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## Formulation and Evaluation of Polyherbal Capsules Containing *Nigella sativa* Seeds, *Pyllanthus emblica* Fruits, *Zingiber officinale* Rhizomes for Diabetes Management



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**Nivetha S\*, Arulkumaran G, Gopalsatheeskumar K,  
Suresh Kumar S, Reshma VB, Manimekalai M**

*Department of Pharmaceutics, KMCH College of  
Pharmacy, Kovai Estate, Kalapatti Road, Coimbatore-  
641048, Tamil Nadu, India (Affiliated to The Tamil  
Nadu Dr. M.G.R. Medical University).*

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### ABSTRACT

Diabetes is the one of the most common disorder is universe. So treating the diabetes is a global problem. Many of the drugs commercially available in market to treat diabetes, however these are the drugs has associated with side effects and toxicity. So that using of herbal therapy as an alternative to treating of diabetes with less side effects and diabetes. The literature says that *Nigella sativa* seeds, *Pyllanthus emblica* fruits and *Zingiber officinale* rhizomes have the potent antidiabetic effect with protective effect. But still there is no reports on solid dosage form in this combination (*Nigella sativa* seeds, *Pyllanthus emblica* fruits, *Zingiber officinale* rhizomes) of herbals. And solid dosage form (Capsule) is one of the conventional and simplest methods for formulation development. So that current study is aimed to formulation and evaluation of solid dosage of above herbal materials for the management of diabetes.



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## INTRODUCTION

Diabetes mellitus is a group of metabolic syndrome characterized by fasting hyperglycemia, postprandial hyperglycemia and hyperlipidemia, resulting from defects in carbohydrate, fat and protein metabolism. It is recognized as the wide-reaching chronic disorder affecting almost people of all age groups [1,2]. India (31.7 million) has topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) and United States (17.7 million) in second and third place respectively. According to a report of IDF 2017, there are 422 million people experiencing diabetes in the world and this figure is expected to rise 629 million in 2045 [3]. Therefore, the management of diabetes mellitus is considered as a global problem and successful treatment is yet to be discovered. Nowadays, several synthetic drugs with anti-diabetic effects including oral synthetic hypoglycemic agents like sulfonylureas, insulin treatment and specific enzyme inhibitors are used for patients [4]. However, these drugs are expensive and commonly associated with side-effects and drawbacks like insulin resistance, anorexia nervosa, brain atrophy, hepatotoxicity, abdominal pain, and flatulence, which limit their applications. Besides these treatments, a couple of scientific data have indicated that medicinal plant and their products possess antidiabetic properties with less toxicity and side-effects [5,6]. Capsules are the conventional dosage form and it is very easy to formulation. Literature says that, the seeds of Black Cumin (*Nigella sativa*), fruits of Amla (*Pyllanthus emblica*) and Rhizomes of Ginger (*Zingiber officinale*) are having the potent antidiabetic activity. So that current research is focused on development of polyherbal dosage form of the above herbals.

## MATERIALS AND METHODS

### Plant material

The seeds of Black Cumin (*Nigella sativa*), fruits of Amla (*Pyllanthus emblica*) and Rhizomes of Ginger (*Zingiber officinale*) were collected from local market of Coimbatore, Tamil Nadu, India month of April 2019 and authenticated by Botanical survey of India (BSI) southern circle, Coimbatore, Tamil Nadu. The authentication certificate numbers are No.BSI/SRC/5/23/2017/Tech/1777. The plant was dried under shade to a constant weight and coarsely powdered in a electronic mixer, sieved through mesh no. 40 and stored in air tight, well closed container till further use [7,8].

## Preformulation parameters

### Bulk density and tap density and Carr's index

A weighed quantity (15 g) of powdered material was taken in a 50 ml measuring cylinder. And recorded the initial volume ( $v_0$ ). Tapped the contents and recorded the powdered volumes after 50 taps ( $v_{50}$ ).

$$\text{Fluff density} = w/v_0 \text{ g/cc}$$

$$\text{Tapped density} = w/v_{50} \text{ g/cc}$$

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Fluff density}}{\text{Tapped density}} \times 100$$

Value for Carr's index below 15 indicate excellent flowing material and value over 20-30 suggested poor flowing material [9].

### Angle of repose

A funnel was fixed at a particular height (1.5, 2.5, 3.5 cm) on a burette stand. A white paper was placed below the funnel on the table. The powdered drug passed slowly through the funnel until it forms a pile. The radius of the pile was noted down.

Angle of repose of the powder material was calculated by using the formula:

$$\tan \theta = h/r$$

$$\theta = \tan^{-1}(h/r)$$

where, h = height of the pile, r = radius.

Values for angle of repose  $30^\circ$  usually indicate a free flowing material and angle  $40^\circ$  suggest a poor flowing material.

### Hausner's ratio

The basic procedure is to measure the unsettled apparent volume,  $V_0$  and the final tap volume,  $V_f$ , of the powder tapping the material until no further volume changes occur. The Hausner's ratio was calculated as follows:

$$\text{Hausner's ratio} = V_0 / V_f$$

Hausner's ratio between 1.00 to 1.11 shows excellent flow and value more than 1.60 shows very, very poor flow.

### **Composition of polyherbal capsule**

Each 500 mg capsule contains:

Black Cumin (*Nigella sativa*) 100 mg,

Amla (*Pyllanthus emblica*) 100mg,

Ginger (*Zingiber officinale*) 100 mg,

Excipients q.s.

### **Preparation of formulation by Wet granulation method**

Black Cumin (*Nigella sativa*), fruits of Amla (*Pyllanthus emblica*) and Rhizomes of Ginger (*Zingiber officinale*) were finely powdered (# 40), and taken for preparation of capsules by wet granulation technique using starch (20%) solution as binder. The wet mass was passed through # 30 to obtain granules. The granules were dried at 45°C in tray dryer. The granules were lubricated with 1% magnesium stearate. Diluents and preservatives were added and filled in capsules colored yellow – red size '00' in capsule filling machine. The capsules were evaluated for weight variation content uniformity, disintegration time and in vitro drug release.

### **Disintegration test**

Disintegration test was performed using the digital microprocessor based disintegration test apparatus. One capsule was introduced into each tube and added a disc to each tube. The assembly was suspended in the water in a 1000 ml beaker. The volume of water was such that the wire mesh at its highest point is at least 25 mm below the surface of the water, and at its lower point was at least 25 mm above the bottom of the beaker. The apparatus was operated and maintained the temperature at 37±2°C.

### Preparation of Calibration Curve

For the preparation of standard curve, stock solution of 100 µg/mL concentration was prepared and it was then serially diluted with water to get 1, 2, 3, 4 up to 5 µg/mL. The absorbances of the solutions were measured against distilled water as blank at 260 nm using UV spectrophotometer. The absorbance values were plotted against concentration (µg/mL) to obtain the standard calibration curve [11].

### *In vitro* drug release

*In vitro* dissolution studies of the polyherbal capsules were performed using USP dissolution testing apparatus II (paddle method). Using 900ml of phosphate buffer pH 6.8 was taken as the dissolution medium at  $37 \pm 0.5^\circ\text{C}$  and 50 rpm. 5ml of the solution was withdrawn from the dissolution apparatus at regular 15 minutes intervals for 60 minutes. The samples were replaced with fresh dissolution medium of same quantity. Absorbance of these solutions was measured at 260nm using Shimadzu UV/Vis double beam spectrometer. The dissolution study was carried out for all the formulations [10].

## RESULTS AND DISCUSSION

The flow property (angle of repose) of the formulated granules was shown in Table 1. The results confirm that the granule has good flow property.

**Table No. 1: Measurement of angle of repose of Polyherbal solid dosage formulation**

Run number	Height of conical powder (cm)	Radius of the petridish (cm)	Angle of repose $\theta = \tan^{-1}(h/r)$
1	1.6	2.3	38.69
2	1.7	2.7	35.77
3	1.9	2.6	38.17
Mean	1.7	2.5	36.21

The various preformulation parameters of the granules were shown in table 2.

**Table No. 2: Measurement of Porosity, Compressibility index, Hausner’s ratio of polyherbal solid dosage formulation**

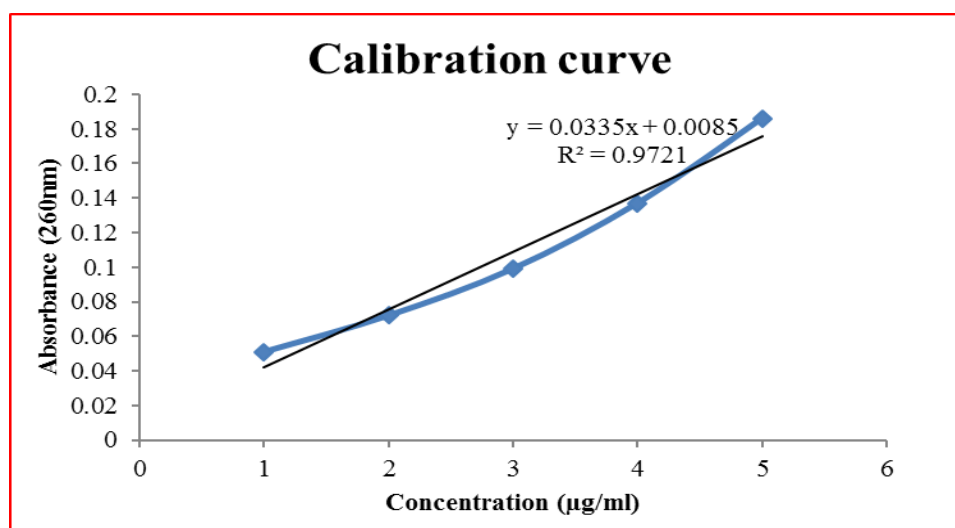
Sr. No.	Bulk volume of the powder (V <sub>b</sub> ml)	Volume occupied by powder after 100 tapping (V <sub>p</sub> ml)	$\frac{\varepsilon = V_b - V_p}{V_b}$	Compressibility index	Hausner ratio $V_b - V_p$
1	33.0	24.3	0.26	30	1.44
2	32.0	22.1	0.3	32	1.5
3	33.0	23.0	0.3	40	1.6
Mean	-----	-----	0.28	34	1.51

The Disintegration time of poly herbal capsules were shown in table 3. The disintegration study confirms the capsule has good disintegrating property thereby increases the dissolution.

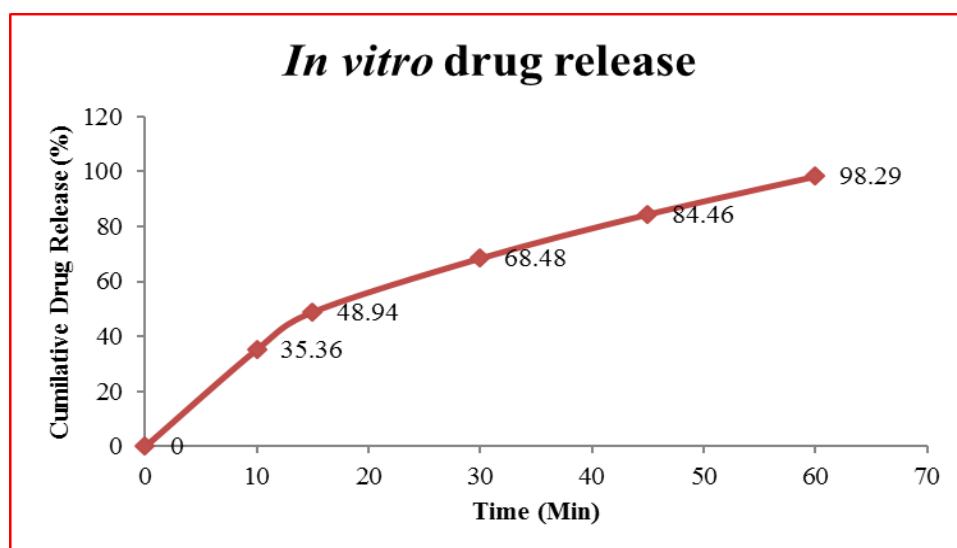
**Table No. 3: Disintegration time of poly herbal capsules (min)**

Capsule	1	2	3	Mean
Time (min)	2.15	2.30	2.39	2.35

The Standard calibration curve of polyherbal mixture was shown in figure 1. The standard calibration curve was plotted against concentration vs. absorbance at 260nm. The calibration curve obtained in various concentrations was linear with the R<sup>2</sup> value of 0.9721.



**Figure No. 1: Standard calibration curve of polyherbal**



**Figure No. 2:** *In vitro* drug release of polyherbal capsule.

The prepared capsules *in vitro* drug release was shown in figure 2. The maximum drug release is obtained at the 60 min of drug release. The prepared formulation has good releasing capacity thereby maintains the bioavailability of the phytoconstituents and controls the blood glucose level.

The seeds of the *Nigella sativa* contain the phytochemicals such as thymoquinone, dihydrothymoquinone, p-cymene, carvacrol,  $\alpha$ -thujene, thymol,  $\alpha$ -pinene,  $\beta$ -pinene and trans-anethole and these phytochemicals has potent antidiabetic and hepatoprotective activity. The fruits of the *Pyllanthus emblica* contain the phytochemicals such as Ascorbic acid (vitamin C), ellagitannins, such as emblicanin A (37%), emblicanin B (33%), punigluconin (12%), and pedunculagin (14%), and also contains punicafofin and phyllanemblinin A, phyllanemblinin other polyphenols such as flavonoids, kaempferol, ellagic acid, and gallic acid, those compounds are responsible for different pharmacological activities (Hypo-cholesterolemic, Hypo-lipidemic, Hepatoprotective, Immunomodulatory, Cardioprotective). The rhizomes of *Zingiber officinale* contain 6-gingerol, 6-shogaol, 6-paradol, Zingiberene, bisabolene, gingerols and shogaols which is having good antioxidant property. The combination of these three medicinal plants may be produced the synergistic action thereby control the blood glucose level with hepato, reno and cardio protection.

## CONCLUSION

The study concluded that, the polyherbal capsule can control the blood glucose level by synergistic phytochemical action. This formulation will be useful for the society to control the blood sugar level with low cost.

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