text{arc tan } H/R$ Where is the angle of repose, R being the radius of the conical pile.^[10, 11]

2.2.9 Hausner Ratio

It is related to interparticle friction and as such can be used to predict the powder flow properties. Powders with low interparticle friction such as coarse spheres have a ratio of approximately 1.2, whereas more cohesive, less flow able powders such as flakes have a Hausner ratio greater than 1.6. The equation for measuring the Hausner ratio is: D_f / D_o , where, D_f = Tapped density and D_o = Bulk density.^[12,13]

Table 3: Physical characteristics of marketed formulation of Triphala churna.

| Parameters | Results |
|-----------------|-----------|
| Tap density | 0.63+2.50 |
| Bulk density | 0.46+3.32 |
| Angle of repose | 32.2+1.69 |
| Hausner ratio | 1.33+1.10 |

3. RESULTS AND DISCUSSIONS

As part of the standardization procedure, the Triphala Churna was tested for the relevant physical and chemical parameters. The powder was smooth, yellow in color having characteristic odour, possessing salty taste. The organoleptic properties of the marketed

formulation were reported in table 1. Quality tests for Triphala Churna and its individual ingredients were performed for moisture content, ash content, water soluble extractive, methanol soluble extractive, acid insoluble ash and water insoluble ash and were found to be within the standard ranges. The extractive values and the ash values of the formulation are given in table 2. The results are expressed as mean (n=6) \pm Standard deviation (SD). Variations were observed in most of the physicochemical parameters studied. Acid insoluble ash value was found to be 3.20%. The extractive values of formulations in water were found to be much higher than alcohol extractive values. The values are mentioned in the Table 2. The flow ability of the formulation was found to be satisfactory, which was further confirmed by high values of Hausner ratio, presented in Table 3.

4. CONCLUSION

The results of the present study confirmed that the marketed formulation of Triphala churna fits to the excellence on the scale of quality when analyzed for the various prescribed parameters. On the whole, the parameters established in the present work would serve as the reference standards for the quality control of the marketed formulation in future. The data obtained will help in the evaluation of the formulation for various purposes. Beside the standards, the present study provides a methodology to the researchers to standardize the marketed formulation on the basis of the norms of the quality control parameters.

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