FORMULATION & EVALUATION OF MULTI-PURPOSE & ANTI-DIABETIC HERBAL CAPSULES

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ABSTRACT :

In current days most of people of world as well as india suffering with the problem of high blood glucose level. To control high blood sugar level many people are treating with synthetic anti diabetic drugs like metformin, sulfonyl ureas and other drugs. Those who are not resonsding to drugs are treated with insulin. These drugs has numorous side effects and also costly. Herbal anti diabetic drugs was found useful in controlling of blood glucose level without any dangerous adverse effect. Hence capsules containing powder of Costus igneus has significant blood sugar level decreasing activity.

In the current market there are many brands that have medicated products with traditional herbal drugs. In this research paper we will have to overview about formulation aspects and evaluation of medicated capsules having multiple purpose property. Capsules containing Liquorice, Ginger, Adulsa, Insulin Plant Powder have their particular pharmacological activity on the human body. Liquorice has antivirals, antibacterial, antidiabetic and anti-asthmatic action. Ginger has anti-emetics and antidiabetic activity. Adulsa is popular due to its multiple pharmacological actions. Capsules containing multiple herbal medications can be proven a good therapeutic dosage form especially in diabetic population. In this research article we will study about formulations of multi-purpose anti diabetic herbal capsule and their evaluations.

KEYWORDS: Capsule, Anti-diabetic, Multipurpose, Costus igneus.

PHYTOCHEMICAL SCREENING OF HERBS:

For determination and confirmation of different phytoconstituents present in herbal phytochemical screening was performed. Chemical reactions of phytoconstituents with different chemical reagents gives presence or absence of chemical compound present in herbal extract. Each compound has their characteristic pharmacological action.

Extracts	Alkaloid	Flavonoid	Phenols	Tannin	Saponin	Anthraquinone	Steroid	Ascorbic Acid	Glycoside	Reducing Sugar
Liquiorice	-	+	-	-	+	-	-	-	-	+
Ginger	+	-	-	-	+	-	-	+	+	+
Adulsa	+	-	+	-	-	+	-	+	-	-
Insulin	+	-	+	-	+	-	+	-	-	+

Table 1: Phytochemical Screening of Herbs [10][11][12][13]

MATERIALS AND METHODS:

Powdered crude drug of liquiorice, ginger, Adulsa and Insulin was purchased from commercial sources. All other excipients and chemicals was obtained from college laboratory.

PREFORMULATION STUDY OF HERBAL POWDERS:

Physical Property Analysis

1) Bulk Density (ρb):
It is determined by measuring the volume of a known mass of powder sample that has been passed through graduated cylinder or through a volume measuring apparatus into a cup.
It is expressed in g/ml and is given by

$\rho b = M/Vo$

Where M is the mass of powder and Vo is the bulk volume of the powder.

2) Tapped Density (ρt):
The tapped density was measured by tapping the powder to constant volume. It is expressed in g/ml and is given by
$\rho t = M/Vt$
Where M is the mass of powder and Vt is the tapped volume of the powder**.**

3) Compressibility index:
The compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content and cohesiveness of materials. All these are closely related to predicting the powder flow characteristics. The compressibility index is determined by measuring both bulk volume and the tapped volume of the powder.
Compressibility index = 100 x (Vo-Vt) / Vo.

4) Angle of repose:
For determination of angle of repose (θ), the blends were poured through the walls of a funnel, which was fixed at aposition such that its lower tip was at a height of exactly 2cm above a hard surface. The drug or the blends were poured till the time when upper tip of the pile surface touched the lower tip of the funnel. Angle of repose was calculated using following equation. The angle of repose θ, was calculated by the formula,
$\tan\theta = h/r$
$\theta = \tan^{-1}(h/r)$
Where θ is the angle of repose, h is the height in cm and r is the radius in cm.

FORMULATION OF CAPSULES:

Poly herbal formulation is done by adding specified quantity of powder of Liquiorice, Ginger, Adulsa and Insulin. The above ingredients mixed together and pass the poly herbal mixer through sieve number 44# to prepare homogenous blend and filled in the empty gelatine capsule.

Ingredients	Quantity		
	F1	F2	F3
Liquiorice	50 mg	50 mg	250 mg
Ginger	100 mg	50 mg	300 mg
Adulsa	50 mg	100 mg	100 mg
Insulin Powder	100 mg	100 mg	300 mg

Table 2: Composition of Herbal Capsules

PREFORMULATION STUDY RESULT:

Run Number	Height of Conical Powder	Radius of Petri dish (cm)	Angle of Repose θ = tan 2h/D
1	1	3.5	16.35

Table 3: Measurement of angle of repose of powder

S. No.	Bulk volume of powder (Vb ml)	Volume occupied by Powder after 100 tapping (Vp ml)	ε = Vb – Vp / Vb	Compressibility index	Hausner ratio Vb - Vp
1	20	17	0.15	15	1.17

Table 4: Measurement of porosity, compressibility index and Hausner's ratio of Powder.

EVALUATION OF CAPSULES:

1) Organoleptic Observations:

The prepared capsules were observed organoleptically for color, taste, shape, texture, and clarity. The texture observation was conducted by mildly rubbing the surface and rubbing the tablets between two fingers.

Parameters	Result		
	F1	F2	F3
Color	Pale Yellow	Pale Yellow	Pale Yellow
Shape	Cylindrical		

Table 5: Organoleptic Evaluations of Capsules

2) Diameter and Thickness:

The diameter and thickness were measured by using Vernier caliper. The three Capsules were selected randomly from the formulation, and then thickness and diameter were measured.

Evaluation Parameter	Result (n=10)		
	F1	F2	F3
Diameter/Length	9 mm	9 mm	9 mm
Thickness	3 mm	3 mm	3 mm

Table 6: Evaluation of Capsules For Diameter And Thickness

3) Weight Variation Test:

Ten capsule from the formulation were randomly selected and weighed together the tablets were then weighed individually. The batch passes the test for weight variation test if not more than two of the individual

capsule weight deviates from the average weight by more than the percentage according to IP limits shown in table.

Table 7: Weight Variation Limit According To IP

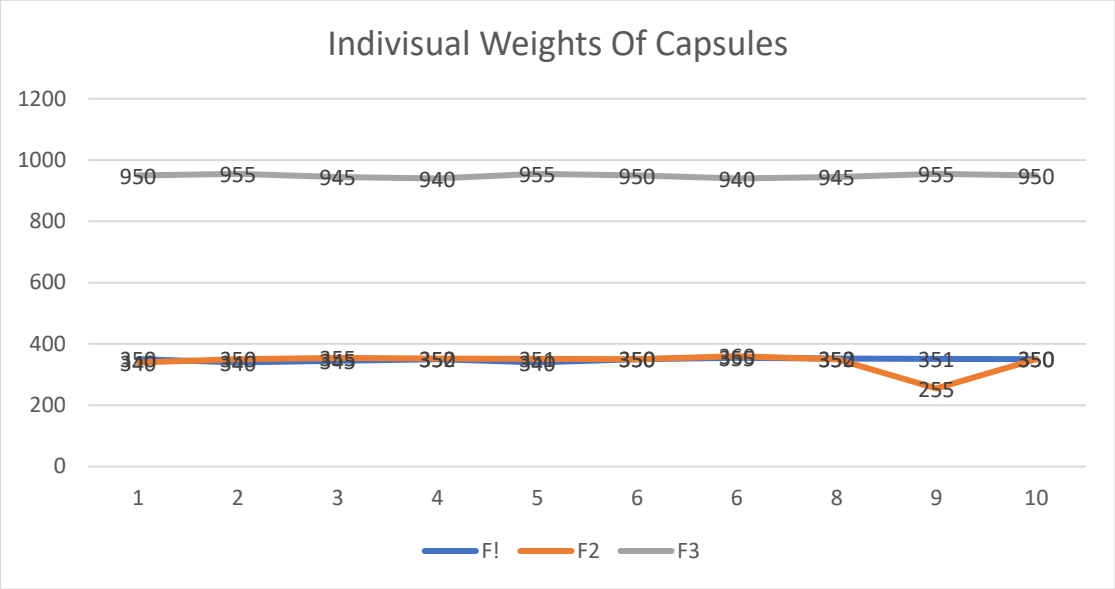

Chart 8: Indivisual Weight of Capsules

4) **Disintegration**

The efficacy of a drug can be dependent on the rate which the tablet or capsule disintegrates in the patient's gastrointestinal tract. The disintegration test is a measure of the time required under a given set of conditions for six randomly selected capsules to disintegrate into particles which will pass through a 10 mesh screen with in a disintegration assembly at maintained temperature 37º C±2 ºC (Varian Model VR100 35-1200). Generally, the test is useful as a quality assurance tool for conventional dosage forms.

Batch	Disintegration time
F1	12 min
F2	12 min
F3	12 min

Table 9: Disintegration Time Of Capsule

5) Stability

Pharmaceutical products are generally studied for stability profile at accelerated temperature, humidity and also at different intensities of light. The studies were performed to determine the physical, chemical, and therapeutic changes occurring in the monoherbal capsule by extrinsic factors.

(a) Light

Sample was stored in different intensities of light i.e. sunrays, fluorescent (tube) light, UV and infrared light for detection of degradation of powder material, then the fruits powder was subjected to TLC chromatography on silica gel fluorescence (254 nm) plate in a suitable solvent system EtOAC: MeOH: H2O (7 ml: 10 ml: 0.1 ml) to monitor the stability of monoherbal capsule.

(b) Temperature

The effect of temperature on the stability of monoherbal capsule was checked by keeping all the capsule at different temperatures i.e. ambient, 35 ºC, 50 ºC, 55 ºC, 65 ºC for 30 minutes, 1, 3, and 6 hours.

Storage condition	Testing condition	Time Duration (hours) ½	1	2	3	Result

Ambient	30	-	-	-	-	No change during 6 hours
Warm (30-40 °C)	35	-	-	-	-	No change during 6 hours
Accelerated	50	-	-	-	-	No change during 6 hours
Accelerated	55	-	-	-	+	Degradation start after 4 hours
Accelerated	60	-	-	+	+	Degradation start after 4 hours

Table 10: Stability test of monoherbal Capsule (250mg) at different Temperature.

(c) Humidity

The effect of humidity on the stability of capsule was checked by keeping the entire capsule at four different humidity percentage i.e.
30%, 50%, 70% and 90%.

Temperature	30% Humidity	50% Humidity	70% Humidity	90% Humidity
30 %	-	-	-	-
35 %	-	-	-	-
55 %	-	-	-	-
65 %	-	-	-	-

Table 11: Stability of monoherbal Capsule (250 mg) at different Humidity with respect to different Temperature

RESULT & DISCUSSION:

In the present research work Liquiorice, Ginger, Adulsa and Insulin powder were used for the oral monoherbal 1000 mg capsule. First it was formulated and then evaluated for quality herbal product which is very important irrespective of their medicinal content and therapeutic states therefore the pre-formulation and formulation studies of the formulated monoherbal capsule were evaluated. The organoleptic evaluation of fruits gives the authentication to the drug which is being utilized for the formulation. Preformulation parameters including angle of repose (a traditional characterization method for pharmaceutical powder flow), porosity (packing geometry), Carr's index and Hausner's ratio (a measure of the interparticulate friction) are useful tools in the development of new formulation. A value of <30° indicates 'excellent' flow whereas >56° indicates 'very poor' flow. Based on this, the flow was rated as 'excellent'. The CI and HR were found to be
15 and 1.17 Lower CI or lower Hausner ratios of a material indicates better flow properties than higher ones. A Carr's CI of <10 or HR of <1.11 is considered 'excellent' flow whereas CI>38 or HR>1.60 is considered 'very very poor' flow. Based on the results obtained flow of powder was rated as 'good'. Good flow of powder help to avoid the extensive costs and time involved in unloading powders that will not flow out of storage containers. As well as help to achieve the best formulation and improve the quality and consistency of the product.

Polyherbal powder was approved as quality drug when undergone by phytopharmaceutical evaluation according to the pharmacopoeial standards. 1000 mg monoherbal capsules disintegrated in meantime 12 minutes and in vitro condition and we determined the release of a drug from solid dosage format which the substance dissolved in the fluid of gastrointestinal tract. Stability testing provides evidence that the quality of drug substance or drug product changes with time under the influence of various environmental conditions such as light, temperature, and relative humidity etc. which are required to demonstrate that a pharmaceutical product meets its acceptance criteria throughout its shelf life and to gain regulatory approval for commercialization.

Effect of temperature was observed and found remain unchanged at ambient temperature to
50 °C up to 6 hours, but only at accelerated temperature after 4 hours slight changing in powder color was observed. In humidity studies of powdered sample of Vitex negundo Linn. at 30%, 70% and 90% sample powdered was found unchanged while slight gradual degradation was seen at 70% and 90% humidity.

CONCLUSION:

Above study indicated that the single unit oral dosage form of polyherbal powder formulated in a capsule 1000 mg. The phytopharmaceutical evaluation showed that the pre formulation
and formulation studies of fruits was stable under required conditions like temperature, light and humidity. However real time revisions on stability are ongoing to confirm these findings.

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