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**Phytochemical Analysis, Preformulation Studies and
Development of Quality Control Standards of the Polyherbal
Capsule**

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Abstract

The study emphasizes on polyherbal antidiabetic formulations of different plants used in the treatment of diabetes mixed in different concentrations. In the current study four medicinal plants with proven antidiabetic were selected for the preparation of formulation. The polyherbal formulation was formulated using the ethanol extracts of leaves of *Gymnema sylvestre* bark of *Pterocarpus marsupium*, stem of *Tinospora cordifolia* and seeds of *Trigonella foenum-garacum* the ratio of 3:3:2:2. In the present study Phytochemical Analysis, Preformulation and Development of Quality Control Standards of the Polyherbal Capsule was studied.

Key words: Polyherbal, Quality Control

Introduction

Diabetes is a complex disorder characterized by hyperglycemia resulting from defective insulin secretion, resistance to insulin action or both (Gavin JR 1997). Management of diabetes without any side effects is still a challenge in the medical field, as presently available drugs for diabetes have one or more adverse effects (Bohannon, 2002). A number of medicinal plants, traditionally used for over 1000 years named rasayana are present in herbal preparations of Indian traditional health care systems (Scartezzini and Sproni, 2000). Herbal drugs are prescribed widely because of their effectiveness, less side effects and relatively low cost (Venkatesh et al., 2003; Devaki et al., 2011). *Gymnema Sylvestre*, *Pterocarpus marsupium*, *Tinospora cordifolia* and *Trigonella foenum-garacum* are the plants profusely used in Ayurveda and supplementary traditional system of medicines to cure both infectious and degenerative diseases. A new polyherbal formulation of antidiabetic activities offered sufficient scope to undertake this research work. Selection of this polyherbal formulation which shows antidiabetic activities is of commercial importance of health benefits.

Material and Methods

Preparation of ethanolic extracts

The shadow-air-dried identified leaves of *Gymnema sylvestre*, bark of *Pterocarpus marsupium*, stem of *Tinospora cordifolia* and seeds of *Trigonella foenum-garacum* was powdered and extracted with 80% absolute ethanol using Soxhlet apparatus for 16 h. The extracts were evaporated to dryness (resinous material) under reduced pressure at 60°C and stored at 4°C until use.

Phytochemical analysis

One gram of each of the ethanolic extracts of *Gymnema sylvestre*, *Pterocarpus marsupium*, *Tinospora cordifolia* and *Trigonella foenum-garacum* were dissolved in 100 ml of its own mother solvent to obtain a stock of concentration 1% w/v and tested for the presence of carbohydrates, proteins, sterols, alkaloids, tannins, glycosides, flavonoids and saponins (Petchi, et al. 2013).

Preparation of polyherbal formulation

The polyherbal formulation (capsules) contained the ethanolic extracts of *Gymnema sylvestre*, *Pterocarpus marsupium*, *Tinospora cordifolia* and *Trigonella foenum-garacum* in the ratio of 3:3:2:2. The quality of the polyherbal formulation was tested as per the WHO guidelines for the quality control of herbal materials. As per the guidelines, specific tests such as sampling, ash content, extractable matter, foaming index, loss on drying, tannin content, and specific powder

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characteristic tests such as angle of repose and bulk density were undertaken.

Table 1: Ingredients for each 500 mg polyherbal capsule formulation

Ingredient	Each 500 mg of herbal capsule contained the extracts
<i>Gymnema sylvestre</i>	90 mg
<i>Pterocarpus marsupium</i>	90 mg
<i>Tinospora cordifolia</i>	60 mg
<i>Trigonella foenum-garecum</i>	60 mg
Excipients	qs

Standardization of formulation

Physicochemical parameters of raw materials were determined as per the guidelines of the WHO, which includes moisture content, total ash value, water-

soluble ash, acid-insoluble ash, heavy metals, water-soluble extractive, alcohol-soluble extractive, and acidity (pH) (Kumar, 2013, Lohar, et al. 2008).

Development of quality control standards for the polyherbal capsule

The physicochemical (moisture content, limit test for heavy metals, monographic analysis of plant material, pH, and disintegration time) and microbial load analyses were performed for the herbal capsules to ensure the content uniformity and quality (Lohar, et al. 2008).

Results and Discussion

The yield of ethanolic extracts of *Gymnema sylvestre*, *Pterocarpus marsupium*, *Tinospora cordifolia* and *Trigonella foenum-garecum* was 6.15 %, 3.61%, 2.45% and 7.62% w/w (moisture free basis), respectively.

Table 1: Results of phytochemical analyses of the selected medicinal plants

Variable	<i>G. sylvestre</i> (Leaves)	<i>P. marsupium</i> (Bark)	<i>T. cordifolia</i> (Stems)	<i>T. foenum-garecum</i> (Seeds)
Tannins	+	+	+	+
Terpenoids	-	+	+	+
Flavonoids	+	+	+	+
Saponins	+	+	-	+
Steroids	-	+	-	+
Carbohydrates	-	-	-	-
Glycosides	-	+	+	+
Alkaloids	+	+	-	-
Proteins	-	-	-	-

[(+) = Presence, (-) = Absence]

Preformulation parameters were obtained for the laboratory granules. The granules showed excellent flow property (Table 2).

Table 2: Preformulation studies and results of flow properties

Parameters	Results
Bulk density	0.718 g/ml
Tapped density	0.695 g/ml
Carr's index	3.98%
Hausner's ratio	1.12±0.05
Angle of repose	18.65°

Final batch samples of polyherbal capsules were analyzed for its organoleptic characters, physico chemical parameters, limits for heavy metals and microbial load [Table 3]. The study on capsules revealed that they were uniform in content and weight. Further, the moisture content, microbial load, limit test for heavy metals, monographic analysis of plant material, pH, and disintegration time were calculated and these values were found to be within normal limits.

Table 3: Standardization of polyherbal capsule

Name of the test	Observations
Organoleptic characters	
Description	Brown color powder filled in transparent cap and body, 0 size capsule
Color	Brown color powder
Ordor	Characteristic
Taste	Bitter
Physicochemical parameters	
pH	7.9
Moisture content	1.01%
Average weight	504 mg

Weight variation	490-520 mg
Disintegration time (Mean \pm SEM)	3 min 15 sec \pm 0.30
Loss on drying	2.52%
Total Ash	5.58%
Acid-insoluble ash	1.18%
Water-soluble ash	3.46%
Ethanol-soluble extractive value	13.39%
Water-soluble extractive value	15.28%
Limits for heavy metal	
Arsenic not more than 5ppm	Complied
Lead not more than 10 ppm	Complied
Microbial load analysis	
Total microbial count NMT 1000 cfu/g	130 cfu/g
Presence of E. Coli	Absent
Presence of Salmonella	Absent
Presence of Streptococcus	Absent
Presence of Pseudomonas	Absent

[NMT: Not More Than]

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