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PHARMACEUTICAL AND ANALYTICAL EVALUATION OF PUSHYANUG TABLETS

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ABSTRACT

Ayurveda covers broad aspects of life with theoretical and practical wisdom, following which physical and mental health can be achieved by humans and ultimately move towards spirituality. It is an ancient and therapeutically efficacious science. Today, inspite of the development of various modern techniques in the field of medicine, Ayurveda is still serving mankind successfully. The natural form of any herb is difficult to use as such due to its non-palatability and less shelf-life. Therefore, ancient scholars were first able to modify the raw material into the forms of *Swarasa* (juice), *Kalka* (paste), *Kwatha* (decoction), *Hima* (cold infusion), and *Phanta* (hot infusion), etc. These are the five basic dosage forms, collectively known as *Panchavidha Kashaya Kalpana*. Since these dosage forms have a short life span, so the formulations which can be preserved for a long time and can be administered conveniently were developed in the later period, such as *churna* (powder), *vati* (tablet), *Avaleha* (semi-solid paste), *Sandhana* (fermented products), *Sneha* (oil) and *arka* (distilled products), etc. In the present study, an attempt is made to prepare tablets of *Pushyanug Churna*, which is widely used for the treatment of uro-genital disorders in females. The binding agent used for making tablets is rice amylum because *tandulodaka* (rice water) is the *anupana* (vehicle- to be taken after taking medicine) of *Pushyanug Churna* as described in the classics.

Keywords: *Pushyanug churna*, *Churna*, Tablets, Uro-genital disorders, Abnormal vaginal discharge

INTRODUCTION

Pushyanug Churna is one of the popular traditional formulations used widely in females suffering from diseases related to the genito-urinary system, particularly abnormal vaginal discharge. Normal physiological vaginal discharge consists of a transudate from the vaginal wall, squames containing glycogen, polymorphs, lactobacilli, cervical mucus, and residual menstrual fluid, as well as a contribution from the greater and lesser vestibular glands. Vaginal discharge varies according to oestrogen levels during the menstrual cycle and is a normal physiological occurrence. The vaginal discharge does not normally have an unpleasant odour, and if this occurs in the presence of a change in colour or copiousness, then it may indicate infection. [1]

First of all, its description of *Pushyanug Churna* is found in the basic text of Ayurveda i.e., *Charaka Samhita* (which is followed in the present study).[2] The formulation comprises 26 different herbs which are believed to possess the astringent property in a synergistic way. The contents of the formulation possess properties such as *Kashaya- Tikta rasa, Katu Vipaka, Laghu & Shita guna,* and *Shita* virya. Due to *Kshaya* and *Tikta* rasa it acts as *Grahi* and *Stambhana*, due to *Shita Virya* it is *Pittashamak* and due to its *Laghu* and *Ruksha guna* it has *Kaphahara* action. [3] Due to the astringent property of the ingredients, it is an excellent hemostatic and it acts especially in the cases of abnormal vaginal discharge. *Pushyanug Churna* is indicated for various *yonivyapad* (menstrual disorders as well as congestion in the female reproductive system). Conditions involving menstrual irregularities such as *pradara* (menorrhagia), *asrigdara* (metrorrhagia), *kashtartava* (dysmenorrhea), and *vataj yonivyapad* (endometriosis) are treated with this formulation. It is also useful in *arsha* (piles), *raktatisara* (diarrhea with bloody stools), and different types of discharges from the vaginal tract as mentioned in *Charaka Samhita*.

In the present study, an attempt is made to form *Pushyanug* Tablets from *Pushyanug Churna* for better compliance of the patient. The vehicle for *Pushyanug churna* is said to be *tandulodaka* which is prepared by keeping rice dipped in water overnight in a ratio of 1:8. [4] Due to this rice starch can be used as a binder for the development of tablets. It possesses better compaction properties than potato, maize, and tapioca starch, and also the binding properties of rice starch are almost insensitive to mixing with magnesium stearate, in contrast to other starches. Rice starch has the worst flowability due to its fine particle size as compared to the other starches. The lack of lubricant sensitivity of rice starch is attributed to its poor flow properties, which would impair the formation of a lubricant film over the particles during mixing with the lubricant. [5] Tablet manufacturing can be done by three basic methods- direct compression, wet granulation, or dry granulation. [6] The most widely used and most general method of tablet preparation is the wet granulation method, and this method is only used in the preparation of *Pushyanug* tablets from *Pushyanug Churna*. The steps required are (a) weighing and blending the ingredients, (b) preparing a dampened powder or a damp mass, (c) screening the dampened powder or damp mass into pellets or granules, (d) drying the granulation, (e) sizing the granulation by dry screening, (f) adding lubricant and blending, and (g) forming tablets by compression. [7]

1. MATERIALS & METHODS

The ingredients of *Pushyanug Churna* were procured from raw traders of Haridwar. The drugs were identified and authenticated in the laboratory of the department of Dravyaguna in Rishikul campus, Uttarakhand Ayurved University, Haridwar. The process of development of tablet was performed in the laboratory of the department of *Rasa-shastra and Bhaishajya Kalpana* in Rishikul campus, Uttarakhand Ayurveda University, Haridwar, and in the laboratory of the department of Pharmaceutical Sciences, Gurukul kangri University, Haridwar. The reagents of analytical grade were used for the study.

1.1. Purification of *Gairika* (Red ochre)

Detoxification of any substance without harming its medicinal properties is known as *shodhan*. The process of detoxification is said to bring about favorable changes in the drug which modifies the therapeutic effect and also renders the drug free from poisonous effects. [8] Therefore, purification of raw *gairika* was done by first converting it into fine particles in a mortar and pestle. Then this powdered *gairika* was kept on fire in a cauldron along with cow's ghee in the ratio of 4:1. During frying, continuous stirring was done till the appearance of chief desire characteristics betel leaves was obtained. [9] Then, the cauldron was withdrawn from the fire and cooled. The *gairika* was pressed in the blotting paper to remove the extra greasiness of the ghee. Then it was weighed and kept in an airtight container for further use. [10]

1.2. Preparation of *Pushyanug Churna* [2]

All the ingredient drugs were taken in equal amounts (100 gm each) and washed & dried [Table 1]. Then these drugs were crushed into coarse powder one by one with the help of an iron mortar and pestle. Finally, they were made into a fine powder form by grinding and passed through 80 no. sieve separately. Each drug was kept in an airtight container for further use. An equal amount (10 gm) of all the powdered ingredients were taken. The powders of *kesar* (*Crocus sativus*) and *mridvika* (*Vitis vinifera*) were not passing through the sieve no. 80. So, *kesar* was passed through sieve no. 60 and mixed while minute pieces *mridvika* were mixed as it is. The mixing was done to obtain a mixture of all ingredient drugs. Then the final product was weighed and kept in a well-dried airtight container. [Fig.1 (a)]

Table 01

Drugs	Botanical Names	Part Used
Patha	*Cissampelos pariera (L.)*	Root
Jambubija	*Syzygium cumini (L.)*	Seed
Amrabija	*Mangifera indica (L.)*	Seed
Pasanbheda	*Bergenia lingulata (Wall.)*	Root
Rasanjana	*Berberis aristata (DC.)*	Stem extract
Ambastha	*Cissampelos pariera (L.)*	Root
Mocharasa	*Salmalia malabarica (DC.)*	Exudate
Samanga	*Mimosa pudica (L.)*	Whole plant
Vatsaka	*Holarrhena antidysentrica (L.)*	Stem bark
Balhika	*Crocus sativus (L.)*	Stamen & Stigma
Ativisha	*Aconitum heterophyllum (Wall.)*	Root
Bilva	*Aegle marmelos (L.)*	Stem bark
Mustaka	*Cyperus rotundus (L.)*	Rhizome
Lodhra	*Symplocos racemosa (Roxb.)*	Stem bark
Gairika	*Ochre*	-
Katvanga	*Ailanthus excels (Roxb.)*	Stem bark
Maricha	*Piper nigrum (L.)*	Fruit
Sunthi	*Zingiber officinale (Roscoe)*	Rhizome
Mridvika	*Vitis vinifera (L.)*	Fruit
Raktacandana	*Pterocarpus santalinus (L.f.)*	Heartwood
Katphala	*Myrica esculenta (Buch. -Ham.)*	Stem bark
Indrayava	*Holarrhena antidysentrica (L.)*	Seed
Ananta	*Hemidesmus indicus (L.)*	Root
Dhataki	*Woodfordia fruticosa (L.)*	Flower
Madhuka	*Glycyrrhiza glabra (L.)*	Root
Arjuna	*Terminalia arjuna (Roxb.)*	Stem bark

Ingredients of *Pushyanug Churna*

Table 02

S. No.	Name of Drugs	Original Amount (in gm)	Mean percentage yield (in %)	Mean percentage loss (in %)
1.	Patha	100	49.7	50.3
2.	Jambubija	100	57.67	42.34
3.	Amrabija	100	70	31
4.	Pasanbheda	100	65.41	32.83
5.	Rasanjana	100	89.17	10.83
6.	Ambhastha	100	49.7	50.3
7.	Mocharasa	100	64.67	35.34
8.	Samanga	100	34	66
9.	Vatsaka	100	42	58
10.	Bahlika	15	97.5	2.5
11.	Ativisa	100	55.34	44.67
12.	Bilva	100	48.34	51.67
13.	Mustaka	100	38.75	61.25
14.	Lodhra	100	57.75	42.25
15.	Gairika	100	58.42	41.58
16.	Katvanga	100	31.08	68.91
17.	Maricha	100	68.08	31.91
18.	Sunthi	100	63.75	36.25
19.	Mridvika	100	95.67	4.34
20.	Rakta Candana	100	70.84	29.17
21.	Katphala	100	62.58	37.41
22.	Indrayava	100	66.25	33.75
23.	Ananta	100	30.75	71.25
24.	Dhataki	100	44.84	55.17
25.	Madhuka	100	33.97	66.04
26.	Arjuna	100	80.67	19.34

The percentage yield of various ingredients of *Pushyanug Churna*

1.3. Formulation of *Pushyanug* Tablet

1.3.1. Selection of rice amylum as a binder

- According to *Acharya Charaka*, the vehicle of *Pushyanug churna* is *tandulodaka* (rice water). So, an attempt was made to use *tandulodaka* as a binder in the preparation of *the Pushyanug* tablet. *Tandulodaka* was prepared by keeping the rice in 8 times of water over night, but it didn't show any binding property.
- Then a fine powder of rice was made and used as the binder in the different ratios (w/w) i.e., 10%, 15%, and 20%. But the tablets obtained were very friable and friability was increasing with the increase in the percentage of rice powder. Therefore, the batches were rejected. [Table 3]
- Finally, the amylum (*manda*) was made by boiling the rice with 4 times water. [Fig.1(b)] First it was dried and made into fine powder. This was used as the binder in the different ratios (w/w) 10% and 15%. The tablets prepared with 15% amylum were the best and friability also came under range. [Table 3]

Table 03

Samples	Form of rice starch	Percentage of rice starch	Friability (in %)
Sample I	Rice powder	10	More than 1 (11.69)
Sample II	Rice powder	15	More than 1 (the whole tablet converted into powder)
Sample III	Rice Powder	20	More than 1 (the whole tablet converted into powder)
Sample IV	Rice amylum powder (from the *manda* extracted from rice)	10	More than 1 (approx. 1. 24)
Sample V	Rice amylum powder (from the *manda* extracted from rice)	15	Less than 1 (approx. 0.69)

Friability of tablets with different forms and different amounts of rice starch

1.3.2. Preparation of *Pushyanug* Tablet

A known amount of rice amylum powder was taken in a beaker and a sufficient amount of water to form a paste was poured into it. Then the content was heated on a hot plate until a paste of rice amylum was obtained. This paste was added to the *Pushyanug churna* and mixed thoroughly in a stainless-steel tray until the granules were obtained.[Fig.1(c)] These granules were dried in a hot air oven for 2hr at 40^{o}C temperature and screened through sieve no. 22. [Fig.1(d)] Then the granules were mixed with lubricants i.e. magnesium stearate & talc powder and compressed into tablets with the help of 12 station tablet punching machine. [Table 4] [Fig.1(e)]

Table 04

Ingredients used	Amount (in gm)
Pushyanug churna	100
Rice amylum/*Manda*	15
Magnesium stearate	3
Talc powder	1

Formulation of *Pushyanug* tablet

2. RESULTS

Organoleptic characters of *Pushyanug churna* and tablet were observed [Table 5]. Physico-chemical analysis, heavy metal estimation, and microbial load of *Pushyanug* tablets were performed and compared with that of *Pushyanug churna* [Table 6,7 & 8]. Also, tablets were then evaluated for the Disintegration test, friability test, and hardness test [Table 9]. All the tests were performed in the international testing centre (ITC), Panchkula, Haryana.

Table 05

Organoleptic characters	*Pushyanug churna*	*Pushyanug* tablet
Colour	Reddish brown	Yellowish brown
Odour	Faint	Faint
Taste	Astringent	Astringent
Touch	Fine	Smooth

Organoleptic characteristics of *Pushyanug churna* and *Pushyanug* tablet

Table 06

Tests	Results (% w/w)	
	Pushyanug churna	***Pushyanug* tablet**
Total ash	12.51	12.23
Acid insoluble ash	1.29	1.54
Water soluble extractive	14.55	16.6
Alcohol soluble extract	13.34	13.74
Loss on drying	5.84	4.20

Results of physico-chemical analysis of *Pushyanug churna and Pushyanug* tablet

Table 07

Tests	*Pushyanug churna*	*Pushyanug* tablet
Lead (Pb)	1.03 ppm	1.04 ppm
Cadmium (Cd)	Not detected	Not detected
Arsenic (As)	Not detected	Not detected
Mercury (Hg)	Not detected	Not detected

Results of estimation of heavy metals in *Pushyanug churna* and *Pushyanug* tablet

Table 08

Microbial load	*Pushyanug churna*	*Pushyanug* tablet
Total bacterial count	393.33 cfu/gm	220.66 cfu/gm
Total Fungal count	Less than 10	Less than 10

The microbial load of *Pushyanug* tablet

Table 09

Tests	Results
Disintegration time	3-4 min
Friability	0.16 %w/w
Hardness	2.4 kg/cm^2

Disintegration time, friability, and hardness of *Pushyanug* tablet

DISCUSSION

Pushyanug churna is advised to administer along with *tandulodaka* i.e., rice water. Therefore, an attempt is made here to develop a tablet from this *churna* using rice amylum as a binder and minimum required the number of additives by wet granulation method. Using rice amylum as a binder could increase the efficacy of the medicine. This could lead to the development of a stable dosage form and also increase patient compliance.

An orally administered drug must disintegrate to attain good absorption of its active substance. The first step toward dissolution is usually the breakdown of the tablet, a process described as Disintegration. The disintegration time of *the Pushyanug* tablet is 3-4min, which is favourable for fast absorption of the tablet in the body. Tablets must be able to withstand the mechanical stresses during their manufacturing, distribution, and handling by the end-user. Friability is a measure of the resistance of the tablets. The value of friability of the *Pushyanug* tablet is 0.16% w/w, which proves that the tablet can withstand mechanical stresses very well. Tablet hardness testing is also called Tablet breaking force testing. This is an essential quality control parameter since compression influences many tablet properties including disintegration, dissolution, and

friability. The value of the hardness of *the Pushyanug* tablet is 2.4 kg/cm^2.

Among heavy metals, Cadmium (Cd), Arsenic (As), and Mercury (Hg) are not detected. A small amount of lead is detected but it is under the permissible limit. [11] The presence of lead might be due to environment-related factors like if herbs are collected from the roadside or grown in contaminated soil etc. [12] Therefore, the drug is safe for clinical use and will not cause any toxic effect on the human being. The microbial load came out to be under the permissible limit. [11] Microbial and fungal contamination not only affects the chemical composition but also decreases the therapeutic potency of herbal drugs.

CONCLUSION

The conversion of *the Pushyanug* tablet from *Pushyanug churna* by adapting modern techniques without altering its therapeutic properties is possible through the wet granulation method. The use of rice amylum as a binder for preparing tablets proved to be feasible, which could also increase the therapeutic efficacy of the medicine.

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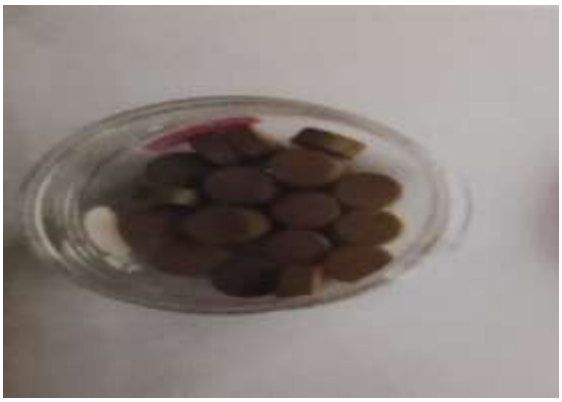
Figure 1

(a)

(b)

(c)

(d)



(e)

Preparation of *Pushyanug* Tablets from *Pushyanug Churna*. a) Crushed ingredients of *Pushyanug Churna* passed through sieve no. 80, b) Preparation of 15% *shali dhanya* (rice) amylum, c) Granules of *Pushyanug Churna* prepared by wet granulation method, d) Drying of granules in a hot air oven, e) Tablets prepared by tablet punching machine.