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Research Article

Standardization of Some Marketed Herbal Formulation Used in Diabetes

Manish A Kamble[1], Mayuri R Mane[2], Ashwini R Ingole[3], Disha M Dhabarde[4]

[1,2,3,4]Kamla Nehru College of Pharmacy, Butibori, Nagpur-441108 (Maharashtra), India.

Abstract

Herbal Drugs have been used since ancient times as medicines for the treatment of range of diseases. The herbal medicine and their preparations have been widely used by the world population in developing and developed countries owing to its natural origin safety, efficacy lesser side effects or dissatisfaction with the results of synthetic drugs. They are effective in all types of diabetes including Polyuria, it has been standardized by modern scientific quality control processes both for the raw material and finished product obeying to WHO's guidelines. The evaluation of herbal formulations provides values for different parameters which will help to put forth new standards to these traditional antidiabetic formulations. These new standards will help to maintain consistency to various batches. The active constituents from various parts of plants will effectively increases the potency & efficacy of herbal formulations. These parameters will help to study pharmacological effect in comparison to modern antidiabetic drugs.

Keywords: Standardization, Antidiabetes formulation, Diabetes mellitus, WHO guidelines

Introduction

The term "herbal drugs" denoted by means of plant or part of plants that have been converted into phytopharmaceuticals. These Herbs and products containing herb(s) have been in trade and commerce and are currently used for a variety of purposes[1]. Traditional herbal medicine and their preparations have been widely used by about 80% of the world population for the thousands of years in developing and developed countries owing to its natural origin safety, efficacy lesser side effects or dissatisfaction with the results of synthetic drugs. In the global context, herbal medicines flourish as the method of therapy of choice in many parts of the world. In recent years, the increasing demand for herbal medicines is being fueled by a growing consumer interest in natural products. Now it is finding new popularity as an alternative conventional medicine even in the industrialized countries and the adoption of crude extracts of plants for self-medication by the general public is in the increase. Phyto-therapeutic agents or phyto-medicines are standardized herbal preparations consisting of complex mixtures of one or more plants, which are used in most countries for management of various diseases. According to the WHO definition, herbal drugs contain as active ingredients plant part or plant materials in the crude or processed state along with certain excipients, i.e. solvents, diluents or preservatives. The active principles responsible for their pharmacological actions are not usually known. The World Health Assembly has emphasized the need to ensure the quality of medicinal plant products by using modern control techniques and applying suitable standards[2]. The need for safety and efficacy has also escalated since the western interest has grown. Thus the need for standardization has come into view. The process of evaluation of the quality and purity of crude drugs by means of various parameters like morphological, microscopical, physical, chemical and biological observations is called standardization[3]. Standardisation of the herbal drug begins from the collection of the herbal drug to its packaging/ use as medicine.

The Impediments in Standardization of Herbal Drugs

Variability in the chemical composition of the soil and changes in the climate in fluence the range of phyto constituents present in the herbal drugs[4]. Growing

Corresponding Author: Mayuri R Mane, Kamla Nehru College of Pharmacy, Butibori, Nagpur-441108 (Maharashtra), India.
E-mail Id: mayurimane121020@gmail.com
Orcid Id: https://orcid.org/0000-0003-3970-7516
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deforestation is leading to increase in the number of endangered species of medicinal plants. This leads to addition of adulterants or substitutes to the herbal drug. Addition of adulterants and substitutes can change the safety and efficacy of the drug.

WHO sets guidelines for standardization of Herbal Drugs as well as focus on the current and future trends of the methods used for analysis of the herbal drug on the basis of some parameters such as:

- Authentication
- Foreign matter
- Organoleptic evaluation
- Tissues of diagnostic importance
- Ash values and extractive values
- Volatile matter present in the drugs
- Moisture content determination
- Chromatographic and spectroscopic evaluation
- Determination of heavy metals
- Pesticide
- Microbial contamination

Diabetes mellitus is a complex metabolic disorder that characterized by hyperglycemia resulting form malfunction in insulin secretion and /or insulin action both caused by impaired metabolism of glucose, lipid and protein[5]. The chronic hyperglycemia of diabetes is associated with long term damage, dysfunction and failure of various organs. Diabetes mellitus is characterized by constant high level of blood glucose(sugar). The principle two idiopathic forms of diabetes mellitus are known as Type 1 (Insulin dependent) and Type 2 (non-insulin dependent). Classical triad of diabetes symptoms is Polyuria, polydipsia, and polyphagia which are respectively frequent urination, increased thrust and consequent increased fluid and increase appetite. Symptoms may develop quite rapidly[6].

In the present study the herbal drugs raw and finished marketed formulations were standardized with respect to WHO guidelines and evaluated and compared antidiabetic activity of all formulations using in-vitro methods.

Experimentals & Results

Selection of herbal drug material

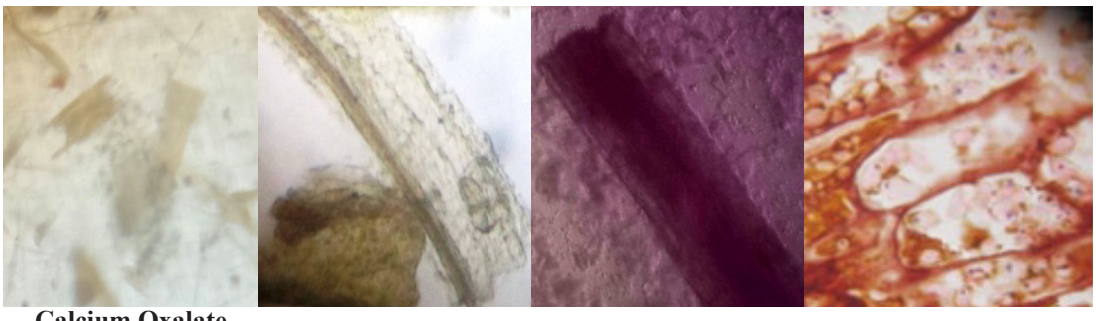
The herbal drugs were selected on the basis of easy availability and traditionally known efficacy and these Raw materials availability in marketed Polyherbal formulation used in Diabetes. The marketed preparations were used for the study were Diactral , Diaba-Tea & Active and the common herbal raw material were in those formulations are as: Amla i.e. *Emblica officinale* (Euphorbiaceae)[7], Jamun Seeds i.e. *Eugenia jambolana* (Myrtaceae)[8], Karela i.e. *Momardica charantina* (Cucurbitaceae)[9], Gudmar i.e. *Gymnema sylvestris* (Asclepiadaceae).

Microscopic Evaluation

It involves the detailed assessment of the herbal drugs and it is used to recognize the organized drugs on the basis of their known histological characters. It is regularly used for qualitative analysis of organized crude drugs in total and powder form with the help of microscope. The inner pseudoparenchyma cells are round or oval shape. They contain protein and fixed oil. Crude drugs are microscopically identified by taking thin TS (Transverse section), LS (Longitudinal Section) in a bark, wood and leaf.

Table 1.Some Microscopic Identification test[10]

Sr. No	Name of Constituents	Procedure for Test/ Reagents	Result
1	Starch	Transverse section of drug + 1 Drop Iodine solution	Blue Color
2	Mucilage	Ruthenium Red	Pink Color
3	Lignin	Transverse section of drug + 1 Drop Phloroglucinol + 1 Drop Conc HCL	Pink color



Calcium Oxalate Crystals | Fibres | Vascular Bundles | Cotyledon (Jamun)

Figure 1.Transverse section of crude drugs

Chemical Evaluation

The most of drug contain definite chemical constituents to which their pharmacological and Biological activity depended. Qualitative chemical test used to identify drug quality and purity. The identification, isolation and purification of active chemical constituents is depends chemical methods of evaluation. Preliminary phytochemical investigation is also a part of chemical evaluation. Some Qualitative chemical test for chemical evaluation crude drug are Saponification value and acid value etc.

Table 2.Some important test used in chemical evaluation[11]

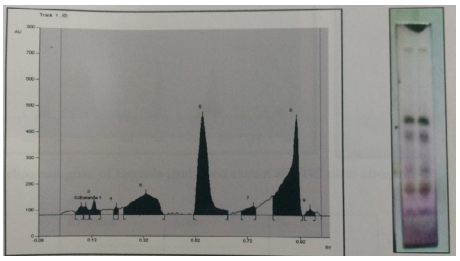
Tests	Methods	Expected observations
Alkaloids	2ml of filtrate in three different test tubes were taken and few drops of dil. HCl was added in each of the tube, then Mayer's, Hager's and Wagner's reagent were added	Mayer's reagent: Cream colored precipitation
		Hager's reagent: Yellow colored precipitation
		Wagner's reagent: Reddish-brown colour
Carbohydrates	**Molish test:** 2ml of filtrate+2 drops of Molish reagent +few drops of cone. H2S04	Violet or reddish colour
	Fehling's solution: 2ml of filtrate+5-8 drops of Fehling's solution and then heated on water bath for half an hour	Brick red precipitation
Flavonoids	2ml of filtrate+few drops of cone. HCl and magnesium turnings were added	Magneta or pink red
Saponins	2mloffiltrate+4mlof dist. H2O were mixed well and shaken vigorously	Foam formation
	2ml of the filtrate+ 1ml ammonia solutions-1ml lead acetate were mixed and shaken vigorously	Black green precipitation or deep green foam
Tanins	2mloffiltrate+10ml dist. H20+a drop of FeCl or	Blue colour
	2mlofthefiltrate+lml 5% FeCl3	Green -black colour

Table 3.Physical characterization on the basis of Physical parameters

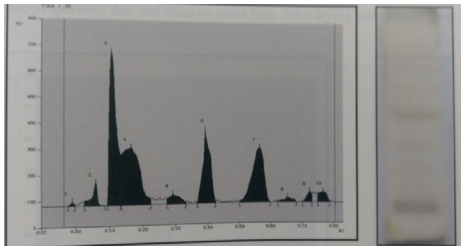
Sr. No	Parameters	Diactral	Diabatea	Active
1	Total Ash Value	4.21%	6.57%	2.12%
2	Acid insoluble Ash	1.07%	1.2%	0.67%
3	Water Soluble Ash	12.41%	12.94%	7.37%
4	Alcohol Soluble Ash	10.82%	17.82%	9.26%
5	Loss on Drying	0.069%	0.026%	0.013%

Identification by HPTLC method

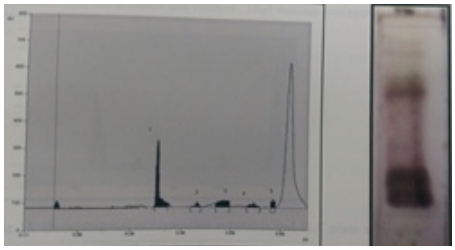
Sample 1: Emblica officinalis
Mobile phase: Toluene: Ethyla Acetate 93: 7
Detection: Anisaldehyde sulphuri acid
Rf Value: 0.56 (Gallic acid)
%: 11.98 Peak: 6



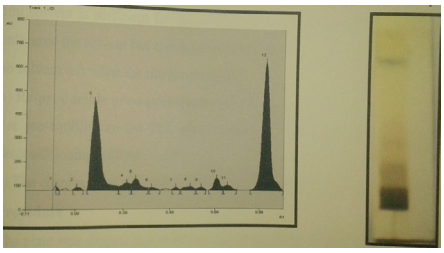
Sample 2: Eugenia jambolana
Mobile phase: Toluene: Ethyl Acetate:Formic acid: Met
3:3:0.8:0.2
Detection: Anisaldehyde sulphuric acid
Rf: 0.47 (ellagicAcid)
%: 21.54, Peak:7



Sample 3: Momardica charantina
Mobile phase: Chloroform: Methanol
8.5: 1.5
Detection: Anisaldehyde sulphuric acid
Rf: 0.32 (Charantin)
%: 6.94, Peak: 1



Sample 4: Gymnema sylvestris
Mobile phase: Chloroform: Methanol
8: 2
Detection: 5% sulphuric acid in methanol
Rf: 0.73 (Gymnemic acid)
%: 1.77, Peak: 12



Estimation of Active constituents of crude drugs using High Performance Thin Layer Chromatography

Selection of Solvent system: A common solvent system was identified which gives maximum separation and which is reproducible
Chromatographic conditions
Stationary Phase: Precoated silica Gel F_{254}
Mobile phase: Toluene: Chloroform: Methanol: Formic acid: Acetic acid (4:4:2:0.8:0.2)
Scanning wavelength: 254nm
Detection: UV-Visible Densitometri Scanning
Mode: Absorbance/Reflectance
Screening for Antidiabetic Activity

The method used for blood glucose determination by Glucometer method.

Animal Use: Swiss albino rats Sprague-Dawley strain (200-250g)

Preparation of alloxan induced diabetes in rats: Diabetes was induced in 12h fasted rats by intraperitoneal injection of 50 mg/kg body weight of Alloxan, freshly dis solved in sterile normal saline immediately before use to give a conc of 50g/l. Diabetic stage was assessed by measuring blood glucose level with the help of glucometer . The rat with blood glucose level above 350mg/dl were selected for the experiment. Animal Were divided in different group contain 6 animal each. Treatment given by triturating the standardized herbal drug extract (100mg0 with saline solution and volume was made up to 10ml.

Table 1.Blood Glucose Level Estimation by Glucometer

Treatment	0Hrs	1 Hr	2Hr	5Hr
Control (Saline)	352 ±3.2	350.2 ±9.2	349.1 ±0.4	343.8 ±1.931
Standard (Metformin 50mg/kg)	364.2 ±3.21	341.25 ±1.31	308.7 ±2.36	267.2 ±0.75
Diactral	350.12 ±1.56	336.4 ±1.03	329.30 ±0.8	320.21 ±3.2
Diaba-tea	352 ±2.47	348 ±2.35	329 ±2.47	280 ±4.92
Active	367.8 ±6.71	349 ±1.06	322 ±7.16	297 ±6.08

Conclusion

The work presented here deals with standardization of some marketed herbal formulations used in diabetes. This study helpful for quality control of single as well as polyherbal formulation. Chromatographic studies helpful as a tool in quality control of raw material as well as final product. This marker analysis of phytoconstituents may also be helpful in studying pharmacokinetics and pharmacodynamics. So it is emphasized to use standardized raw material for the preparation of formulations as it influences activity potential positively. Apart from this other factors like source of raw material, storage practices, manufacturing processes need to be standardized and the product should be evaluated further by doing their stability studies.

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Conflict of Interest: None

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