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Effect of Ethanolic extract of *Michelia champaka* Linn. on the Physical characteristic of pellet

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Abstract

Indian medicinal plants are used as ancient style of providing helps too many ailments. Presently, variant peoples are looking on healthful plants for his or her primary health care wishes. *Michelia champaca* L. belonging to family Magnoliaceae commonly known as Svarna champa, a tall handsome tree with yellow fragrant blossoms.It is commonly used by many traditional herbal preparations. Being it's a vital healthful plant in Indian medication this are supposed to vary medical specialty activities like antipyretic, antifertility, analgesic, anti-inflammatory, antihyperglycemic, antiulcer, antimicrobial, antioxidant and wound healing activities. The aim of this study is to formulate ethanolic extract of *Michelia champaka* L. into a solid dosage form. Pelletization was developed to formulate the extract. The formula was prepared using various ratios of extract with 30 % PVP as a binder and MCC as a filler.The influence of extract concentration was studied on the pellet characteristics. Pellet was prepared by extrusion-spheronization technique. In order to produce pellet with optimum diameter, the moisture of the extrudates and speed of spheronizer was mantained properly. In particular for flow property, all pellets containing more than 5% of *Michelia champaka* extract were found to be better than blank pellets. The study finally concluded that the presence of extract in the pellet formulas improved the physical characteristic of pellet. The self binding property of the extract is suggested as a key parameter for this improvement.

Key-Words: *Michelia champaka L.*, Pellet, 30% PVP, MCC, Extrusion-spheronization, Self binding property

Introduction

Michelia champaca Linn. known as *champaca* is belonging to the family of Magnoliaceae1. It consists of 12 genera and 220 species of evergreen trees and shrubs, native to tropical and subtropical South and Southeast Asia (Indomalaya), including southern China. It's commonly referred as yellow *champaca*. There are three species of *Michelia* available in Malaysia. They are *Michelia Alba* (white chempaka), *Michelia champaca* (orange chempaka) and *Michelia figo* (dwarf chempaka). They are also very fragrant and when a *Michelia* tree is in flower the fragrance produced is noticeable some distance from the tree. The flowers have 15 tepals that curve up towards the tips and many stamens (pollen producing structures).

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The fruit of *Michelia champaca* is made up of up to 3-20 brown follicles that are dry at maturity and split open at one side. Each follicle contains 2-6 reddish seeds. It is found throughout Indo-China, Malaysia, Sumatra, Java, and southwestern China. Outside of India the native range of this species is difficult to determine as it has been dispersed extensively by humans throughout Southeast Asia and Indonesia on account of the use of the trees. it is widely used in both Ayurveda and Siddha medicine. It is being used in fever, colic, leprosy, post-partum protection[1] and in eye disorders[2]. Juice of the leaves of *Michelia champaca* is given with honey in cases of colic. The flower oil is useful in cephalalgia, opthalmia and gout[3]. The bark is used as a stimulant, expectorant, astringent and febrifugal properties[4]. The dried root and roots bark, mixed with curdled milk, is useful as an application to absecesses, clearing away or maturing the inflammation. In the form of an infusion it is valuable

emmenagogue. It is also considered purgative. Root and bark are used as purgative and in the treatment of inflammation, constipation and dysmenorrhea. The flowers and fruits are considered stimulant, antispasmodic, tonic, stomachic, bitter and cool remedies and are used in dyspepsia, nausea and fever.

Pellet is a pharmaceutical dosage form spherical in shape normally the size ranged from 0.5- 1.5 µm. Pellet dosage form is a multiparticulate and flexible dosage form;it can be transformed into capsule, make into tablet, or packed into sachet. Pellets have numerous pharmacokinetic and biopharmaceutical advantages over tablets. Pellets provide an alternative for blending incompatible active ingredients, obtaining various release profiles, and developing multidrug controlled-release formulations (Sreekhar *et al.*, 2004). Pellets as drug delivery systems offer not only technological advantages, such as better flow properties, less friable dosage form, narrow particle size distribution, easy for coating process, and uniform packing, but also therapeutic advantages as compared to other solid dosage forms. Therapeutic advantages include less irritation of the gastrointestinal tract, a lowered risk of side effects associated with dose dumping, and a uniform distribution in the gastrointestinal tract resulting in a reduction of peak plasma fluctuations.

In addition, the optimum concentration of extract was studied to produce good physical characteristic of pellet. The active ingredient is ethanolic extract of *Michelia champaca* and the excipients are polivinylpyrrolidone (30% PVP) and MCC[5]. MCC is used as filler and helps to form a stable and firm pellet while PVP as the binder. Due to pellet has an elegant property as compared to other solid dosage forms, the development formulation of this extract was into pellet preparation. Various factors are suggested to influence the physical characteristic of pellet as well as the release of drug from pellet. To confirm this, we studied two main factors in the pellet formulation: composition and process. Parameter determining the proper optimization is including particle size and shape, surface morphology,distribution, moisture content, friability, flowability and macroscopic properties. In addition, chemical evaluation of compounds in the extract by thin layer chromatography (TLC) analysis was also performed to check whether degradation of active compound occurred after pelletization process[6].

Material and Methods

Collection of plant material

The *Michelia champaca* leaves were procured from the local areas of Pune. The collected plant material was botanically identified and confirmed by Dr.P.G.Diwakar, The Director, Botanical Survey of India, Maharashtra, India. The herbarium specimens were preserved and submitted to Department of Pharmacognosy, JSPMs Charak College of Pharmacy and Research,Wagholi,Pune-412 207 for further reference (Voucher no. MCPS-01).

Preparation of the extract

The leaves were broken down into small pieces thenafter they were shade-dried and coarsely powdered by using a pulverizor. The coarse powders were then subjected to continuous successive extraction with ethanol by Soxhlet method[7].

Preliminary Phytochemical Screening

Phytochemical screening of ethanolic extract of *Michelia champaca* leaves was carried out using standard qualitative methods[8,9].

Chemicals and reagents:

Ethanolic extract of *Michalia champaka L.* leaves, MCC, polyvinylpyrrolidone i.e. PVP K-30 and ethanol.

Method

There are three steps involved in pellet formation which helps in the whole procedure which are as follows;

- Optimization of granulating solvent shown in table 1.
- Optimization of amount of MCC and PVP shown in table 2.
- Optimization of amount of extract of *Michalia champaka* leaves shown in table 2.

The characterization of these pellets including size analysis using mesh analyzer, friability test, moisture content, flow ability, chemical stability of active compound in the extract by thin layer chromatography, organoleptic and morphology of the pellet using scanning electron microscope.

Optimization of solvent

Selection of the concentration cum amount was done by optimising the solvents with different ratios. The ratio of ethanol and water which is also called as aquadest was manipulated until the good pellet is produced. The ratios used for the study were a) ethanol: water (1:1) and b) ethanol: water (1:2).

Optimization of PVP and MCC

The optimization of granulating fluid and the binder was done. The amount of MCC and PVP were manipulated until good pellet is formed. To choose the selected concentration of PVP and MCC, observation and evaluation of the resulting pellet were made including pellet size analysis, and the organoleptic of the pellets.

Pellet preparation

Blank pellet

It is a pellet obtained without extract. First optimization (Table 1) was done to see the influence of ratio of

ethanol: water as granulating fluid and the amount of PVP on physical characteristics of pellet without extract.

Table 1: The formula optimization of Blank pellet

Formula	PVP K-30 taken in %	Ratio of ethanol: water	MCC taken in %
F1	5	1:1	95
F2	5	1:2	95
F3	3	1:1	97
F4	3	1:2	97

Blank Pellets were prepared with extrusion-spheronization technique and evaluated carefully to observe the most suitable formula for next step *i.e* pellet preparation containing extract.

Pellet containing extract

Table 2 shows the formulas of pellet containing EEMC. The pellets were prepared using different amount of extract. Other components *i.e* ratio of granulating fluid, MCC and PVP K-30 were constant referring to previous optimization.

Table 2: Formula optimization of pellet containing extract

Formula	PVP K-30 taken in %	MCC taken in %	Ethanolic extract taken in %
F5	3	92	5
F6	3	87	10
F7	3	82	15
F8	3	77	20

Pelletization process by extrusion-spheronization method

Extract was powdered using grinder and then mixed with MCC and PVP in tubular mixer for 15 minutes. Further, ethanol was added until a mass of granule with proper consistency for extrusion is formed. Then, extrusion method was performed to the wet granule mass until it formed rod-like-extrudate. The next step was spheronizing the extrudate in spheronizer. Finally, the pellets were dried in the oven at 60°C. After obtaining the dry pellets, evaluation procedures were performed[10].

Evaluation and Characterization of Pellets

The consistency of particle size distribution, porosity, density, surface area, hardness and friability of pellets as well as morphologic properties were evaluated.

Results and Discussion

Ethanolic extract of *Michalia champaka* Linn. Leaves were formulated into pellet due to high dose for therapy in common. There are two important parameters explored in this study: composition of formulation and the pelletization process. Factors influencing the formulation were including ratio of granulating solvent, amount of extract, concentration of binder and filler. While, in the pelletization process, variation in spheronization speeds, extrusion speed and the length of extrudate were observed on the pellet properties. In the extrusion step, optimizing granulating solvent is important as influencing degree of wetting. The solvents used were ethanol and water. Ethanol was chosen because it can easily evaporate, subsequently easy and faster to dry the pellets. However, using ethanol alone, the extrudates might be very fragile and will not form into spherical shape perfectly. Water, therefore, was also used in combination with ethanol, making the extrudate were not dried up very fast during the process. The extrudate formed better when using combination granulating solvent ethanol: water 1:1. High degree of wetting of the mass will result in sticky extrudates, further resulting in big size of pellets during spheronization step. Too dry granule however, lead fragile extrudates which eventually do not form spherical pellets. For good pellet, the granules must have strong mechanical strength to produce good extrudates during extrusion and the extrudates must easy to be cut and spheronized into pellet with good distribution size. Extrusion step is one of the critical point in pelletization process. The extrudates must be in almost the same length so that the pellet produced will be almost the same size. For this study, extrudates must be in very short rods in order to produce pellet with size ranging 500-900 µm. The appropriate formulas resulting good physical characteristic of pellet are presented in Table 3.

Table 3: Organoleptic properties of the pellet

Parameter	F5	F6	F7	F8
Colour	Light Brown	Light brown	Brown	Redish Brown
Odor	No odour	No odour	No odour	No odour
shape	Spherical	Spherical	Spherical	Spherical

The shape, odor, physical appearances and colour were observed. All pellets showed spherical shape with good distribution in size. The smoothness of the pellet surface was also confirmed by other physical parameters presented in Table 4.The friability of the pellet as shown in Table 4, exhibited that only the pellet with 10% extract of *EEMC* leaves passed the requirement. Friability test is important to determine whether the pellet can withstand the handling, shipping, storage and other processing, such as coating, which the pellets may be subjected to. Variation in the

formulation and/or process of pellets, as well as variability in the raw materials, can potentially result in significant variations in the hardness and/or friability of pellets. Based on data presented in Table 4, all pellet formulas containing the extract showed good performance as compared to blank pellet, in particular the flow property and apparent density. Shortly, it can be concluded that addition of the extract to the formula improved the physical characteristic of the pellets. It may be that the extract itself has binding effect leading to good particle consolidation during the pelletization process[11]. However, there is an optimum concentration of the *EEMC* leaf extract resulting in an ideal pellet *i.e.*10 %.

Table 4: The physical characteristic of the blank pellets

Formula	Friability (%)	Moisture content (%)	Flowability (g/sec)
F1	1.99	1.49	0.49
F 2	4.88	4.30	2.74
F3	5.12	5.75	3.20
F4	3.68	2.18	3.28

Table 5: The physical characteristic of the pellets with EEMC

Formula	Friability (%)	Moisture content (%)	Flowability (g/sec)
F5	5.19	0.85	3.22
F6	0.99	4.43	7.83
F7	2.58	1.47	10.45
F8	2.77	1.78	8.79

Conclusion

Finally presented study concluded that the presence of *EEMC* in pellet influenced the physical characteristics of the pellet. It may due to the self binding property of the pellet improving the solid consolidation during pelletization. Pellet which contains 10% of extract which is present in formula-6 i.e. F6, produced the best pellet in term of physical characteristics. Further analytical method is still required to confirm the chemical stability of the extract upon pelletization process. The sphericity,odour and surface properties were found to be similar in the formula for pellets with extract in it.

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