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DEVELOPMENT AND STANDARDIZATION OF HERBAL ANTIDIABETIC CAPSULE

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ABSTRACT

According to WHO, Diabetes Mellitus is defined as heterogeneous metabolic disorder characterized by common feature of chronic hyperglycemia with disturbance of carbohydrate, protein and fat metabolism. The recent global resurgence of interest in herbal medicine has lead to increase in demand for herbal drugs and consequently a declined in their quality, particularly due to lack of adequate evidence proof data for assessing the quality of drug. The dried seeds of *Withania Coagulans* of *Solanaceae* family play an important role in indigenous system of medicine for treatment of diabetes mellitus, ulcer, etc. Organoleptic parameters are not much reliable in establishing the standards of herb drugs for which an attempt was made through aqueous extract of *Withania Coagulans*. Other parameter studied such as, phytochemical study and Evaluation of capsule studied behavior to lay down the standard for genuine drug.

KEYWORDS: Diabetes Mellitus, Withania Coagulans, aqueous extract.

INTRODUCTION

Diabetes is a Chronic metabolic endocrine disorder which can be characterized by high blood sugar levels. Hyperglycemia is caused by insufficient amount of insulin secreted in our body either absolute or relative or cellular resistance to insulin. Diabetes is becoming more common all across the world increasing at an alarming rate. With the biggest number of diabetes subjects, India ranked #1. The most distressing illness trend is a shift in disease beginning age of ten years. Long-term uncontrolled hyperglycemia can increase the risk of diabetic problems later in life. There are a variety of current drugs available for glycemic management, but the main disadvantage is the long-term adverse effects. In both developed and developing countries, herbal medications are in high demand. According to a WHO, 85%

of the people still rely on herbal products for their primary treatment. Potent herbal formulations have re-emerged as a safer medicine for numerous health concerns, including many chronic disorders. In this work, we make an herbal solid form of the above-mentioned extract, i.e. capsules.

Herbal drug technology is used for convert botanical materials into medicines, where standardization and quality control with proper integration of modern scientific techniques and traditional knowledge is important. Seeds of Withania coagulans Dunal used in Unani System, known as Tukm-e-Hayath which is a small genus of shrubs, popularly known as Indian cheese maker.

Withania coagulans is commercially important for its ability to treat the Type 1 diabetes mellitus.

In this work we make Capsules from *Withania Coagulans* (seeds).

MATERIALS AND METHODS

Herbal antidiabetic formulation consists of two herbs viz., *Withania Coagulans (*Berries*), Azadirechta Indica* (leaves).

Collection of Herb

The raw material for extraction included plant *Withania Coagulans, Azadirachta Indica*. These plant material were collected from the local market.

Fig.1 *Withania Coagulans* Berries.

Fig.2 *Azadirechta Indica* Leaves

Processing of Raw Materials

The procured plant materials were cleaned thoroughly. They were dried for a week or so. Once they were completely dried, they were ground into coarse powder and stored in Desicator and preserved for the further processing.

Standardization of Raw Materials

Shade dried powdered plant materials of the plants, Withania *Coagulans* (Dried Fruits), *Azadirechta Indica* (Dried leaves) used for the standardization of raw materials.

Fig 3: Dried Powder of Neem.

Fig 4: Dried Powder of W. Coagulans Berries.

Organoleptic Evaluation

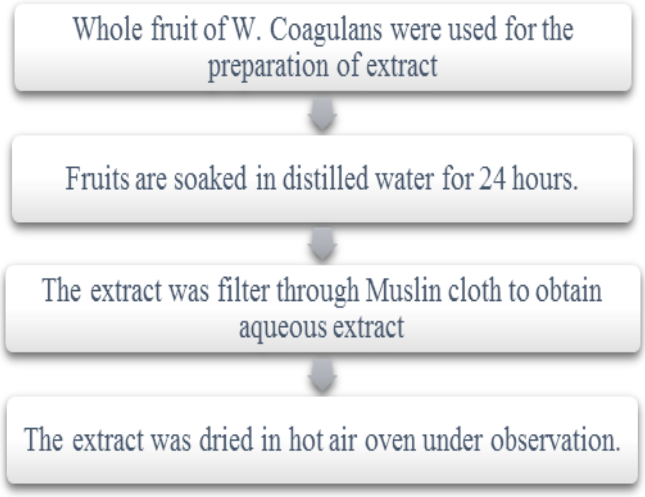
Table No. 1: Organoleptic Evaluation.

Sr.no.	Parameter	Observation
1.	Colour	Light brown granule
2.	Odour	Characteristics odour
3.	Taste	Bitter Taste

Preparation of Extract

Extraction is the primary step involved in the phytochemical studies. The method of extraction is Cold Maceration method.

Extraction of *W. Coagulans*



Extraction of Neem

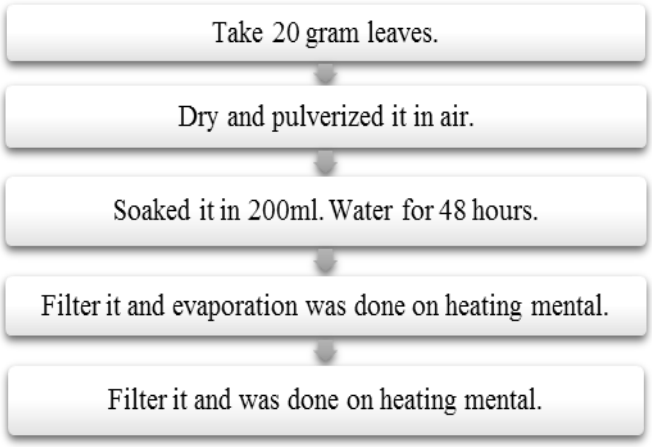


Fig.5 Heating Mantle.

Table no. 2 Formula for Capsule.

Sr. No.	Name of Material	Quantity	Use in Formulation
1	W. Coagulans	0.6 gm.	Antidiabetic
2	Neem	0.4 gm.	Antihyperlipidemic
3	Lactose	0.1 gm.	Binder
4	Talc	0.01 gm.	Glidant
5	Magnesium Stearate	0.01 gm.	Lubricant
6	Starch	0.5 gm.	Disintegrant
7	Acacia	0.3 gm.	Thickening Agent
8	Vanilla	0.4 gm.	Flavouring Agent
9	Methyl Paraben	0.001gm.	Preservative

Experimental Procedure for Capsule

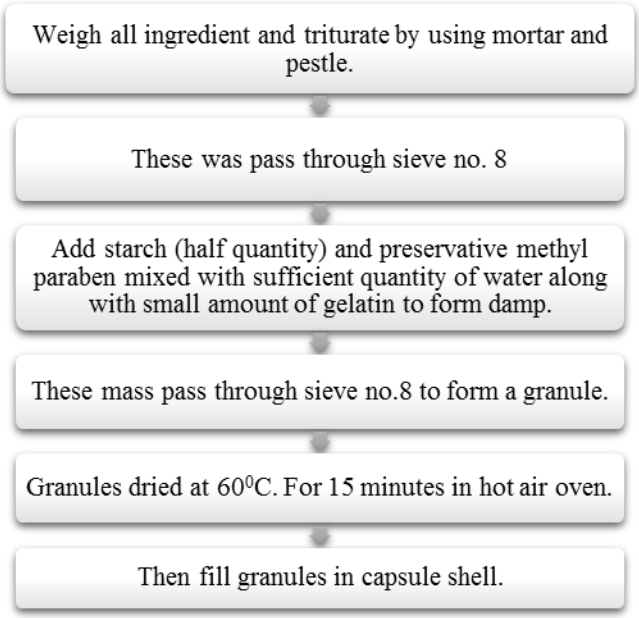


Fig.6 Formed Granules.

Phytochemical Studies

Herb contains chemical compounds such as carbohydrates, proteins and lipids that are utilized as food. It also contains secondary products like glycosides, alkaloids, flavonoids, tannins etc. The detection of these active principles in medicinal plants plays a important role in the phytochemical investigation of crude drugs and extracts and is very important in regard to their potential pharmacological effects.

1) Alkaloids

Dragondroff's reagent

To the powdered crude drug, few drops of potassium bismuth iodide solution was added, reddish brown color indicates the presence of alkaloids.

2) Carbohydrates

Molisch's test - In a test tube containing powdered drug, 2 ml of distilled water and 2 drops of freshly prepared 20% alcoholic solution of α- naphthol were added. Mixed well and added 2ml of concentrated sulphuric acid along the sides of the test tube. Formation of red violet ring, which disappears on addition of excess alkali solution, indicates the presence of carbohydrates.

3) Proteins (Biuret test)

To 1ml of alcoholic extract of the drug, 5 to eight drops of cupric sulfate (10%) was added. The violet color is fashioned that indicates the presence of proteins.

4) Saponin

To five ml of an extract of the drug, a drop of bicarbonate solution was added. Shake the mixture vigorously and left it for three minutes. Honey comb like froth developed indicates the presence of Saponin.

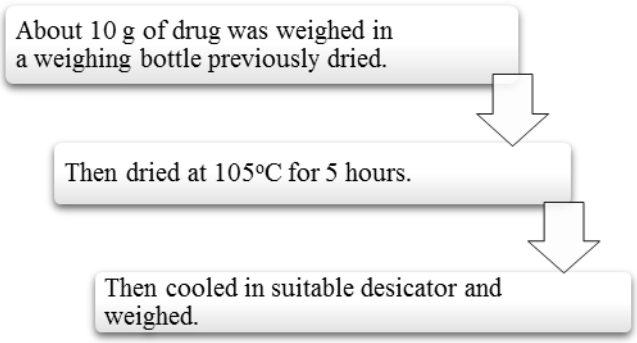
Physicochemical Evaluation

Physicochemical assessment is done for the assessment of crude drugs. The assessment of those parameters indicates the concept approximately the precise feature of crude drugs.

1) Loss on Drying

The LOD determines both water and volatile matter in the crude drug. If the herbal substance is hygroscopic then LOD is very important. If an excess of water is present in herbal materials it will be encourage microbial growth, presence of fungi, insects and deterioration. Loss on drying is the loss of mas expressed as % w/w.

Procedure



5) Determination of total Ash Value

Incinerated 2g of the powdered drug in a silica crucible at 450ºC in a muffle furnace until carbon completely ashes and ignited to constant weight, removed, cooled in a suitable dessicator for 30 minutes and weighed. Percentage of total ash content was calculated with reference to the air-dried drug.

6) Flow Property Measurement

- Bulk density
- Tapped density
- Compressibility index
- Hausner's ratio
- Angle of repose

i) Bulk density (ρb)

Bulk density is determined by measuring the volume of a known mass of powder sample that has been passed through a screen into a graduated cylinder. The unit of bulk density g/ml and is given by,

ρb = M/Vo

Where, M - mass of powder

Vo- bulk volume of the powder.

ii) Tapped density (ρt)

It is achieved by mechanically tapping a measuring cylinder containing a powder sample. After observing the initial volume, the cylinder is mechanically tapped and volume readings are taken until little further volume change is observed. It is expressed in g/ml and is given.

ρt = M/Vt

Where, M - Mass of powder and Vt- Tapped volume of the powder.

iii) Hausner's Ratio

It is measurement of frictional resistance of the granular material. The Ideal range should be 1.2 -1.5, it was determined by the ratio of tapped density and bulk density.

iv) Hausner's Ratio = Vi / Vo

Where,

Vo -Untapped density,

Vi -Tapped density

v) Angle of repose

The tangent of angle of repose is equal to the coefficient of friction between the particles. Hence the rougher and more irregular the surface of particles, the greater will be angle of repose

Tan θ **= h/r,** θ **= tan^{-1} (h/r)**

Where,

θ - angle of repose,

h- height in cm and

r- radius in cm.

Based on the Angle of repose, Compressibility index and Hausner's ratio, the flow property of the granules can be characterized.

Evaluation of Herbal Capsules

The developed herbal capsules were standardized for its Description, uniformity of weight, disintegration time, pH, physicochemical parameters, and phytochemical studies. Determination of uniformity of weight, disintegration time and moisture content of capsules were carried out as per Indian pharmacopoeial procedures.

1) PH

The pH value of a solution was determined potentiometrically by means of a digital pH meter. The pH meter was calibrated using buffers of 4, 9 and 7 pH. 1g of capsule content was taken and dissolved in 100ml demineralized water. The electrodes were immersed in the solution and the pH is measured.

2) Average Weight & Uniformity of Weight

6 individual units were selected at random and this content was weighed and their average weight was calculated. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the table and none deviates by more than twice that percentage.

3) Disintegration Time

This test is done to measure the time taken by the drug to disintegrate in the body. This is done to determine whether the capsule disintegrates within the prescribed time when placed

in a liquid medium under the prescribed experimental conditions. One each capsule was added to each of the six tubes of the basket and a was added to each of the tube. The tubes were dipped in 0.1N HCl solution maintained at 37°C.

RESULT AND CONCLUSION

Herbal medicines are the oldest form of health care known to mankind. Traditional herbal medicinal practices have been adopted for the diagnostic, prevention and treatment of different diseases.

1. Phytochemical analysis

The chemical tests for various Phytoconstituents in the raw materials were carried out and the results were recorded and detailed in table.

Table no. 3: Phytochemical test.

Sr.No.	Test	Observation
1	Alkaloids	
	Dragondroff's Test	++
2	Carbohydrates	
	Molisch Test	++
3	Protein	
	Biuret Test	++
4	Saponin Test	
	Foam Test	++

2. Evaluation of Capsules

Table no. 4 Organoleptic Characters.

Sr.No	Parameter	Observation
1.	Description	Light brown granule in blue cap and body "0" size capsule
2.	Colour	Light brown granule
3.	Odour	Characteristic odour
4.	Taste	Bitter taste

3. Physical parameters.

Table no. 5 Physical Parameters.

Sr.No	Parameter	Observation
1.	pH (1% aqueous solution)	7.33 ± 0.21
2.	Moisture content	3.98 ± 0.5%w/w
3.	Uniformity of weight	519.3 ±3.4mg
4.	Disintegration time	2' 32secs ± 0.34

Results are reported as Mean ± Standard deviation

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CONFLICT OF INTEREST

The author declared no conflict of interest.

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