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ANALYTICAL STANDARDIZATION OF BALADI MANDURA

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ABSTRACT

Due to commercialization the manufacturers of Ayurveda medicine industry is facing various problems such as availability of good quality raw material, the authentification of raw drugs and its standardization method. Hence Standardization is an essential entity to establish the quality, efficacy and authenticity of any drug or finished products. In the pharmacopoeias various standardization methods for raw herbal drugs, formulations of herbal drugs as well as herbo mineral formulations are given in detail. Baladi Mandura is one among the herbo mineral preparation prepared in the form of granules. According to the pharmacopoeias the granular dosage forms has to be undergo certain analytical quality control measures in order to authenticate it. To prove the therapeutic actions of various drugs with its safety profile, certain amount of expertise and new information is needed. Hence the drug Baladi Mandura was standardized here by analyzing the organoleptic characteristics, Physico-chemical evaluation and HPTLC analysis.

KEYWORDS: Moisture content, Ash value, Extractive values, p^H.

INTRODUCTION

The Ayurveda system of medicine uses plants, animal origin substances metals as well as minerals either in the form of single drug formulation or compound formulations. The preparation of such formulations carried out by various pharmaceutical processing. It is evident from the ancient classics that there are plenty of drugs of the same species present on

earth which may pretend to be identical. Hence Acharyas have been explained in detail regarding the identification protocols for the raw materials, different procedures to test the purity and safety as well as the therapeutic properties of each drug with the toxic properties of metals, minerals and some herbal drugs. It also suggests the different therapeutic properties of a drug contributing to its actions on various diseases. However, lot of changes have been occurred due to various factors and these changes have an impact on the therapeutic efficacy of the drugs as well as formulations. Hence the classical references are not sufficient enough to justify the actions of certain drugs and this need certain amount of expertise and new information. On this regards the drug Baladi Mandura[1] which is a herbo mineral preparation has been studied here under various analytical parameters.

MATERIAL AND METHOD

The standardization of Baladi Mandura was carried out in the S.D.M Centre for Research in Ayurveda and Allied Sciences, Udupi. The Organoleptic characteristic such as color, taste, smell and consistency of Baladi Mandura granules were assessed immediately after the preparation. Further the physico-chemical evaluation of Baladi Mandura was carried out and they are as follows.

1. Determination of p^H[2]

P^H value fundamentally represents the value of hydrogen ion activity in solutions. It expresses whether the aqueous solution is acidic or alkaline. From the stand point of stability and physiological suitability, p^H as a measure of hydrogen activity is very important.

1 ml of sample (Baladi Mandura granules) was taken and 10 ml distilled water was added, stirred well and filtered. The p^H was noted by using a p^H meter.

2. Moisture content[3]

It is the amount of volatile matter drying off from the drugs.

10 g of sample was placed in tared evaporating dish and dried at 105˚C for 5 hours in hot air oven and weighed. The drying was continued until difference between two successive weights was not more than 0.01 after cooling in desiccator. Percentage of moisture was calculated with reference to weight of the sample.

3. Total Ash[4]

2 g of sample was incinerated in a tared platinum crucible at temperature not exceeding 450˚C until carbon free ash is obtained. Percentage of ash was calculated with reference to weight of the sample.

4. Acid insoluble ash[5]

To the crucible containing total ash, 25ml of dilute HCl is added and boiled. The insoluble matter on ash-less filter paper (Whatmann 41) is collected and washed with hot water until the filtrate becomes neutral. The filter paper is dried and ignited and allowed the residue to cool in suitable desiccator for 30 min and weighed without delay. The content of acid insoluble ash with reference to the air dried drug was calculated.

5. Water soluble ash[6]

The ash was boiled for 5 min with 25 ml of water; the insoluble matter on an ash less filter paper was collected, washed with hot water, and ignited for 15 min at a temperature not exceeding 450˚C. The weight of the insoluble matter was subtracted from the weight of the ash; the difference in weight noted, this represents the water soluble ash with reference to the air-dried sample.

6. Alcohol soluble extractive[7]

4 g of the sample was taken in a glass stoppered flask and 100 ml of distilled Alcohol was added Shaken occasionally for 6 hours. It was then allowed to stand for 18 hours and later filtered rapidly. 25 ml of the filtrate was pipetted out in a 100 ml beaker and evaporated to dryness on a water bath. Kept in a hot air oven at 105^0C for 6 hours. Cooled in a desiccator for 30 minutes and weighed. The percentage of alcohol extractable matter was calculated.

7. Water soluble extractives[8]

The procedure is as same as the determination of alcohol soluble extractive value, here water is added instead of alcohol.

8. Angle of repose[9]

The angle of repose is one among the measurements of flow properties of powder dosage forms. It is defined as the internal angle between the surface of the pile and the horizontal surface. It usually depends upon the density, shape of the particles, surface area and the coefficient of friction of the material.

9. Bulk density[10]

The sample of Baladi Mandura was taken in a dry graduated cylinder of 250 ml (readable to 2 ml), gently introduced without compacting. Approximately 85 g of the sample occupied in 72 ml. The powder was leveled carefully without compacting and the reading noted. The bulk density calculated by the following formula, ρbulk = M/V, where M= Weight of powder and V= Volume of powder.

10. Determination of Tapped density[11]

After measuring the bulk density, the graduated cylinder containing the sample was kept over the tap density instrument and the initial reading noted. After this a specified compaction process was followed. The powder was compacted each time by tapping. 50 consecutive tapping was done and the 50^{th} reading was noted and the tapped density calculated by the following formula, ρtapped = M/Vt.

The volume occupied by the sample after tapping = 60

11. Hausner's ratio: (HR)[12]

The Hausner's ratio is a number that is correlated to the Flowability of a powder or granular material and calculated by the formula, HR = ρtapped / ρbulk.

12. Compressibility index: (or Carr's index)[13]

The Hausner's ratio is a number that is correlated to the Flowability of a powder or granular material and calculated by the formula, HR = ρtapped / ρbulk.

13. HPTLC[14]

1g of Baladi mandura was suspended in 10 ml of alcohol. 3, 6 and 9µl of the above extracts were applied on a pre-coated silica gel F_{254} on aluminum plates to a band width of 7 mm using Linomat 5 TLC applicator. The plate was developed in Toluene: Ethyl acetate (9.0: 1.0). The developed plates were visualized under short UV, long UV and then derivatised with vanillin Sulphuric acid and scanned under UV 254nm, 366nm and 620nm (After derivatisation). R_f, colour of the spots and densitometry scan were recorded.

RESULTS

The results of organoleptic characteristics, Physico-chemical evaluation and HPTLC evaluation of Baladi Mandura is depicted in the following Tables 1, 2, 3 and 4. The HPTLC images are shown in the figure 1 and 2.

Table 1: Results of Organoleptic characteristics of Baladi Mandura.

Color	Coffee brown
Odor	Aromatic and pleasant
Taste	Sweet, Spicy
Texture	Fine to course powder
Final weight	363.1 g
Weight loss	52.9 g

Table 2: Results of Physical properties of Baladi Mandura.

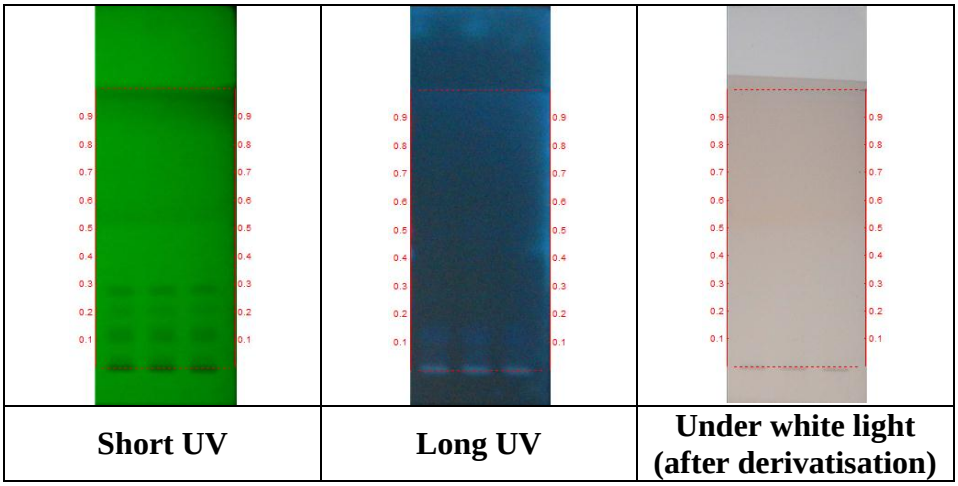
Parameters	Analytical study results
P^H	6.28
Loss on drying	1.99 ± 0.01
Total ash	82.08 ± 0.57
Acid insoluble ash	75.36 ± 0.01
Water soluble ash	1.39 ± 0.01
Alcohol soluble extractive	6.66 ± 0.01
Water soluble extractive	12.21 ± 0.01

Table 3: Results of Flow property of Baladi Mandura granules.

Parameter	Baladi Mandura
Angle of repose	42 (Passable)
Bulk density	1.18
Tapped bulk density	1.41
Hausner's ratio	1.19 (Fair)
Carr's index	57.31 (poor)

Table 4: Result of HPTLC showing the Rf value of Baladi Mandura.

Short UV	Long UV	Under white light (after derivatisation)
0.11 (Green)	0.11 (F. blue)	-
-	0.14 (F. blue)	-
0.20 (Green)	-	
0.28 (Green)	-	-



Short UV	Long UV	Under white light (after derivatisation)

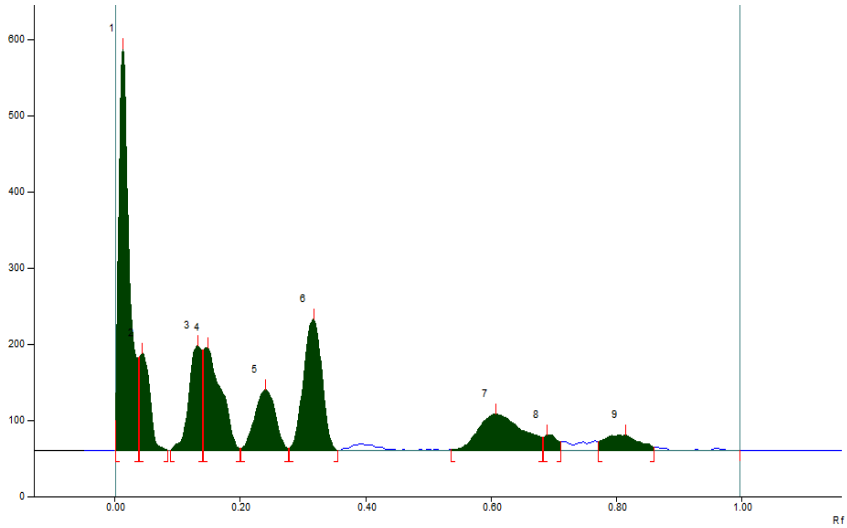
Figure 1: HPTLC photo documentation of ethanolic extract of *Baladi mandura.*

Track 1- ***Baladi mandura***– 3µl

Track 2- ***Baladi mandura***– 6µl

Track 3- ***Baladi mandura***– 9µl

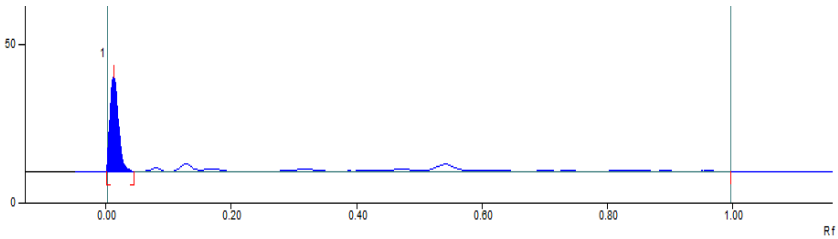
Solvent system – Toluene: Ethyl Acetate (9:1)



Track 17, ID: Baladi mandura

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	39.8 AU	0.01 Rf	527.1 AU	41.61 %	0.04 Rf	21.1 AU	6337.7 AU	29.22 %
2	0.04 Rf	122.3 AU	0.04 Rf	127.8 AU	10.09 %	0.08 Rf	0.3 AU	1553.4 AU	7.16 %
3	0.09 Rf	0.3 AU	0.13 Rf	136.9 AU	10.81 %	0.14 Rf	31.2 AU	2084.4 AU	9.61 %
4	0.14 Rf	131.8 AU	0.15 Rf	135.0 AU	10.66 %	0.20 Rf	3.1 AU	2690.3 AU	12.40 %
5	0.20 Rf	3.1 AU	0.24 Rf	79.9 AU	6.31 %	0.28 Rf	3.4 AU	1879.5 AU	8.67 %
6	0.28 Rf	3.6 AU	0.32 Rf	171.7 AU	13.55 %	0.36 Rf	0.0 AU	3605.0 AU	16.62 %
7	0.54 Rf	1.3 AU	0.61 Rf	47.9 AU	3.78 %	0.68 Rf	17.1 AU	2407.2 AU	11.10 %
8	0.68 Rf	17.2 AU	0.69 Rf	19.9 AU	1.57 %	0.71 Rf	11.1 AU	320.7 AU	1.48 %
9	0.77 Rf	11.6 AU	0.82 Rf	20.5 AU	1.62 %	0.86 Rf	4.5 AU	810.2 AU	3.74 %

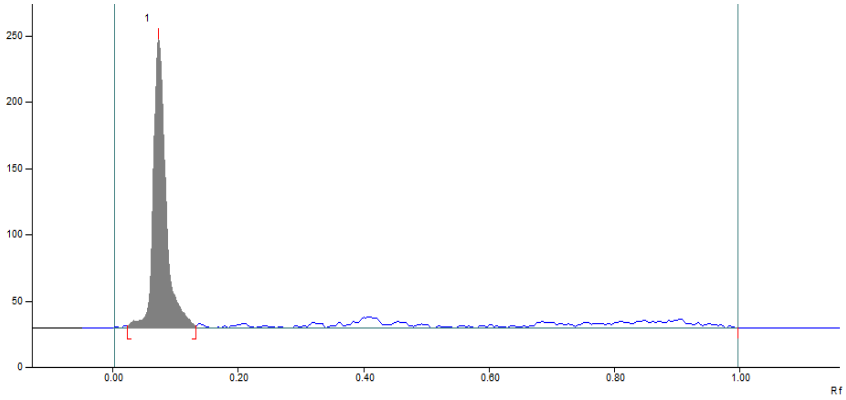
At 254nm



Track 17, ID: Baladi mandura

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.00 Rf	0.0 AU	0.01 Rf	29.9 AU	100.00 %	0.05 Rf	0.0 AU	291.0 AU	100.00 %

At 366nm



Track 17, ID: Baladi mandura

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.02 Rf	1.7 AU	0.07 Rf	218.1 AU	100.00 %	0.13 Rf	1.9 AU	3156.0 AU	100.00 %

At 620nm (Post derivatisation)

Figure 2: Densitometric scan of *Baladi mandura.*

DISCUSSION

The analytical standardization of Baladi Mandura was carried out on the basis of its Physico-chemical properties along with HPTLC analysis.

The p^H usually ranges from 0-14, where p^H less than 7 are acidic in nature while p^H more than 7 are alkaline in nature. The p^H of Baladi Mandura was found to be 6.28 which indicates the weak acidic nature of the drug. Loss on drying (LOD) gives the amount of moisture content and volatile matter in the sample. Chances of getting microbial contamination will be high if the moisture content is more, and the drug will spoil fast. Here for Baladi Mandura the LOD obtained was 1.99% which indicate the longer shelf life of the product. Determination of ash value gives the amount of organic and inorganic constituents present in the sample, which suggests the quality and purity of the drug. The amount of acid insoluble ash was 75.36 ± 0.01, this suggests the quantity of total ash which is insoluble in diluted hydrochloric acid. The water soluble ash was found to be 1.39 ± 0.01suggests the presence of organic matter present in the sample.

Extractive values indicate the presence of different constituents in the sample. If the extractive value is lesser or more than the permeable limit that indicates adulteration. The sample of Baladi Mandura showed 6.66 ± 0.01 alcohol soluble extractive value whereas the water soluble extractive value was found to be 12.21 ± 0.01.

A higher range of Angle of repose indicates the rough and irregular shape of the particles of that product. Here Baladi Mandura is a granule dosage form and it has both crystal particles and powder particles hence the angle of repose found as 42 (passable). The bulk density found as 1.18 whereas the tapped bulk density found to be 1.41.

Here the Hausner's ratio of BM was found as 1.19 which indicate the moderate flow property of the BM granules. The Carr's index (CI) is an indication of the compressibility of a powder or granule. Here the CI of Baladi Mandura showed a poor value i.e. 57.31 may be due to the rough nature of Baladi Mandura granules.

The preliminary HPTLC profile of vanillin Sulphuric acid extract of Baladimandura has been developed and the Rf values were analyzed at short UV and long UV (254 nm, 366 nm and 620 nm) and the colour of the spots and densitometry scan were also recorded. The constituents were observed at 254 nm, with Rf value of 0.00, 0.14, 0.28 and 0.54 (Area in %). This can be taken as the standard reference of chromatographic evaluation of Baladi Mandura for the future studies.

CONCLUSION

The analytical standardization of Baladi Mandura was done as a part of quality control measure to prove its quality and safety profile and the results were interpreted. Baladi Mandura is a drug of choice in Amlapitta and Parinamashoola according to reference of Rasakamadhenu. By analyzing the p^H value (6.28) it is understood that the weak acidic nature of the drug can give a better therapeutic action in both Amlapitta and Parinamashoola by neutralizing the gastric contents.

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