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A Recent Approach for Development and Standardization of Madhushoonya Churna: Ayurvedic Polyherbal Formulation

Sonali Patil, Shruti Shah

BK Birla College Road, Gauripada, Kalyan, Maharashtra 421304, india

ABSTRACT

The quality of herbal medicine depends on the profile of the constituents in the final product and has significant implications in its efficacy and safety. Due to the complex nature and inherent variability of the phytoconstituent in the plant based drugs, it is difficult to establish quality control parameters for Ayurvedic formulations..These Traditional herbal formulations must follow regulatory guidance to create scientific evidence base with robust chemistry, manufacturing and controls. Traditionally *Madhu Shoonya Churna* helps keep diabetes in check. The research aims to standardize the preparation and to set the quality control parameters for manufacturing of this Churna. The powder characteristics, test for phytochemical constituents and organoleptic characteristics were performed on formulation. Instrumental analysis was done by using HPLC & HPTLC. The results obtained were useful for standardization of ASU drugs.

Keywords: Herbal medicine, *Madhu Shoonya Churna,* HPLC & HPTLC

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***Address for Correspondence:**

Sonali Patil, BK Birla College Road, Gauripada, Kalyan, Maharashtra 421304, india

INTRODUCTION

Pharmaceutical ayurvedic research is aimed at meeting the medical needs of the population for whom appropriate therapeutic remedies are not available or at those that are available are but not effective for various disorders. While meeting medical needs of a polyherbal formulation set some parameters to ensure that the formulation shows desired pharmacological action against various diseases. The selection of an appropriate drug should take into account apart from medical needs and innovative potential for success. In the past decade, there has been renewed attention and interest in the use of traditional medicine (Ayurveda, Naturopathy, Unani, Siddha, and Homeopathy) and Yoga globally. Under the parasol of traditional medicine systems, the Ayurveda system of medicine is also gaining global acceptance due to the amazing clinical efficiency of the formulations. There are different forms of medicines prescribed in Ayurveda. One of the most common form is Churna.

Churna is defined as a fine powder of drug or drugs in ayurvedic system of medicine. Drugs mentioned in patha, are cleaned properly, dried thoroughly, pulverised and then sieved. The churna is free flowing and retains its potency for one year, if preserved in an airtight containers. These forms of medicament are prescribed generally because of their particle size. Smaller the particle size greater is the absorption rate from g.i.t and hence the greater is bioavailability (Mukharjee Pulok K, 2008). The present study aims at standardizing the different parameters for the formulation – *Mashu Shoonya Churna.*

The *Madhu Shoonya Churna* helps keep diabetes in check. Prepared with gudhal, jamuna, karela, as the main ingredients, it helps keep diabetes under control. Effective in bringing down high sugar level, the natural ingredients purifies blood while stimulating the pancreas and regulating digestion. It works as an appetizer and will help normalise high blood sugar levels. Madhu shoonya Churna has been made from the best quality herbs that is completely safe and effective against diabetes. It is a product of time-tested and assiduous research and is prepared from precious natural herbs that are excellent for controlling Diabetes.

MATERIALS AND METHODS

1. Raw Materials, Chemicals and Reagents

Plant Raw materials used for the preparation of *Madhu Shoonya Churna* were procured Ayurvedic Proprietory Medicines Shop (Mumbai) with the knowledge of Ayurvedic physician. The materials were dried in an oven preset at

45°C, powdered, sieved through an 85-mesh (BSS) sieve and stored in air tight containers.

The Eugenol standard was procured from Himedia and Assigned purity: 98%.

2. Preparation of *Madhu Shoonya Churna*:

Raw materials complying the pharmacopoeial quality and quantity were subjected to the preparation of *Madhu Shoonya Churna* as per the composition [Table 1] . All the prepared powders were mixed thoroughly as per the standard protocol and stored in air tight container .Quality control test like microscopic evaluation was carried out for all the raw materials.

Table 1: Formulation composition

Sr.no	Sanskrit Name	Botanical Name/ English Name	Weight in gram (Equal Part)
1.	Vijayasaar	(Pterocarpus Marsupium) Wood	1 Part
2.	Karela	(Momordica Charantia) Seed	1 Part
3.	Ashwagandha	(Withania Somnifera) Root	1 Part
4.	Jamun	(Syzygium Cuminii) Seed	1 Part
5.	Neem	(Azadirachta Indica) Seed	1 Part
6.	Tulsi	(Ocimum Basilicum) leaf	1 Part
7.	Gudhal	(Hibiscus Rosa-sinensis) Flower	1 Part
8.	Shudh Shilajit	(Asphaltum)	1 Part

3. Quality Evaluation of *Madhu Shoonya Churna*

- **Organoleptic evaluation**:

The formulation was studied for its preliminary characters like colour,texture,odour and taste.

- **Preliminary Phytochemical**

Phytochemical screening of some major secondary metabolites (Flavonoids, Tannins, Alkaloides, Glycosides, Terpenoids,Steroids, Phlobatannin, starch and Saponins) in *Madhu Shoonya Churna* was carried out by performing preliminary colour based tests.

- **Physicochemical Evaluation :**

The prepared formulation was subjected for physical studies like Bulk density,Tap Density, Compressibility Index, Housner Ratio, Loss on drying and Ash Value.

Heavy Metal determination Test:

The prepared formulation was subjected for determination of heavy metal like cadmium, Lead and Bismuth.

- **Chromatographic Evaluation:**

Preparation of Standard:

Eugenol standard was prepared in methanol with initial concentration of 1000 ppm.Further dilution of 100 ppm was prepared using mobile phases.

Preparation of Sample:

All the raw materials and prepared formulation powders were dissolved in Methanol and kept overnight.Next day al the solutions were filtered through whattman filter paper to obtain clear extracts.

- **High Perfiormance Thin Layer Chromatography (HPTLC) Fingerprinting :**

10 µl of the filtered solution of formulation extract and standard was applied on the HPTLC plate as per condtions mentioned in table 1a followed by development.

Table 1a: Chromatographic Conditions for HPTLC:-

Stationary Phase	HPTLC plates silica gel 60 F 254
Plate size	10.0x10.0 cm
Mobile Phase	Methanol: Ethylacetate:Glacial acetic acid (9:1:0.1)
Saturation Time	20 min.
Standard Used	100 ppm Eugenol
Spot Volume	10 µl
Band Length	8.0mm
Solvent Front	80mm
Wavelength and Lamp	366nm & Mercury lamp
Sample Applicator	CAMAG Linomat 5
Sample Detection	CAMAG Visualizer : 200480
Number of Tracks	9

RESULTS AND DISCUSSION

Madhu Shoonya Churna was prepared in the laboratory as given in standard Ayurvedic literature.The observed results clearly indicates good quality of *Madhu Shoonya Churna*. The organoleptic characters (table 2) help to indentify the formulation from its external appearance. Studies on physicochemical constants (table 3) can provide valuable source of information and suitable standards to determine the quality of the formulation. Phytochemical evaluation helped to understand the presence of various therapeutically active constituents in Triphala Churna. It was found that tannins,Steroides, saponins and phenolic compounds were present (table 4). The heavy metal determination showed absence of cadmium, bismuth and lead. (table 5). The presence and absence of these phytoconstituents in particular formulation depends upon raw materials present into it and the procedure used for ots preparation..These Phytochemical and Biochemical tests are important to obtain preliminary information on the quality. According to Mohan et al. different chemical compounds detected in whole plant extracts could make the plant useful for treating different ailments as having a potential of providing useful drugs of human use.

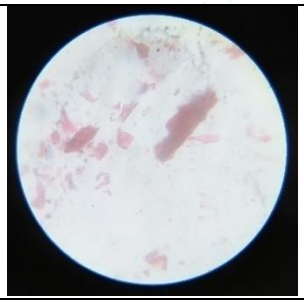
The prepared formulation was then assesed for its quality by checking the presence of marker compound Gallic acid by hyphenated techniques like HPTLC. HPTLC fingerprinting is very useful techniques to check the presence or to confirm raw materials in formulations. For monitoring quality ,one can visualize the presence of various plant chemical constituents in raw materials as well as formulation , out of these a marker compound can serve as a characteristic fingerprint for that formulation (Fig 1).

Quality control analysis of raw material:

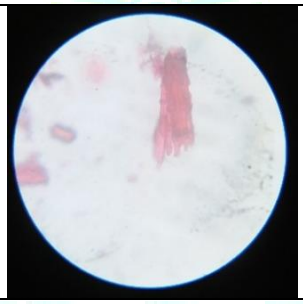
Powder characteristic of raw material

Ingredients	Characteristics
Vijaysaar	Phloem Parenchyma Phloem fibres
Karela	Chlorenchyma
Ashwagandha	Parenchymatous cell Xylem Parenchyma Xylem
Jambul	Parenchymatous cell Oval rounded starch grains
Neem	Parenchyma Palisade
Gudhal	Phloem fibres Palisade

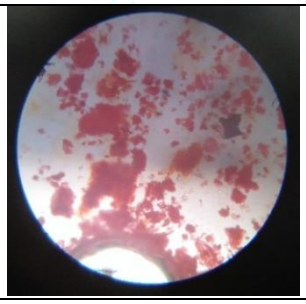
Microsocpic evaluation:-



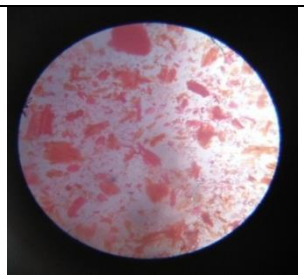
Phloem



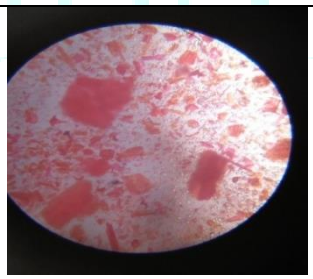
Parenchyma Phloem fibres



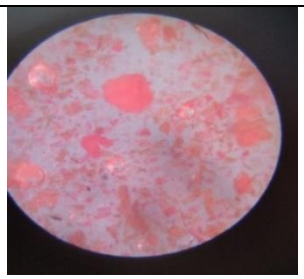
Chlorenchyma



Parenchymatous cell

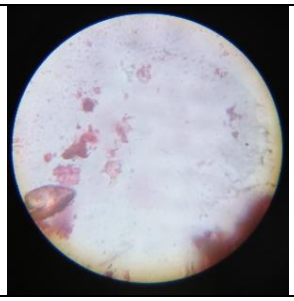


Xylem Parenchyma



Xylem

Oval rounded starch grains



Parenchyma

Palisade

Table 2: Organoleptic Characters

Sr. No.	Characters	Triphala Churna
1	Colour	Light Brown
2	Taste	Bitter
3	Texture	Powder
4	Odour	Acrid

Table 3: Physicochemical evaluation

Sr. No.	Parameters	Triphala Churna
1	Bulk Density	0.381gm/ml
2	Tap Density	0.561gm/ml
3	Hausner Ratio	1.174 gm/ml
4	Compressibility Index	32.16%
5	Total Ash	0.049
6.	Loss on drying	4.374 %

Table 4: Phytochemical Evaluation

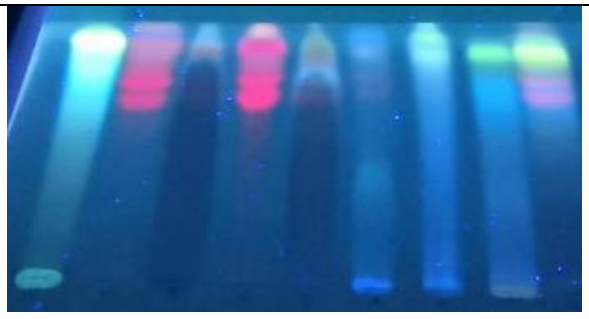
SR NO.	TESTS	OBSERVATION	RESULTS
1	Tannin: 1ml Aq. Extract + 0.1% $FeCl_3$ dropwise	Brownish green or Blue black colour	+
2	Alkaloids: 1ml Alc. Extract + 1ml conc. HCl + Hager's Reagent	Yellow ppt	+
3	Glycosides: 1ml extract + 0.5ml Glacial Acetic acid + few drops of Dil. $FeCl_3$ till colourless + 1ml Dil. H_2SO_4	Brown Ring	+
4	Flavonoids: 1ml extract+ 1ml Dil. ammonia solution + Conc. H_2SO_4	Yellow colour disappear	-
5	Steroids: 1ml extract + 1ml chloroform + Conc H_2SO_4	Red colour after stand	+
6.	Phlobatannin: 0.5ml aq. Extract+ Boil with 1ml 1% HCl	Ppt present	-
7.	Phenolic Compounds: 1ml extract + dropwise $FeCl_3$	Violet colourppt	-
8.	Saponin: 1ml extract + Few drops of olive oil+ Shake vigorously	Froth	-
9.	Terpenoids: 1ml extract +0.5ml $CHCl_3$+ 1ml Conc. H_2SO_4	Yellow colour	-

Key : + positive, - Negative

Table 5: Heavy Metal determination

Test	Observation	Inference
Lead: (1.) Dil HCl added in sample. (2.) KI is added in sample solution.	No white ppt. of $CaCl_2$ soluble in boiled water & conc. HCl. Yellow ppt. soluble in boiling water.	Lead absent. Lead absent.
Bismuth: NH4OH added	White ppt. insoluble in excess NH4OH dissolved in dil. HCl.	Bismuth absent.
Cadmium: Potassium ferrocyanide added	White ppt. of cadmium ferrocyanide.	Cadmium absent.

Fig 1 : HPTLC fingerprint of Raw Material and Formulation



Methanol: Ethylacetate:Glacial acetic acid (9:1:0.1)

Key: From left to right lane- Vijaysaar, Tulsi, Jamun, Neem, Gudhal, Ashwagandha, Karela, Madhushoonyachurna (water extract), Madhushoonyachurna (methanol extract).

CONCLUSION

Quality control parameters are of key importance if traditional medicines are to be given credibility as modern medicine has.In order to have consisitancy and uniformity in the production of these medicines on large scale,there is a need to set a standard protocol for preparation and for assesment of quality,efficacy. Ayurvedic formulation *Madhu Shoonya Churna* was prepared as described in classical texts and it has been assessed for its quality by intervention of modern scientific quality control measures in the traditional preparation. The quality profile obtained from the present study for the formulation could be employed for evaluating its identity and can be used for routine analysis. It can be concluded that this profile might be helpful in establishing standardization of the formulation.

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