



STANDARDIZATION OF A POLYHERBAL FORMULATION: DIA-CARE

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ABSTRACT

After post general agreement on tariffs and trade (GATT) era there is big surge in Herbal based medicines to find out their potential for treatment and cure of diseases and ailments which can or cannot be cured by well established allopathic formulations. Most of the traditional systems of medicine are effective but they lack of standardization. So there is need to develop standardization technique. Central council for research in Ayurveda has given preliminary guidelines for the standardization of conventionally used formulations. The present study deals with standardization of Dia-care, known to be effective in diabeters mellitus. One sample was procured from manufacturers and subjected to standardization on the basis of organoleptic properties, physical characteristics, physico-chemical evaluation and was compared using in-house formulation. It was observed that the commercial samples matched exactly with that of in -house preparation after performing the standardization.

Keywords: Standardization, polyherbal formulation, Carr's index

1. INTRODUCTION

The Indian system of medicine, mainly comprising of Ayurveda, Siddha and Unani, is one of the oldest holistic management system with thoroughly documented remedies. Of all these, Ayurveda is being practiced by a large population in India and abroad [1] In the present era, market of all commodities has become global. Health has been of utmost importance since ancient times for the mankind. Market of health-related products has been active and these products are manufactured at different parts of the world and sold all over. Standardization is necessary to make sure the availability of a uniform product in all parts of the world. Standardization assures a consistently stronger product with guaranteed products [2]. The main requirement in polyherbal formulation is the presence of each ingredient has to be established. The microscopic characters of each ingredient are very difficult to identify and also sometime these are overlapping with the character of other ingredient. Standardized ayurvedic formulations of uniformity are essential for beneficial therapeutic use. Due to lack of standards and quality control methods, there are batch to batch variations in the same formulation procured from different sources [3]. Standardization is an essential factor for polyherbal formulation in order to assess the quality of the drugs based on the concentration of their active principle [4]. This study reports on the standardization of Dia - care based on organoleptic properties, physico-chemical investigations, preliminary

phytochemical analysis, fluorescence analysis, heavy metal analysis and microbial evaluation.

2. MATERIAL AND METHODS

2.1. Plant material

The sample was collected from Admark herbal limited (formulation code F1) which is being used as antidiabetic drug. For in house preparation, the ingredients were purchased from local raw material traders, which were authenticated (formulation code F2). Polyherbal formulation consists of 19 ingredients.

2.2. Preparation of polyherbal formulation

All the ingredients (table 1) were collected, dried and powdered separately, passed through 80# sieve and then mixed together in specified proportions in a geometrical manner to get uniform mixture.

2.3. Chemicals, reagents and instrument

All the chemicals and reagents used in the study were obtained from the standard supplier and were of good quality. For heavy metal analysis Atomic Absorption spectroscopy 6300 (SHIMADZU) was used and for microbial analysis nutrient media was procured from standard supplier.

Table 1: Composition of Dia-care

S.No	Botanical name	Quantity
01	Eugenia jambolona	20%
02	Tinospora cardifolia	10%
03	Gymnema sylvestre	10%
04	Cressa cretica	5%
05	Csekria esculenta	5%
06	Curcuma longa	5%
07	Swertia chirata	5%
08	Centratherum anthelminticum	5%
09	Picrorrhiza kurroa	5%
10	Trigonella foenum graecum	5%
11	Terminalia chebula	5%
12	Holarrhena Antidysentrica	2.5%
13	Pterocarpus marsupium	2.5%
14	Glycyrrhiza glabra	2.5%
15	Mineral pitch	2.5%
16	Tribulus terrestris	2.5%
17	Withania somnifera	2.5%
18	Nordotachyns jatamansi	2.5%
19	Bacopa monniera	2.5%

3. RESULTS

Table 2: Physical and chemical evaluation of samples of Dia-care

Parameters	Formulation code	
	F1	F2
Total Ash value(%w/w)	12.5±0.17	12.3±0.03
Alcohol soluble extractive value(%w/w)	24.8±0.01	23.5±0.04
Foreign organic matter(%w/w)	Nil	Nil
Water soluble extractive value(%w/w)	24±0.9	24±0.8
Ethylacetate soluble extractive value(%w/w)	20±0.26	20±0.25
Chloroform soluble extractive value(%w/w)	9.6±0.04	9.6±0.04
Methanol soluble extractive value(%w/w)	15.2±0.02	15.2±0.02
Petroleum ether soluble extractive value(%w/w)	12±0.01	12±0.04
Loss on drying at 105°C(%w/w)	7.26±0.02	6.89±0.01

Values are expressed as mean±SEM; (n=3)

Table 3: Organoleptic evaluation of samples of Dia-care

Organoleptic characters	Formulation 1	Formulation 2
Colour	Yellowish Green	Green
Odor	Pungent	Pungent
Taste	Bitter	Bitter

Table 4: Fluorescence analysis of samples of Dia-care

Parameter	Formulation 1	Formulation 2
Powder + 1 M NaOH	Brownish yellow	Brownish yellow
Powder+conc.HNO ₃	Orange yellow	Orange
Powder+ Br ₂ water	Light brown	Light brown
Powder+ CCl ₄	Dark brown	Dark brown
Powder+methanol	Greenish yellow	Greenish yellow
Powder+ NH ₃	Yellowish brown	Yellowish brown
Powder+I ₂	Blackish brown	Blackish brown
Powder+5%H ₂ O ₂	Greyish green	Greyish green
Powder+FeCl ₃	Dark grey	Dark grey
Powder+10% HNO ₃	Yellow	yellow
Powder+AgNO ₃	Buff brown	Buff brown
Powder+HCl	Greyish yellow	Greyish yellow

Table 5: Phytochemical screening of Dia-care

Parameters	Formulation 1	Formulation 2
Carbohydrates	+	+
Steroids	+	+
Cardiac glycosides	+	+
Flavonoids	+	+
Alkaloids	+	+
Tannins	+	+
Phenolic compounds	+	+

Note: + indicates presence – indicates absence

Table 6: Physical characteristics of samples of Dia-care

Parameters	Formulation 1	Formulation 2
True density (1% Soln)	0.66±0.012	0.65±0.018
Bulk density (gm/ml)	0.30±0.018	0.28±0.016
Tapped density	0.692±0.005	0.691±0.003
Angle of repose	42.90±0.23	42.92±0.20
Viscosity (1% soln)	1.304 cp	1.209cp
Surface tension	45.0	44.0
Fluff density (gm/ml)	0.290±0.010	0.270±0.010
Hausners ratio	1.20±0.004	1.10±0.002
Carr's compressibility index	18.20	16.10

Table 7: heavy metal analysis of samples of Dia-care

Heavy metals	Formulation 1	Formulation 2
Arsenic	----	----
Lead	----	----
Mercury	----	----
Copper	----	----

Table 8: Microbial analysis of samples of Dia-care

Microbes	Formulation 1	Formulation 2
<i>E.coli</i>	----	----
<i>Salmonella typhi</i>	----	----
<i>Pseudomonas aeruginosa</i>	----	----
<i>Staphylococcus aureus</i>	----	----

4. DISCUSSION

According to WHO, the macroscopic and microscopic determination of the formulation is the first step towards establishing its identity and purity should be carried out before any tests are undertaken. In the present work the macroscopic study of both formulations of Dia-care were carried out. The results of macroscopic study might be useful for distinguishing from its substitutes and adulterants. There is no foreign organic matter in both the formulations.

The physico-chemical parameters are helpful in judging the purity and quality of the drug. Loss on drying at 105°C of both formulations (F1 & F2) is 7.26% and 6.89% respectively. It signifies the considerable amount of moisture in formulations.

Ash values were used to detect the presence of any siliceous contamination and water soluble salts. These values are important quantitative standards as it is useful in determining authenticity and purity of drugs. The results suggest that both the formulations have high water soluble extractive value than ethyl acetate, chloroform, methanol, petroleum ether soluble extractive values. The water soluble extractives indicate the presence of water soluble matters such as alkaloid, carbohydrate and flavonoids. The fluorescence character of powdered drug plays a vital role in the

determination of quality and purity of the drug material. The results of preliminary phytochemical test showed the presence various phytoconstituents in both formulations. Both formulations have carbohydrates, steroids, cardiac glycosides, flavonoid, alkal-oid, tannin, phenolic compounds. The flow properties of formulations was determined by hausners ratio, carr's index, true density ,bulk density [5]. Both formulations tested negative for the presence of heavy metals. For safe use of polyherbal formulations microbial content were checked whether total bacterial count, total yeast and mould count are within the prescribed limits and for the absence of micro-organisms like salmonella, Escherichia coli, staphylococcus aureus, pseudomonas aeruginosa [6]. Analysis of manufacturers sample compared with in-house formulation but the variation was significant. The results which were obtained in this study may be considered as tools for assistance to the regulatory authorities, scientific organization and manufacturers for developing standards.

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6. REFERENCES

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