Original Article

Evaluation And Standardization Of Marketed Poly Herbal Formulations Of Different Brands

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Abstract

Objective: To set a preliminary quality control parameters this may be helpful to the scientific community as well as manufacturing industries.

Material and Methods: Five different sealed packs of Mahasudarshan Tablet were procured from the Pharmacy Shop, which were evaluated on Organoleptic tests, Physico-chemical parameters such as pH, water soluble extractive, Alcoholic soluble extractive, Loss on drying, Ash value, Acid insoluble ash, Water soluble ash, and Specific tests for tablets such as weight variation test, friability, disintegration, dissolution time as per standard guidelines were carried out.

Results and Discussion: Phytochemical test indicates the presence of alkaloid, glycosides, terpenoids, tannins, and steroids in both formulations. Parameters for loss of drying, ash values, and extractive values documented. Pharmaceutical parameters, such as hardness, friability, weight variation, and disintegration, were found to be within acceptable values.

Conclusion: Quality control parameters are the fundamental factors for evaluating the purity, standards and effectiveness of any formulation. Therefore, the findings of the present study may be considered as first step towards generating scientific evidence of quality assurance for marketed formulations.

Key words: Maha Sudarshana Tablet; Quality control; Dissolution

1. INTRODUCTION:

The word Ayurveda (Sanskrit word) is the form in the combination of “Ayur” means life and “Veda” means knowledge or science which means “the science of life,” and based on the theory of Tridosha. According to a WHO report, 70% of the population in India uses an old medical system, and demand for this system is steadily growing day by day [1]. A procedure called standardisation assures that each dose of chemicals has a specific amount, level of quality, and therapeutic effect. If the medicine examined has not been authenticated and characterised in order to ensure reproducibility in the product's manufacturing, then a herbal product cannot be declared scientifically genuine. In addition, numerous harmful and fatal side effects, including as direct toxic effects, allergic reactions, impacts from impurities, and interactions with herbal medications, have lately been recorded. The creation of reliable analytical techniques, such as quantitative studies of markers, bioactive substances, and other key components, that can accurately profile the phytochemical composition. [2, 3] There has been a lot of demand for plant-based products in developed nations in recent years. These goods are becoming more and more sought after as pharmaceuticals, nutraceuticals, and cosmetics. [3, 4] In India, there have been about 6000 makers of herbal products. Ayurvedic medications have been produced by more than 4000 units. Due to a lack of infrastructure, skilled labour, debatable processes, and challenging regulatory requirements, the majority of these producers supply their product on a really sporadic basis. [5, 6, 7]

The goal of the current study is to standardise and evaluate five commercial polyherbal formulations (Madhusudan). Chemical, biological, quantitative, and qualitative measures are needed, per the WHO recommendations for standardisation and evaluation of herbal formulation. [8] Therefore, appropriate analytical procedures are used for evaluation in order to demonstrate the composition and quality of polyherbal products advertised.

2. MATERIALS AND METHODS:

2.1 Materials: Three different sealed pack of Madhusudan Vati purchased from Pharmacy Shop, Gwalior, MP, India.

2.2 Organoleptic Evaluation: Organoleptic evaluation refers to evaluation of formulation by colour, odour, taste etc. The organoleptic characters of the samples were carried out based on the method described by Siddique et al., [9, 10].

2.3 Physico-chemical parameters: Water soluble extractive, Alcoholic soluble extractive, Loss on drying, Ash value, Acid insoluble ash, Water soluble ash were performed as per standard guidelines and results are placed at Table 5. [11-16]

2.4 Preliminary Phytochemical Investigation: Tablet extracts were qualitatively evaluated by chemical tests for the presence of various phytoconstituents like alkaloids, glycosides, saponins, phenolic compounds tannins and phytosterols. [17]

2.5 Pharmaceutical analysis:

i) Hardness: The hardness of gutikas was evaluated using hardness tester.

ii) Friability: Dedust the ten tablets weighed and kept in a curved part of the plastic chamber and closed the lid. Switched on and rotate it with 25 rpm for 100 times. After completion of the cycle, open the lid, remove dust from tablets, and reweighed it. Values are compared with the IP standard. [19, 20]

iii) Weight variation: Weighed 20 tablets and calculated its average weight. Values are compared with the standard [21, 22].

iv) Disintegration test: On USP device, taken six tablets on each tube covered and poured it on 1000 ml beaker. After 28–32 cycle per min at temp 37°C in 1.2 pH buffer, disintegration time was noted and compared the value with the standard.

v) Dissolution Test: The dissolution testing of polyherbal medicines become difficult to oversee authority requirements due to widely varying constituents. The ingredients of polyherbal medicinal products often cover a mixture of multiple herbal constituents; dissolution method development is much more complex than for defined single constituent [23, 24].

3. RESULTS AND DISCUSSION:

3.1 RESULTS

i) Organoleptic Evaluation: Marketed formulation of Madhusudhan Tablet (Baidyanath and Unjha) have black color, characteristics odor with sour taste; Madhusudhan Tablet (Dabur; Vyas and Zandu) have yellow colour, characteristic odour and sour taste.

Figure 1: Different marketed brands of maha-sudarshan tablets

Table 1: Study On Organoleptic

S. No.	Drugs	Colour	Odour	Taste
1	Baidyanath	Black	Characteristic	Sour
2	Dabur	Yellow	Characteristic	Sour
3	Unjha	Black	Characteristic	Sour
4	Vyas	Yellow	Characteristic	Sour
5	Zandu	Black	Characteristic	Sour

ii) Analysis Of Physico-Chemical Standards: The percentage of loss on drying of Different Marketed Formulation by Baidyanath, Dabur Unjha, Vyas, Zandu were found to be 0.183; 0.233; 0.320; 0.200 and 0.140 %w/w respectively. Different Marketed Formulation by Baidyanath, Dabur Unjha, Vyas, Zandu have total ash, water- soluble ash acid insoluble ash and sulphated ash mention in figure 3-7.

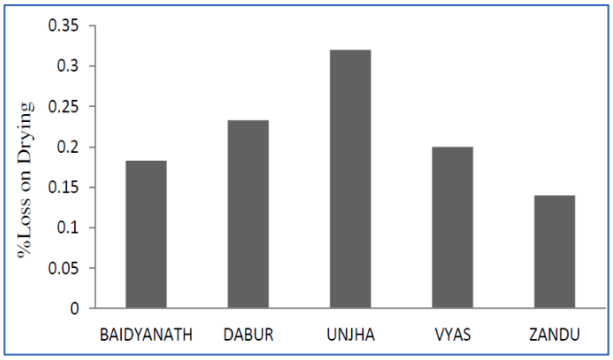

Figure 2: Loss On Drying of Different Formulations

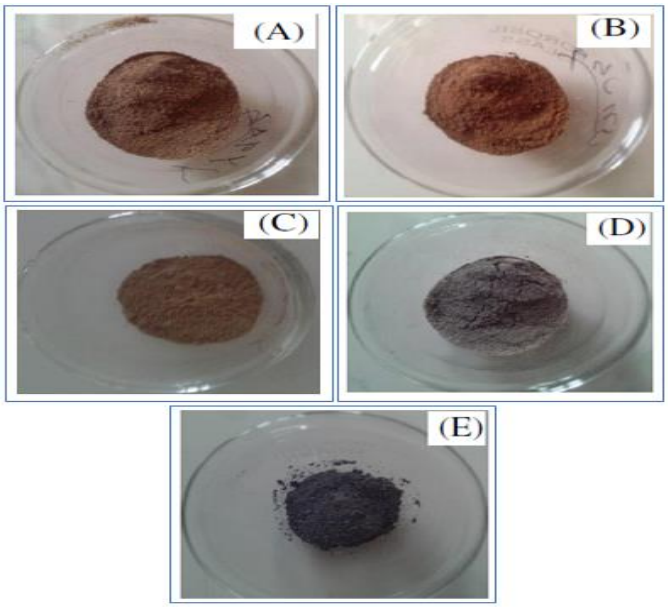

Figure 3: Total ash study on A(Vyas), B(Unjha), C(Dabur), D(Zandu), E(Baidyanath)

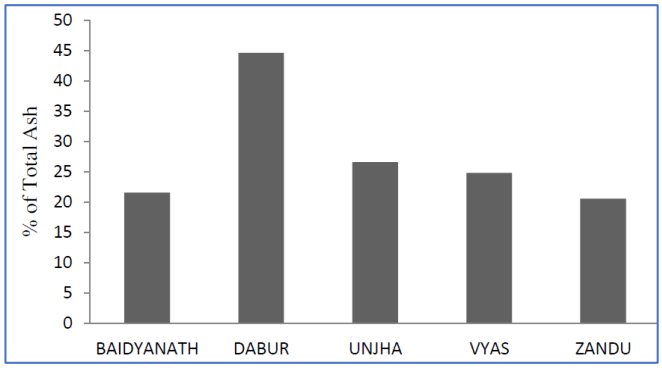

Figure 4: Total Ash of Different Formulations

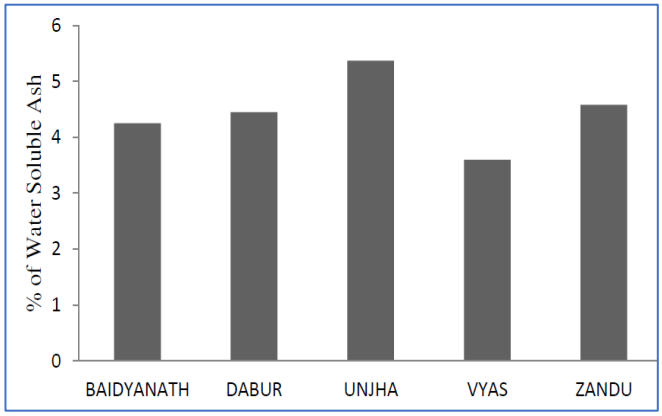

Figure 5: Water Soluble Ash of Different Brands

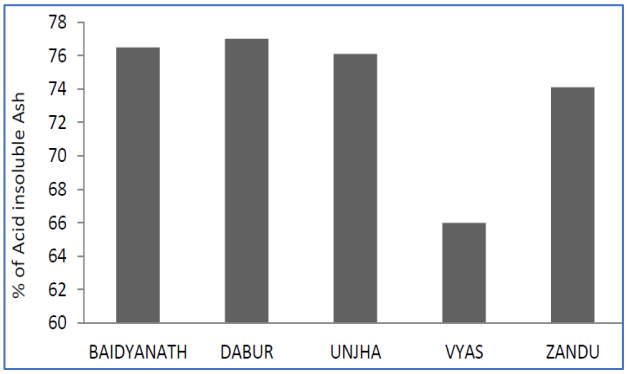

Figure 6: Acid Insoluble Ash Different Brands

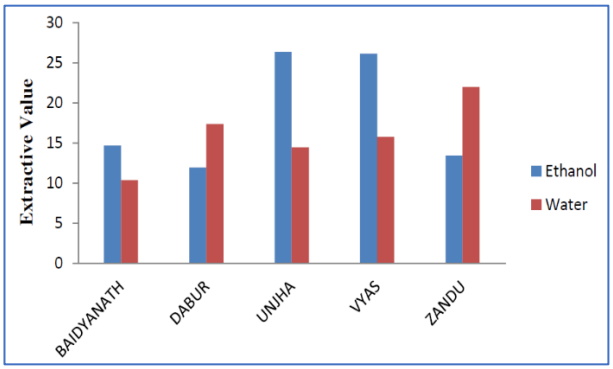

Figure 7: Extractive Values of Different Brands

iii) Analysis Of Phyto-Constituents: Preliminary Phytochemical tests were performed for Carbohydrate, Protein, Amino acid, Steroids, Glycosides, Alkaloids, Flavonoids and Tannins. Preliminary Phytochemical tests showed the presence of all the phytochemicals analysed in both formulation, except steroids. The presence of phytochemical constituents mentioned in Table 2.

Table 2: Phytochemical screening of Mahasudarshan Tablet in Various Brands

Chemical Constituents	Brand Name				
	Baidyanath	**Dabur**	**Unjha**	**Vyas**	**Zandu**
Alkaloids	-	+	-	+	-
Glycosides	+	+	+	-	-
Tannins	+	-	+	-	+
Saponin	+	-	-	-	-
Carbohydrates	-	+	-	-	+
Steriods	-	-	+	-	-
Terpenoid	+	-	-	+	-
Protein	-	+	-	-	+

'+' Indicates presence, '-' Indicates absence

iv)Analysis of Pharmaceutical Evaluation: In pharmaceutical analysis, hardness (kg/cm^2), friability (%), weight variation, dissolution, and disintegration time (min) were determined, all the value under the IP limits and depicted in Figure 8 and 9.

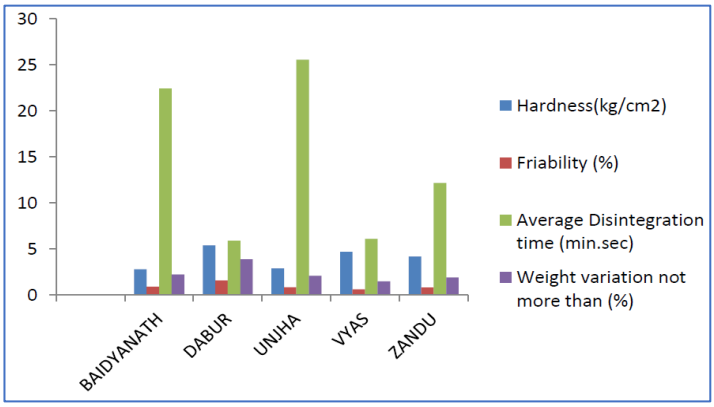

Figure 8: Hardness, Friability, Disintegration Time, Weight Variation, of Different Marketed Brands

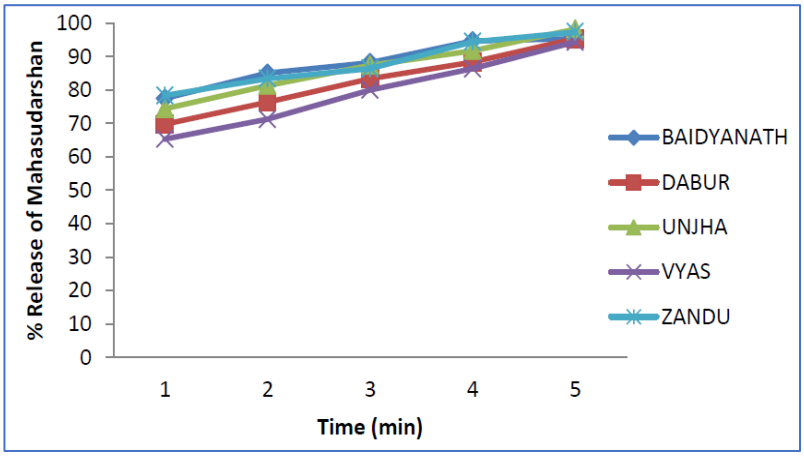

Figure 9: Drug release study at different brands mahasudarshan tablets

3.2 DISCUSSION:

- Mahasudarshan Tablet (vati) is a safe poly-herbal formulation containing many phyto-constituent. Mahasudarshan tablet ware evaluated based on different physical and chemical evaluation parameters for ingredients as well as both Formulations.
- The formulations are free from any toxic material.
- Mahasudarshan tablets (Powder) were smooth, having characteristic odour, possessing bitter (sour) taste. All marketed brands colour have different such as Baidyanath, unjha and zandu are black and dabur and vyas. The organoleptic properties of the marketed formulation were reported in figure 4.
- Quality tests for Mahasudarshan 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 standard ranges.
- Loss on drying of different formulation were perform and found in order of Unjha> Dabur> vyas> Baidyanath> Zandu. Loss on drying is representing at Figure 2.
- Total ash of different formulation were perform and found in order of Dabur> Unjha> Vyas> Baidyanath> Zandu. The total ash minimum value is Zandu and maximum value is Dabur. Total ash value is represent at Figure 3-4.
- Water soluble ash of different formulation were perform and found in order of Unjha> Zandu> Dabur> Baidyanath> Vyas. Water soluble ash is representing at Figure 5.
- Acid soluble ash value of different formulation were performed found in order of Dabur> Baidyanath> Unjha> Zandu> Vyas Figure 6.
- Water soluble extractive value was found minimum for Baidyanath and maximum for Zandu. Alcohal soluble extractive value was found minimum for Dabur and maximum for Unjha. Water soluble extractive value were found in order of Zandu> Dabur> Vyas> Unjha> Baidyanath and ethanol soluble extractive value were found in order at Unjha> Vyas> Baidyanath> Zandu> Dabur at Figure 7.
- The results of phytochemical tests indicate the presence of glycosides, alkaloids, tannins, saponins, steroids, terpenoid, protein and carbohydrates in the formulation and reported in table 2.
- Hardness was found minimum for Baidyanath and maximum for vyas brands tablet.
- Friability was found minimum for vyas and maximum for Dabur brands.
- Disintegration time were found in the order at Dabur> Vyas> Zandu> Baidyanath> Unjha.
- Weight variation of the pharmaceutical dosage form is percentage minimum value Vyas and maximum value Dabur.
- Pharmaceutical parameters were evaluated for different mahasudarshan tablet brands found to up standards.
- These data can be provided valuable information on standardization and evaluation of the marketed polyherbal formulation at selected mahasudarshan tablet.

4. CONCLUSION:

The medication content of each unit in a batch should be within a specific range that is close to the declared label strength in order to ensure the consistency of dosage units. Setting up quality control parameters will show you this. The claimed efficacy is ultimately supported by standard quality. Quality control is therefore a crucial step in the production process. Physicochemical criteria such total ash, acid insoluble ash, water and alcohol soluble extractive values, loss on drying, phytochemical analysis, flow qualities, and safety evaluation were among the several regularity factors that were examined. Testing for phyto-constituents revealed no alkaloid, tannins, or carbohydrates. Results from the current investigation indicate that MSGV passed QC testing with flying colours. The results of the current study may be used as a preliminary tool for developing more reliable quality control parameters of Maha Sudarshana Tablets for subsequent researchers in the absence of any documented data.

5. CONFLICT OF INTEREST: Nil

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