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QUALITY EVALUATION AND STANDARDIZATION OF AN AYURVEDIC ANTI-DIABETIC FORMULATION: MEHARI CHOORNA

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ABSTRACT: To access the quality of drug the standardization is very critical. As per WHO guidelines, 80% of the peoples have relied on traditional medicine in a rising nation. Most of the conventional system is valuable but a lack of standardization. The parameters studied are physicochemical parameters, phytochemical parameters & qualitative chemical tests. These values will help to obtain the batch to batch variation in traditional preparation of Mehari Choorna which is used to treat diabetes mellitus. We calculated and discussed extractive values, moisture content and ash value. The scientific method for its quality and safety evaluation is not yet to be documented. Hence in the current work, an attempt has been made to evaluate the quality parameters to be used for its preparation and processing.

INTRODUCTION: As per the recent estimates, more than 285 million people worldwide (6.6%) in the 20–79 year age group are suffered from diabetes and by 2030, 438 million people (7.8%) of the adult population, is expected to have diabetes. The largest increases will take place in the regions dominated by budding economiesm ¹. In India, diabetes is a serious disease due to ridiculous food lifestyle. Most of the hypoglycemic agents used in allopathic practice to treat diabetes mellitus are reported to have side effects in long term use ². Standardization is a vital issue for poly-herbal formulation in categorize to review the quality of the drugs based on the concentration of their active principles.



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essential to establish of It system a standardization for every herbal medicine in the market ³. WHO has also issued Guidelines for quality control methods for medicinal plant material in 1992 with an apparent purpose to endow with general test methods for correct botanical evaluation and identification of medicinal plants widely used in traditional and home remedies ⁴. World Health Organization (WHO) encourages, recommends and promotes traditional/ herbal remedies in natural health programmers' since these drugs are readily available at little cost, safe and people have confidence in them. The WHO assembly in some resolutions has emphasized the need to ensure quality control of medicinal plant products by using modern techniques and applying appropriate standards ⁵.

Anti-diabetic churna is polyherbal formulations consist of Jamun and 11 other ingredients in churna form it supposed to have multi-faceted action in all types of the diabetic condition including polyurea.

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Due to lack of modern Pharmacopoeial standard laid down and followed for processing of anti-diabetic churna using the traditional method the medicine prepared may not have wanted effect and batch to batch consistency; hence there is a need for standardization of anti-diabetic churna ⁶.

In the last few decades, there has been an exponential growth in the field of Ayurvedic medicine. There is huge call for standardization and quality control of Ayurvedic formulations. Standardization and quality control depends upon the nature of crude drug and compound drugs; it's the source, i.e. factors associated with raw materials which are beyond of human control like seasonal, geographical, the age of the plant, time of collection, type of drying, etc. due to these natural conditions. The percentage of chemical constituents of the drug does not remain uniform as our expectation 7. In recent years, plant-derived products are increasingly being required out as medicinal products, nutraceuticals, and cosmetics and are available in health food shops and pharmacies over the counter as self-medication or also as drugs prescribed in the non-allopathic systems. ⁸

The present study revealed a scientific evaluation and standardization of polyherbal ayurvedic characteristics, organoleptic phytochemical investigation, Thin Layer Chromatography, and High-Pressure Thin Layer Chromatography. This study is useful for maintaining consistency and quality of formulation. These values should help to develop new pharmacopoeial standard to overcome batch to batch variation in the traditional preparation. Antidiabetic formulation followed by quality control tests. The physicochemical parameters,

Mehari Choorna: 9



FIG. 1: AYURVEDIC ANTIDIABETIC POWDER

Ingredients: Asansal, amalaki, kade chirayat, karali, khair sal, gulwel, jambhul beej, daru haladi manjishta, halad, methi, haritaki. Mehari Choorna was introduced by Arkashala in 1995 after conducting extensive research on Ayurvedic drugs described as antidiabetic.

Properties: When blood glucose level increases patient suffers from thirst, burning sensation, frequent urination, vertigo, constipation, etc. When such symptoms appear & diabetes is diagnosed 'Mehari Choorna' can be advised.

Indication:

Diabetes: Mehari Choorna can be used alone or as an adjunct to allopathic therapy. Regular use of Mehari Choorna helps to reduce the dose of hypoglycemic drugs.

Dosage: 1 to 2 Teaspoonfuls twice a day with warm water.

Presentation: Packs of 100 g, 500 g.

TABLE 1: LIST OF PLANT ARE USED IN MEHARI CHOORNA

S.	Plant	Biological	Part
no.	name	name	used
1	Guduchi	Tinospora	Stem, leaves
		cardiofolia	
2	Asana	Pterocarpus	Heartwood,
		marsupium	leaves, and
			flowers
3	Amalaki	Emblica Officinalis	Fruits
4	Kiratatika	Swertia chirata	Leaves
5	Karavelleka	Momordica charantia	Fruits
6	Khadir	Acacia catechu	Extract of
			Heartwood
7	Jamunbeej	Syzygium aromaticum	Seeds
8	Daruharidra	Berberis ariastata	Root, stem, fruits
9	Manjishtha	Rubia cordifolia	Root, stem
10	Haridra	Curcuma longa	rhizome
11	Haritki	Terminalia chebula	Fruit, root,
			bark
12	Methi	Trigonella foenum	Seed, leaves
		gracecum	

Problems which may Influence the Quality of Herbals: Herbal drugs are usually mixtures of several constituents. The active principles are in most cases mysterious. Selective analytical methods may not be available commercially. Plant materials are chemically & naturally variable. The

method of harvesting, drying, storage, transportation & processing has an effect.

Need for Standardization: The modern system of medicines is based on sounds experimental data, toxicity studies & clinical studies. C-GMP for the herbal industry is not well defined nor are the barest minimum standards of medicinal plants product maintained. The lack of quantitative and qualitative standards has resulted in mild to serious adverse effect hanging from hepatoxicity, which may be life-threatening. Hence, herbal ingredients require tools for determination identity, purity & quantity of products.

MATERIALS AND METHOD:

Parameters Involved in the Standardization Process: $^{10, \, 11, \, 12}$

Study of Organoleptic Characters:

- Color
- Odor

• Taste

Determination of Physicochemical Parameters:

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- Moisture content
- Total ash
- Acid-insoluble ash
- Water soluble ash
- Water-soluble extractive
- Alcohol soluble extractive
- Ether soluble extractive

Qualitative Chemical Test: Test for various secondary metabolites.

Evaluation of Churna:

- I. Bulk density
- II. Tap density
- **III.** Angle of repose
- IV. Compressibility
- V. Hausner ratio

TABLE 2: THE SCALE OF FLOWABILITY:

S. no.	Flow Properties	Angle of Repose	Compressibility Index	Hausner Ratio
1	Excellent	25-30	<10	1.00-1.11
2	Good	31-35	11-15	1.12-1.18
3	Fair	36-40	16-20	1.19-1.25
4	Possible	41-45	21-25	1.26-1.34
5	Poor	45-46	26-31	1.35-1.145
6	Very Poor	55-56	32-37	1.46-1.59
7	Very Very Poor	>66	>38	>1.6

Determination of pH:

Heavy Metal Test:

RESULTS:

TABLE 3: ORGANOLEPTIC CHARACTERS

Color	Yellowish
Odor	Odorless
Taste	Bitter

Physicochemical Standards:

TABLE 4: ASH VALUE

S.	Type of	% of ash value
no.	ash	(S.E.M.)
1	Total Ash	5.14 ± 0.014
2	Acid-insoluble Ash	3.12 ± 0.012
3	Water-soluble Ash	2.11 ± 0.015

TABLE 5: MOISTURE CONTENT/LOSS ON DRYING

TABLE 5: WOISTOKE CONTENT/LOSS ON BRITING		
S. no.	% loss on drying	
1	6.33 ± 0.116	

TABLE 6: EXTRACTIVE VALUES

S.	Name of the	Extractive values
no.	Solvent	(% w/w)
1	Water	10.12 ± 0.016
2	Alcohol	5.3 ± 0.014
3	Ether	2 ± 0.013

TABLE 6: QUALITATIVE CHEMICAL TEST

	S. no.	Chemical Constituent	Alcoholic Extract
Ī	1	Alkaloids	+
	2	Glycosides	+
	3	Tannins	+
	4	Saponins	+
	5	Plant Steroids	+

Determination of Physical Characteristics of Powder:

TABLE 7: BULK DENSITY & TAP DENSITY

THE TOTAL OF THE PERSON OF THE		
S.	Bulk Density	Tap Density
no.	(S.E.M.)	(S.E.M.)
1.	0.48 ± 0.01	0.54 ± 0.01

S.	Carr's index	Hausner ratio
no.	(S.E.M.)	(S.E.M.)
1	9.13 ± 0.05	1.1 ± 0.01

TABLE 9: THE ANGLE OF REPOSE

S. no.	Angle of repose
1	28.3 ± 1.13

TABLE 10: DETERMINATION OF pH OF THE **SAMPLE:**

S. no.	pH (IN 1%)	pH (IN 10%)
1.	6	4.4

Heavy Metal Test:

TABLE 11: TEST FOR CADMIUM

Test	Observation	Result
NH ₄ OH added in	No white	Absence of
the solution	precipitation	Cadmium
Potassium	No white	Absence of
ferrocyanide added	precipitation	Cadmium

TABLE 12: TEST FOR BISMUTH

Test	Observation	Result
H ₂ S gas added in the	Dark brown	Absence of
sample solution	precipitation absent	bismuth
NH ₄ OH added in the	No white	Absence of
sample solution	precipitation	bismuth

TABLE 13: TEST FOR LEAD

Test	Observation	Result
Dil. HCl added in the	No white	Absence of
sample solution	precipitation	lead
KI is added in the	No Yellow	Absence of
sample solution	precipitation	lead

DISCUSSION: Ayurvedic medicine Mehari Choorna has been standardized by the intervention of scientific quality Control measures in the traditional preparation describe in established texts. All the parameters revealed their significance where total ash value is indicative of the total amount of inorganic material after complete incineration & acid insoluble ash is indicative of silicate impurities which may be the result of improper washing of raw material. The loss on drying value obtained indicates the amount of moisture content in the drug may lead to enzymatic action which deteriorates the final product. The extractive value indicates the amount of drug soluble in a particular solvent. Purity and potency of the material and formulations following the procedure given could be performed in quality control or quality assurance laboratory of the pharmaceutical house.

CONCLUSION: Present study revealed various standardization parameters such as physic-chemical standards like total ash, insoluble acid ash, water, alcohol, qualitative chemical test, powder flow analysis were carried out. It can be concluded that it passes all the standardization parameters. The efficacy of the drug can be judged only by pharmacological activity. The study shows that contents of formulation present within the permissible limits as per WHO, all these investigations of Mehari Choorna are not specified in the standard literature like Pharmacopoeia which could be helpful in the authentication of the Mehari Choorna. The result of the present study will also serve as reference monograph in the preparation of drug formulations.

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