IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
April 2018 Vol.:12, Issue:1

Formulation and Evaluation of Herbal Capsules Containing Dried Ethanol Extract of *Gnetum gnemon* Fruits

IJPPR
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ISSN 2349-7203
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Anbu Jeba Sunilson John Samuel[1*], Roslizam Binti Said[2], K Anandarajagopal[2], Anita Gnana Kumari Anpumoni Vimala[2], Abdullah Khan[2], Mamudha Muthumani[1]

[1]Department of Siddha Medicine, Tamil University, Thanjavur 613010 Tamil Nadu, India

[2]School of Pharmacy, KPJ Healthcare University College, Kota Seriemas, Nilai 71800, Negeri Sembilan, Malaysia

Submission: 25 March 2018
Accepted: 02 April 2018
Published: 30 April 2018

Keywords: *Gnetum gnemon* fruits, Formulation, Herbal capsules, Evaluation

ABSTRACT

Medicinal plants are commonly known for their therapeutic value and free from side effects. Keeping this in view, the development of antidiabetic drug from the natural plants being a major thrust area has drawn the attention of the researchers in the field of natural product research because synthetic drugs may cause unwanted side effects. But the lack of complete evaluation for herbal formulations is the most important challenges faced. So, the quality control evaluation is necessary to ensure the quality of the herbal formulations. Hence the present study was aimed to formulate the herbal capsules using the dried ethanol extract of *Gnetum gnemon* fruits and evaluated the pharmaceutical quality of herbal capsules formulated. The evaluation parameters include weight variation, disintegration time and *in- vitro* dissolution tests. The herbal capsules formulated were achieved the criteria within permitted range for conventional dosage forms as per pharmacopoeial standards. The findings suggested that the formulated herbal capsules of dried ethanol extract of *G. gnemon* fruits have passed through all the evaluation parameters tested.

INTRODUCTION

The most important challenges faced by herbal formulations arise because of their lack of complete evaluation. So evaluation is necessary to ensure quality and purity of the herbal product. It is very important to establish a system of evaluation for every plant medicine in the market [1]. Herbal medicines are prepared from materials of plant origin which are prone to contamination, deterioration and variation in composition. Therefore, quality control of herbal medicines offers a host of problems. The acceptance or the popularity of herbal products is on the rise, one of the hindrance in its total acceptance is that somewhere the reproducible quality benchmark parameters are lacking, the reasons may be known or unknown, for example due to the highly complex nature and known nature of variation of the phytochemical of drugs of natural origin [2]. To solve this problem, first and foremost task is the selection of the right kind of plant material which is therapeutically efficacious [3]. Consequently, herbal drugs are formulated in various dosage forms such as tablets, capsules, syrups etc. for the ease and acceptability of patients to treat various ailments. The World Health Organization (WHO) has appreciated the importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation of its quality, safety and efficacy [4]. As the ethanol extract of *Gnetum gnemon* fruits was reported for its antidiabetic activity [5], the present study was aimed to continue this research by undertaken to formulate the herbal capsules using the dried ethanol extract of *Gnetum gnemon* fruits and evaluated the pharmaceutical quality of herbal capsules formulated.

MATERIALS AND METHODS

Materials

The collected *G. gnemon* fruits was washed thoroughly with distilled water and dried. The dried fruits were pulverized into coarse powder.

Preparation of extracts

The coarsely powdered *G. gnemon* fruits were successively extracted with organic solvents such as hexane, chloroform, ethanol and water by soxhlet extraction method. All the extracts were filtered separately and the excessive solvent was evaporated and concentrated using

rotary vacuum evaporator. The antidiabetic activity of all the extracts was assessed in diabetic rats. Diabetes was induced by single dose of streptozotocin followed by nicotinamide which was already reported [5]. The pharmacologically active ethanol extract was used to formulate the herbal capsules.

Formulation of Herbal Capsule contains dried ethanol extract of *G. gnemon* fruits:

Accurately weighed 40 g of dried ethanol extract was mixed with 10 g of adsorbent contained Magnesium oxide and Calcium carbonate (MgO & $CaCO_3$) in the ratio of 1:1 using trituration method. After trituration, blend was passed through sieve no- 26. The fine powder was collected and filled in capsule shell (#0) using hand operated capsule filling machine [6]. The composition of herbal capsules was recorded in Table 1.

Evaluation of Herbal Capsule of *G. gnemon* fruits

Weight Variation test for herbal capsules

The variability in the amount of powder contained in each herbal capsule was measured by the weight variation test. Twenty herbal capsules were randomly selected and weighed. Then the average weight was calculated and compared with individual herbal capsule weight. The percentage weight variation was calculated as per USP (2010) Specification. The herbal capsule shall not be less than 90% and not more than 110% of the theoretically calculated weight of each unit [7].

Disintegration test for herbal capsules

To assure the quality of conventional dosage forms, the disintegration test is very useful. The test is carried out using disintegration test apparatus. The efficacy of a drug or dosage form is exclusively dependent on the rate which formulation disintegrates in the patient's gastrointestinal tract. Six herbal capsules were randomly selected to perform the disintegration test. The temperature, 37ºC±2ºC was maintained for the disintegration apparatus during the experiment. The capsule was placed in each tube and then suspended in the beakers which contain simulated gastric fluid (SGF, pH 1.2) to move up and down for 30 minutes. The disintegration test is a measure of the time required under a given set of conditions in which selected capsules were disintegrated into particles which pass through a 10 mesh screen within a specified time [8]. The results were tabulated in Table 3.

In-vitro dissolution studies for herbal capsules

Preparation of Stock solution

100 mg of the ethanol extract *G. gnemon* fruits was dissolved in small amount of distilled water and made upto 100 mL using distilled water to get the Stock solution at the concentration of 1000 µg/mL.

Determination of Absorption maxima

The Absorption maxima was determined for the stock solution by running the sample from 200-400 nm using UV spectrophotometer.

Preparation of Calibration Curve

The stock solution was serially diluted with distilled water to get 50, 100, 200, 300, 400 up to 500 µg/mL. The absorbance was measured for all the concentrations against distilled water as blank at 304 nm using UV spectrophotometer (Table 2). The standard calibration curve was obtained by plotting the graph using the absorbance values against the concentration (µg/mL) [6].

In vitro dissolution test

Dissolution is considered as a tool for predicting rate of absorption and bioavailability of the drugs administered by orally. The Paddle type dissolution apparatus containing 900 ml of dissolution medium, simulated gastric fluid (SGF, pH 1.2) was taken into the jar and the temperature was maintained at 37ºC±2ºC. The paddle was allowed to rotate at 50 rpm for 30 minutes. 5 mL of the dissolution medium was withdrawn at predetermined intervals at 0, 5, 10, 15, 20, 25, 30, 35 and 40 and fresh dissolution medium was replaced. The samples withdrawn were analyzed by UV Spectrophotometer at 304 nm. The % Cumulative drug release (CDR) was calculated [9] and tabulated in Table 4.

RESULTS AND DISCUSSION

Formulation of Herbal capsule contains dried ethanol extract of *G. gnemon* fruits

The herbal capsule was formulated using the pharmacologically active dried ethanol extract of *G. gnemon* fruits and adsorbents such as Magnesium oxide and Calcium carbonate as

formulation excipients. Magnesium oxide provides stability to the dosage form and also prevents the effect of gastric acid and calcium carbonate aids in disintegration and enhanced dissolution rate. Table 1 depicted the composition of herbal capsules.

Table 1: Composition of herbal capsules

Ingredients	Amount (gm/capsule)	Amount (gm/100 capsules)
Extract	0.4	40
Magnesium oxide	0.05	5
Calcium carbonate	0.05	5

Preparation of Calibration Curve

The standard calibration curve was plotted using the absorbance values against the concentration (µg/mL). The R^2 value of 0.9121 indicated that the model very well fitted to the empirical data and considered as satisfactory and effectiveness as sufficient (Fig 1).

Table 2: Absorbance of various concentrations of dried ethanol extract of *G. gnemon* fruits

Concentration (µg/mL)	Absorbance
50	0.164
100	0.189
200	0.215
300	0.175
400	0.223
500	0.210

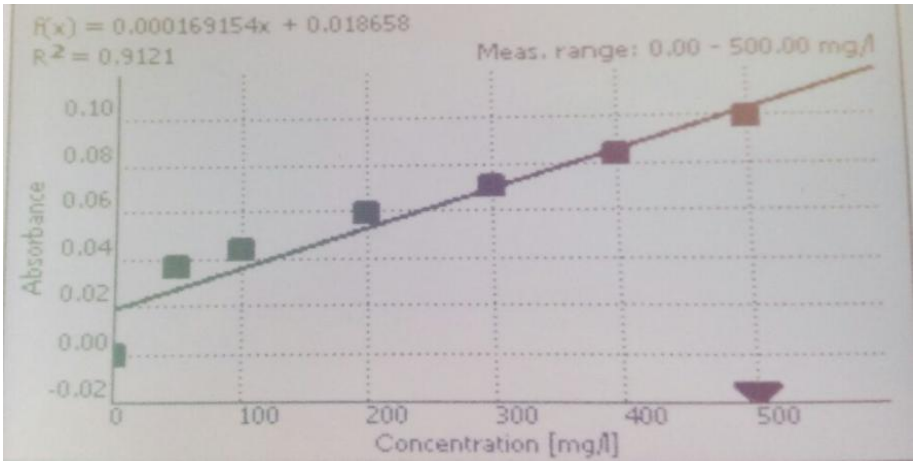

Fig 1: Calibration Curve for the ethanol extract of *G. gnemon* fruits

Evaluation of Herbal Capsule of *G. gnemon* fruits

The standardization is the most essential part for any formulation to ensure the quality, safety and reproducibility [10]. The prepared herbal capsules were evaluated for Quality control parameters such as weight variation, disintegration and *in-vitro* dissolution studies.

Weight Variation test

As per the USP Specification, the percentage deviation is 10% if the average weight of the capsule is less than 300 mg [11]. The percentage deviation for the formulated herbal capsules is not more than ± 2.68 %.

Disintegration Test

The herbal capsule passed the test as no residue of drug was remained. The capsule complies with the test according to USP, if all of the capsules have disintegrated completely [11]. The disintegration time was noted for the herbal capsules as 9.32 ± 0.31 minutes (Table 4).

Table 3: Disintegration test of the herbal capsules of *G. gnemon* fruits

Capsule	1	2	3	4	5	6	Mean ± SD
Time (min)	9.2	8.6	9.5	9.8	10	8.8	9.32±0.31

***In vitro* Dissolution Test**

93.17% of drug was released in 35 minutes indicating an acceptable time for conventional dosage forms (Table 4 and Fig 2).

Table 4: *In vitro* Dissolution study of the herbal capsules of *G. gnemon* fruits

Time (min)	CDR	% CDR
0	0	0
5	34.08	8.52
10	54.64	13.66
15	101.12	25.28
20	193.36	48.34
25	256.88	64.22
30	346.12	86.53
35	372.68	93.17
40	368.08	92.02

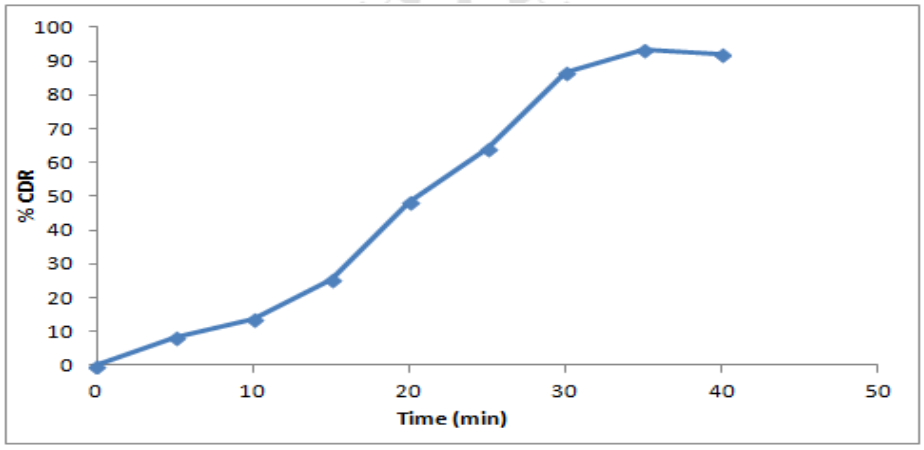

Fig 2: *In vitro* dissolution study of the herbal capsules of *G. gnemon* fruits

CONCLUSION

The formulated herbal capsules were found to possess characteristics within permitted range for conventional dosage forms as per pharmacopoeial standards. The findings suggested that the formulated herbal capsules of dried ethanol extract of *G. gnemon* fruits have passed through all the parameters tested. Future prospects include the animal studies, stability studies

and clinical trials of the finished product are necessary to explore the safety and efficacy of this formulated herbal capsules for the treatment of diabetes.

ACKNOWLEDGMENTS

The authors would like to thank the Management of KPJ Healthcare University College, Kota Seriemas, Nilai, Malaysia, for their continuous encouragement and support.

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