

Development and Evaluation of Herbal Tablet Loaded with *Pueraria tuberosa* Water Extract with Use of Different Excipients

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Abstract

Aim: The aim of present paper is to develop the best quality of low cost tablets and with better effectiveness. **Material and Methods:** In this experiment we have used starch and some other excipients such as Microcrystalline cellulose, Acacia, Gellatin, Polyvinylpyrrolidone and sodium Aliginate. The Water extract of plant *Pueraria tuberosa* belonging to the family of fabaceae. The herbal tablet of PT was made by wet granulation method. The finished products were characterized by standered method. For the determination of concentration, we have drawn the standard calibration curve of PT extract having absorption maxima at 221 nm in 0.1 N HCL solution. The drug obeyed Beer's lamberd law in the concentration range of 10 µg/ml to 50 µg/ml and was found to be linear with $r_2 = 0.988$ and regression equation $y = 0.003x - 0.009$. **Result and Discussion:** The parameters of pre formulation such as Angle of repose, Carr's index and Husnner ratio showed good flow property. Tablets were evaluated by both official and non official testing, according to Indian Pharmacopoeia. After the official testing, the tablets made up by starch were not shown any significant change in properties. The friability of all formulations is less than 1%, except F0. Out of all, one of our formulation of herbal tablet mixed with 5% starch (FA) showed good release property within 1 hour in dissolution media, studied through in vitro method. **Conclusion:** These results concludes that starch can be proved as the better excipient for preparation of herbal tablets.

Key words: Angle of repose, dissolution, *Pueraria tuberosa*, tablet

INTRODUCTION

Herbal medicines are the oldest form of health care known to mankind; herbs had been used by all cultures through histography. It was an integral part of the development of modern civilization. As time went on, each tribe added the medicinal power of herbs in their area to its knowledge base. They methodically collected information on herbs and developed well-defined herbal pharmacopeias.

A number of traditional herbal medicinal practices have been adopted for the diagnosis, prevention, and treatment of various disease.

Here, we have prepared a tablet of *Pueraria tuberosa* (PT) Linn Fabaceae. PT, commonly known as kudzu, Indian kudzu, or Nepalese

kudzu, is a climber with woody tuberculated stem. It is a climbing, coiling and trailing vine with large tuberous roots. In *Sanskrit* it is called *Swadukanda*, *Ikshugandha*, *Kandapalaash*, *Bhumikushmaand*, and in Hindi, it is called *Vidarikanda*. PT is a perennial plant as health promotive and also for the disorder of kidney disease, as diuretic, cardiogenic, anti-aging, and galactagogue. It is distributed in the tropical parts of the India.^[1] The various literature showed its antihyperglycemic, antihyperlipidemic, hepatoprotective, anti-inflammatory, antioxidant properties,

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and antifertility in the male rat.^[2-5] In the plant kudzu some chemical constituents such as Daidzin, tuberosin, puerarin, genistein, pterocarpintuberosin, puerarone, coumarin, hydroxytuberosone, anthocyanin, lupinoside, and puetuberosanal.^[6-8]

Its tubers are in clinical use since centuries as health promotive supplement and improve the digestive power, thus considered as good rasayana (Rejuvenate). We also reported its nephroprotective role by the mechanism of action through the activation of MMP-9 resulting to degradation of accumulated of the extra cellular matrix (ECM).^[9] We have investigated the role of PT water extract (PTWE) in expression HIF - 1 α and its target gene, i.e., VEGF and change in expression of nephrin which is a podocyte that chronic hypoxia is one of the main factor leading to renal ECM accumulation and renal fibrosis, which is mediated by HIF - 1 α .^[10]

PT used as medicine in Ayurveda (Indian system of Medicine) to manage cough and cold.^[11] It has shown nephroprotection against cisplatin-induced kidney damage.^[12] It has also shown inhibition of DPP4,^[13] resulting higher level of serum GLP 1^[14,15] and incretin receptor agonist.^[16]

Originally use of PT tubers in Ayurveda is in the form of powder. It is a bulky dose, inconvenient for the user, inaccurate amount of drug administration, and not patient friendly. The shelf life is also limited as it absorbed moisture from the environment and thus subject to rapid degradation and microbial growth. To overcome these problems, we made tablets by wet granulation methods. It has low cost, effective and stable for longer time. The oral route of drug administration is the most important method of administering the drug for systemic effects. Tablet and capsule represent unit dosage forms in which one usual dose of the drug has been accurately placed.^[17] The tablet has a number of advantages over the capsule; tablet is an essentially tamperproof dosage form.^[18] Tablet should be an elegant product having its own identity while being free of a defect such as chips, crack, discoloration, and contamination, and^[19] should have the strength to withstand the rigors and must have suitable chemical stability over time so as not to allow alteration of the medicinal agent. Tablet should have the chemical and physical stability to maintain its physical attributes over time.^[20]

In the formulation of PT tablet, various types of excipients were used here such as Starch, *Microcrystalline cellulose*, *Acacia*, sodium aliginat, gelatin, talc, and magnesium stearate.

In this work, we have also tried to prove that starch has all three properties, i.e., binder, disintegrator, and lubricator.^[21] Their physical properties of granules such as angle of repose, compressibility, and Carr index and tablet including weight

variation, friability, tablets hardness, and disintegration time (DT), and dissolution study were investigated.

MATERIALS AND METHODS

The tubers of PT plant were collected from Ayurveda pharmacy, of BHU. Talc, starch, polyvinyl pyrrolidone, *M. cellulose*, *Acacia*, and magnesium stearate were purchased from CDH laboratory reagent.

Preparation of extract

PT powder was taken 250 g, boiled with 2 L of distilled water for 2 h until the volume reduced to 500 ml these decoction was cooled and filtered by cheese cloth. The filtrate was concentrated on the water bath and also sunlight. Finally, the dried form of powder was obtained. Its yield was 36.4 w/w%. This powder was used for tablet preparation.

Preparation of granules for tablet

Wet granulation method

Here, the PTWE was mixed with talc 1%, magnesium stearate 2% by the geometric dilution method. Water was then added into the mixture powders until a damp mass occurred, sieved through an 18-mesh sieve to produce granules. The granules were dried in a hot air oven at 60°C for 4 h. The following excipients such as starch, *M. cellulose*, Gelatin, *Acacia*, and sodium alginate were mixed together in 5% with have different properties.

The dried granules were sieved all over again through a 20-mesh sieve and mixed together for 3 min. The mixture powders were tested and evaluated by preformulation studies before tablets compression. Then, the mixture powders were compressed into tablets using a single punch tableting machine.

Experimental design

We have prepared 8 types of tablets. Those ingredients ratio is shown in Table 1 which designed as F0, FA, FB, F1, F2, F3, F4, and F5, respectively. After that, the tablets were tested the physical properties of official test such as weight variation, disintegration, dissolution release study, and non-officially such as tablet hardness, friability, and waiting time.^[22,23] Tablets of formulation FA are shown in Figure 1.

Preparation of tablet

Tablet was prepared by tablet punching machine (Rotary Cadmach Ahmedabad) with the help of Surya pharmaceutical situated in industrial area Varanasi. 20 tablets were prepared in a single batch. After tablet preparation batch was sent for evaluation of physical property of tablet and released study.

Table 1: Formulation chart

Ingredient (in mg)	Formulation code							
	F0	FA	FB	F1	F2	F3	F4	F5
Talc	5	5	5	5	5	5	5	5
Magnesium stearate	10	10	10	10	10	10	10	10
Starch		25	50					
PVP				25	-	-	-	-
<i>M. cellulose</i>				-	25	-	-	-
<i>Acacia</i>				-	-	25	-	-
Gelatine				-	-	-	25	-
Sodium alginate				-	-	-	-	25
PTWE	500	460	435	460	460	460	460	460
Total (in mg)	500	500	500	500	500	500	500	500

PVP: Polyvinylpyrrolidone, *M. cellulose*: Microcrystalline cellulose, PTWE: *Pueraria tuberosa* water extract



Figure 1: Tablets of formulation FA

Preformulation studies of Granules^[22]

Angle of repose

The Angle of repose was tested by the fixed funnel method. The 5 g of powder mixture was poured into a glass funnel. The lower tip of the glass funnel was 5 cm height from the ground. The height (h) and radius (r) of pile were measured, and then calculated as follow:

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

θ = angle of repose (°)
 h = height (cm)
 r = radius (cm).

Bulk density

The 20 g of powder mixture was weighted accurately, gently poured into 100 ml glass cylinder without compacting. The volume of powder mixture was recorded, and then calculated as follow:

$$\text{Bulk density} = m/v_0$$

m = mass (g)
 V_0 = unsettled apparent volume (cm³).

Tapped density

The glass cylinder with powder mixture from bulk density testing was used to test tapped density. It was tapped using a

tapped density tester (Erweka D-63150, Germany) for 1,250 strokes. The volume of tapped powder mixture was recorded, and then calculated as follow:

$$\text{Taped density} = M/v_f$$

m = mass (g)
 V_f = final tapped volume (cm³).

Carr's index

Data from bulk density and tapped density testing were used to calculate compressibility index follow Eq. 4:

$$\text{Compressibility index} = [(Taped\ density - Bulk\ density) / Tapped\ density] \times 100.$$

Hausner's ratio

It is a direct indices of ease of measuring the flow of powder.

Hausner ratio was calculated as follow:

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

V_0 = unsettled apparent volume (cm³)
 V_f = final tapped volume (cm³).

Evaluation of formulated tablets of PTWE

Weight variation

Weight variation 20 tablets were individually accurately weighed. Each tablet weight was recorded. Results were reported as mean±standard deviation (SD) in mg.^[17]

Friability

The tablets dust was removed before testing. 10 tablets were accurately weighed together, and friability was tested using a Roach Friability tester (K.S.L. Engineering, Thailand). After 4 min of rotation at 25 rpm, any loose dust from the tablets was removed before accurately weighing again. If friability was not more than 1.0%, it was considered acceptable.^[17,24]

Hardness

Tablet requires some amount of strength and resistant to friability to mechanical shock of handling in manufacture, packaging, and shipping. Hardness is thus sometimes termed as the crushing strength.^[17] 10 tablets were measured using a hardness tester (Digital tablet Hardness tester IKON Delhi). Results were reported as mean \pm SD in kilopond (kP) units.

DT

For most tablets, the first important step toward solution is break down of the tablet into smaller particles a process known as disintegration. The DT of the tablet was determined in phosphate buffered saline (PBS) buffer (PH 7.4) at 37 \pm 0.5°C using a Veego Disintegration Tester.^[17]

Waiting time

Circular tissue papers were placed in a Petri dish of 10 cm diameter. 10 mL of water containing 0.5% Eosin, a water-soluble dye, was added to the Petri dish, the dye solution was used to identify wetting of tablet surface.^[25] A tablet was carefully placed on the surface of tissue paper in the Petri dish at 25°C. The time required for water to reach the upper surface of the tablet and to completely wet them was noted as the wetting time. The measurement was carried out in triplicate of six in number. Waiting time was recorded using a stopwatch.

Thickness

Thickness of tablet was calculated by Digital Vernier calipers. Tablet was put in between jaws and measured thickness and 6 tablets were used for this test and unit expressed in mm.^[23]

Dissolution testing

Dissolution is the process by which a solid enters into a solution. The dissolution rate is defined as the amount of drug substance that goes into solution per time under the standardized condition of liquid/solid interface, temperature, and solvent composition. Dissolution is one of most important quality control tests and considers a tool for predicting bioavailability. The most direct assessment of a drug's release from various tablet formulation is accomplished through *in vivo* bioavailability measurement.^[21] The instrument USP dissolution apparatus II was used in this studies.

Calibration curve with ultraviolet (UV) spectroscopy

Before dissolution test, we have scanned the solution of PTWE in \times 1 PBS solution with UV range 190–400 nm. We got absorbance maxima of our herbal extract at 221 nm.^[26,27]

Dissolved 20 mg of PTWE powder in 5 ml \times 1 PBS stock solution, make the concentration 4 μ g PTWE in 1 μ l solution. The final concentration range was 10–50 μ g/ml and draws the standard calibration curve in Figure 2.

In vitro drug release of tablets PTWE

Dissolution profile of pueraria tablet was determined at 37 \pm 0.5°C at a stirring rate of 100 rpm using the USP dissolution apparatus II 900 ml of \times 1 PBS. Various samples were withdrawn 5 ml with replacement simulated fluid of same amount at 2, 5, 15, 30, 45, and 60 min, respectively, and sample was filtered using Whatman filter paper and taken absorbance at wavelength 221 nm with the help of UV spectrophotometer.^[28,29] The study of released was done by dissolution apparatus in 1 h. The releasing property of formulation was checked by how many percentage of release of tablet up to 1 h which is shown in Table 2.

Statistical analysis

A total of all parameters such as preformulation study, evaluation of tablets and drug release profile of tablets were tabulated and analyzed. Data are expressed as the mean \pm SD. The mean value and SD were calculated for each variable analyzed by Newman–keuls multiple comparison test of ANOVA to determined significant difference between groups at $P < 0.05$.

RESULTS

Preformulation study

The granules study result was shown in Table 3. The granules study was satisfactory of the all formulation FA, FB, F1, F2, F3, F4, and F5 except F0 because F0 has no any binder and excipients were mixed them. After evaluation of preformulation study, the flow property of powder was good except F0. The angle of repose of all formulation FA–F5 was good except F0. F0 value was passable that was classed by USP 33/NF 28.^[28] Bulk density of each formulation was 1.16 and 1.17 g/cm³. Tap density of all formulation was 1.33–1.66 g/cm³. Compresibility index and Hausner ratio revealed that the flow character of formulation FA–F5 was good, and F0 was poor. Hence, the result showed that the powder has good flowing property which does not cause affect the process of tablet punching. Those are shown with reference scale in Table 4.

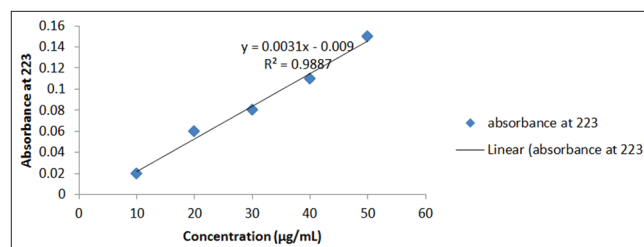


Figure 2: Standard calibration curve of *Pueraria tuberosa* water extract in \times 1 phosphate buffered saline solution

Physical property evaluation of tablets

The result of evaluation of PT tablets

Hardness

Hardness of all formulation was found in b/e the ranges of 1–7.2 kg/cm² the hardness of formulation was measured by digital hardness tester. Hardness of F0 was poor, FA, F1, F2, F3, F4, and F5 were better, and the hardness of formulation of FB more than another tablet because 10 % starch was mixed them [Table 5]. Interestingly, the 5% starch-based tablet also show good hardness property because its hardness was 4.07, and its also remained intact after dropping from 3 feet height these it appears that using starch the cost of tablet will be less without compromising the quality of the tablets.

Friability

The friability range was shown in Table 5. Friability of all formulation was found to be 0.39–0.83 except F0 which was not acceptable. The friability of PT tablet FA, FB F1, F2, F3, F4, and F5 was found to be an acceptable limit, i.e., <1% [Table 5]. There was no capping problem occurs in tablet so it could be considered for commercial use. It produced no loss during shipping process.

Weight variation

The physical appearance was brown, smooth, and concave tablets. The weight of 20 tablets was measured, and it was found to be formulation FA, FB, F1, F2, F3, F4, and F5 was 1.14–1.98 except F0 was more than as compare another tablet [Table 5]. All tablets of PT passed weight variation test, as the average percentage weight variation was within the USP limit of ±5%.

DT

The DT of tablet was between 5 and 6 min for FA, F1, F2, F3, F4, and F5. Only 2 min was found in F0 because it was

no use of binder and 10 min of FB because 10% starch was mixed [Table 5].

Waiting time

The range of waiting time of all formulation was below the 2 min. The waiting property of tablet was depends on percentage excipients. In formulation, FB waiting time was little bit high because 10 % starch was found them [Table 5].

Thickness

The thickness of PT tablet was found to be ranges b/w 3.9–5.5 mm. The thickness was depends on size of die, function of die fill and compression force [Table 5].

In vitro released study

The drug released in medium of FA, F2, F3, and F4 tablet was found to be more than 90% of initial concentration in 1 h. Formulation F0 was not significantly released because no any type of excipients were mixed. FA tablet was shown significantly 91% of release concentration because it has only 5% starch [Table 2].

DISCUSSION

The tablet is the main solid unit form of applied science. The various types of excipients were used to prepare herbal tablet PT formulation are shown in Table 1. The micromeritic properties were determined for all granules of PTWE with various excipients. The results of angle of repose, Carr's index, and Hausner ratio were shown in Table 3, indicated that the granules mixture possess good flow property and good packing ability. Various types of excipients were used for the herbal tablet formulation such as talc, magnesium stearate, starch, gelatin, *Acacia*, polyvinylpyrrolidone, sodium

Table 2: Drug release profile for tablet of PTWE

Time in min	F0%DR	FA%DR	FB%DR	F1%DR	F2%DR	F3%DR	F4%DR	F5%DR
2	5±0.56	7.7±0.66	6.5±0.57	8.24±0.55	9±0.66	10±0.66	9.8±0.62	7.6±0.73
5	23±0.57	25±0.87	17±0.68	26±0.58	25.8±0.72	27.2±0.55	29±0.53	27.6±0.64
15	32±0.80	43±0.86	45±0.66	45.1±0.69	46.2±0.55	51.0±0.72	45±0.85	49.6±0.56
30	47.2±0.96	67±0.78	55±0.55	63.2±0.74	67.2±0.68	65.0±0.67	67.6±0.77	68.4±0.55
45	56±0.75	85.2±0.55	65±0.67	81.2±0.81	88.6±0.53	85.0±0.68	87.8±0.66	82.8±0.52
60	68.2±0.55	91.6±0.58	81±0.55	85.8±0.74	93.7±0.54	90.2±0.52	91.8±0.56	88.2±0.67

PTWE: *Pueraria tuberosa* water extract

Table 3: Preformulation study of granules

	F0	FA	FB	F1	F2	F3	F4	F5
Bulk density (g/ml)	1.17±0.01	1.16±0.01	1.17±0.02	1.20±0.03	1.17±0.01	1.19±0.02	1.17±0.02	1.16±0.01
Tap density (g/ml)	1.66±0.02	1.35±0.03	1.33±0.01	1.38±0.02	1.36±0.03	1.38±0.02	1.38±0.01	1.35±0.02
Carr's index (%)	29±1.15	14.07±1.19	12.03±1.18	13.0±1.14	14.6±1.17	13.7±1.18	15.2±1.17	14.17±1.15
Hausner ratio	1.41±0.02	1.16±0.02	1.13±0.01	1.15±0.02	1.16±0.04	1.15±0.03	1.17±0.01	1.16±0.03
Angle of repose (°)	38±1.73	27±1.81	26±1.75	28±1.57	27±1.69	29±1.62	28±1.73	26±1.78

alginate, and *M. cellulose*. In this experiment, our aim was to try only 5% starch in best tablet formulation. We know that starch has binding, lubricating, and disintegrating capacity.

The functional property of starch is due to the presence of its various compositions like phosphorus. Phosphorus is mainly responsible for chloroplast synthesis, enhances water binding capacity and swelling power due to the ionic repulsion generated by its negatively charged phosphomonoester group.^[32,33] The herbal tablet was prepared mainly by two methods, direct compression and wet granulation method. Wet granulation method is better as compared to direct compression. Tablet was punched by tablet punching machine available by Surya Pharmaceuticals, Varanasi. Tablet surface and some of its physical properties depend on the size of die and punching pressure of the machine. During tablet punching, we have faced some problem such as capping, lamination, picking, and sticking.^[17]

Table 4: Reference table of angle of repose, Carr's index, and Hausner's ratio^[30] as an indication of powder flow property^[31]

Parameters of Preformulation	Type of flow
Angle of repose	
<20	Excellent
20–30	Good
30–40	Passable
>40	Vary passable
Carr's index (%)	Flowability
5–15	Excellent
12–16	Good
18–21	Fair to passable
23–35	Poor
33–38	Very poor
>40	Extremely poor
Hausner's ratio	Flowability
<1.25	Good
>1.25	Poor

After preparation of tablet, some official and non-official evaluation was carried out by standard guidelines.^[28] In this experimental study, we have found that the physical property of formulation FA is similar to the standard parameters, [Table 4] because here we have used only 5% starch as excipients. The physical properties of tablet were determined, and the results of the uniformity of weight, hardness, and friability are shown in Table 5. Results are reproducible, even on tablets that had been stored for 2–3 months at 25°C and 60% relative humidity. In *in vitro* release study, we have found that the drug release for FA, F2, F3, and F4 formulation was >90% for 1 h dissolution testing.

Before the dissolution study, we have scan the powder of PTWE with the help of UV spectrophotometer. The PT water extract powder showed maximum absorption at 221 nm in $\times 1$ PBS.^[28,29] The drug obeyed Beer's Lambert law in the concentration range of 10–50 mcg/ml and it was found to be linear with $R = 0.988$ and regression equation of $Y = 0.003x - 0.009$ [Figure 2]. *In vitro* dissolution studies were conducted on herbal tablet for each formulation, i.e., F0, FA, FB, F1, F2, F3, F4, and F5. The mean cumulative percent of drug release at different time interval for each formulation is shown in Table 2. According to these results, here we conclude that 5% starch only with talc and magnesium stearate (1% and 2%), respectively, are sufficient for better herbal tablet formulation.

The best formulation of tablet FA is shown in Figure 1, and its cumulative release profile as compared other formulations are shown in Table 2.

CONCLUSION

The prepared PT tablet formulation FA showed good physical properties such as disintegration, hardness, and dissolution rate. After the comparative study of different formulation having different excipient yielded a conclusion that starch as 25 mg (5%) is suitable for the preparation of 500 mg herbal tablet of PTWE, satisfying all parameter and official testing.

Table 5: Evaluation of PT tablet

Formulation	Disintegration time (min)	Hardness kg/cm ²	Thickness (mm)	Friability %	Wt. variation %	Waiting time (min)
F0	2.0±0.15	1.39±0.05	5.4±0.05	2.51±0.34	3.14±0.15	1.40±0.05
FA	5.10±0.10	4.07±0.30	4.1±0.17	0.68±0.12	1.68±0.03	1.15±0.03
FB	10.50±0.15	6.15±0.27	3.9±0.23	0.58±0.14	1.28±0.02	1.56±0.04
F1	5.0±0.16	4.10±0.42	4.2±0.28	0.73±0.13	1.14±0.04	1.40±0.04
F2	6.0±0.14	4.24±0.51	4.3±0.15	0.39±0.14	1.94±0.05	1.30±0.05
F3	5.20±0.13	4.71±0.46	4.1±0.16	0.67±0.12	1.94±0.03	1.40±0.04
F4	6.14±0.17	4.20±0.52	4.2±0.24	0.83±0.12	1.98±0.04	1.50±0.03
F5	5.50±0.14	3.15±0.47	4.2±0.16	0.73±0.16	1.96±0.04	1.30±0.05

PT: *Pueraria tuberosa*

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