

PHARMACEUTICAL STANDARDIZATION OF *PANCHAGUNA TAILA* (MEDICATED OIL) AND PRODUCT DEVELOPMENT AS OINTMENT, GEL, CREAM, AND PHYSIOWAX

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ABSTRACT

Objective: The present study aimed to prepare *Panchaguna taila* (PGT) and its development in various dosage forms, i.e. ointment, gel, cream, and physiowax to exemplify the characteristic parameters according to pharmaceutical standards.

Methods: PGT is polyherbal medicated oil used externally for treating wounds, cut, and burn and used for massaging in rheumatoid arthritis, muscular pain, sprains, and joints pain. Prepare the decoction using *Haritaki*, *Vibhitaki*, *Amalaki*, *Nimba*, *Sambhalu* and prepare paste (*kalka*) from *Madhuchishta*, *Gandhaphiroja*, *Shilarasa*, *Rala*, and *Guggulu*. Mix all the ingredients and heat till watery portion not evaporated from the oil with constant stirring then filter it. Add eucalyptus oil, turpentine oil, and kejobuti oil at the end and stir it well. Prepare various dosage forms like ointment, gel, cream, and physiowax using suitable base for the better and improved therapeutic application. Analytical standards for PGT such as acid value, saponification value, iodine value, and peroxide value were performed, and obtained results were appeared under the prescribed limit of the official monograph. Various physicochemical parameters such as homogeneity, spreadability, pH, and melting point were performed for PGT ointment, PGT gel, PGT cream, and PGT physiowax. Stability study of PGT was done for 3 days under the accelerated conditions.

Results: In PGT, various physicochemical parameters were performed on the interval of 24, 48, and 72 hrs, and no significant variation found in their physicochemical properties when observed values were compared. PGT ointment, PGT gel, PGT cream, and PGT physiowax containing PGT as active pharmaceutical ingredient with various suitable excipients and base are easy to formulate and convenient to apply over the affected area. Rf observed between the ranges 0.21 to 0.84 as given in the standard monograph. In PGT, PGT ointment and PGT physiowax, 10 spots were found, and in PGT gel and PGT cream, 7 spots were found. 0.11, 0.15, and 0.34 spots were found in the PGT gel, PGT cream, and PGT physiowax, respectively, that can be given by the excipients or base used for their preparation.

Conclusion: It is possible to make other dosage form of PGT which can be more convenient to the customers. Hence, the issues related to the PGT like staining and sticking can be resolved by developing or converting the PGT into various convenient dosages.

Keywords: *Panchaguna taila*, *Sneha kalpana*, Ointment, Gel, Cream, Physiowax.

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INTRODUCTION

Sneha kalpana provides an idea that *Sneha kalpas* are superior to other dosage forms due to its advantages such as increased absorption, bioavailability, and extraction of fat soluble as well as a water soluble active principle at a time in a single formulation [1]. *Panchaguna taila* (PGT) is polyherbal medicated *taila* used externally for treating wound, cut, burn, and earache and used for massaging in rheumatoid arthritis, muscular pain, and joint pain. [2]. PGT form is beneficial; it poses certain inconveniences while application, handling packaging, and transportation. The big hurdle is its sticky nature, and when applied over the skin, it leaves stain on the applied area and the cloth. Thus, this creates the need to better and improved therapeutic application as various dosage forms of PGT. Hence, an attempt has been made to develop the new dosage form of PGT as ointment, gel, cream, and physiowax on trial and error basis for better acceptability and compliance. Further attempts were made to evaluate preliminary phytochemical and physicochemical profile of the PGT and its conventional prepared dosage forms.

MATERIALS AND METHODS

Procurement of raw material/collection of raw material and authentication of raw material

All the raw materials required for the project purchased from the local market of Jalandhar. *Sambhalu* leaves (Nirgundi) and Neem leaves were collected from the herbal garden of the Lovely Professional University.

Authentication of all the raw material is carried out by Dr. Satiwinderjeet Kaur, Head, Department of Botanical and Environmental Sciences, Guru Nanak Dev University Amritsar, Punjab, with Ref. No. 1087, Date 18/10/16.

Preparation of PGT

Before formulating, PGT *Guggulu* was purified [3,4] and *Taila murchana* [5] was done. PGT was prepared according to the procedure mentioned in the Ayurvedic Pharmacopoeia of India Part II; Volume III [2]. Master formula for PGT is mentioned in Table 1.

Preparation of ointment

PGT ointment was prepared using PGT as API and white paraffin wax as base, and the composition given in Table 2 [6-9].

Preparation of gel

PGT gel master formula for different batches prepared is given in Table 2. PGT of required quantity was taken in a mortar, added with thickening agents given in specified proportion. The contents were homogenized using stirrer. Stirring was continued till desired consistency of product was obtained and stored in airtight container [10].

Preparation of cream

PGT cream was prepared using PGT as API, and the master formula for the batches prepared is given in Table 2 [7,10].

Preparation of physiowax

PGT and white paraffin wax required quantity was taken in a beaker and heat over a water bath at 60°C and then transferred it to the mortar. The contents were homogenized by the action of stirrer. Stirring was continued till desired consistency of product was obtained and stored in airtight container. PGT cream master formula for the batch is given in Table 2.

Characterization of PGT and its dosage forms**Analytical study**

The raw materials and formulations were first analyzed for organoleptic parameters like color, odor, taste, texture, etc., as shown in Table 3.

The formulations were analyzed for the presence of various chemical constituents like alkaloids, glycoside, tannin, phytosterols, etc., [11,12]. Physicochemical analysis includes acid value, iodine value, saponification value, peroxide value, pH, and spreadability. Analysis of samples was performed as per the API standards and PLIM (Pharmacopoeial Laboratory of Indian Medicine) protocol as shown in Tables 4-6 [2, 13-15].

Thin-layer chromatography (TLC) study

Shook the 1 ml of sample with 10 ml of Toluene and kept the mixture for 12 hrs. Filtered the extract and carried out TLC [2].

- Mobile phase - Toluene, ethyl acetate, methanol, and glacial acetic acid (8.5:0.5:0.2: 0.1).

Table 1: Master formula for PGT [16]

S. No.	Raw drug	Part used	Quantity (AFI)	Quantity taken	Quantity obtained
1.	<i>Haritaki</i>	Fruit pulp	60 g	110 g	1,670 ml
2.	<i>Amalaki</i>	Fruit pulp	60 g	110 g	
3.	<i>Bibhitaki</i>	Fruit pulp	60 g	110 g	
4.	<i>Nimba patra</i>	Leaves	180 g	330 g	
5.	<i>Sambhalu patra</i>	Leaves	180 g	330 g	
6.	<i>Jala</i> reduced to	-	4,320 ml	7,920 ml	
7.	<i>Tila taila</i>	Oil	1,080 ml	1,980 ml	
8.	<i>Madhucchistha (Mom)</i>	-	960 ml	1,760 ml	
9.	<i>Gandhaviroja (Saral)</i>	Resin	48 g	88 g	
10.	<i>Sila rasa (Turusk)</i>	Exudate	48 g	88 g	
11.	<i>Raal</i>	Exudate	48 g	88 g	
12.	<i>Guggulu (Suddha)</i>	Exudate	48 g	88 g	
13.	<i>Karpura</i>	-	60 g	110 g	
14.	<i>Tarpina taila</i>	Oil	30 ml	55 ml	
15.	<i>Eucalyptus taila</i>	Oil	30 ml	55 ml	
16.	<i>Cajuputi taila</i>	Oil	30 ml	55 ml	

AFI: Ayurvedic formulary of india

Table 2: Formulas for various batches of PGT dosage forms

Chemical name	Ointment (quantity)			Gel (quantity)			Cream (quantity)			Physiowax (quantity)		
	Batch			Batch			Batch			Batch		
	I	II	III	I	II	III	I	II	III	I	II	III
PGT	10 ml	10 ml	3 ml	10 ml	10 ml	9.6 ml	3 ml	4 ml	5 ml	7 ml	6 ml	5 ml
White paraffin wax	5 g	10 g	2 g	-	-	-	-	-	-	3g	4g	5g
Emulsifying wax	-	-	1.2 g	-	-	-	1g	1g	1g	-	-	-
Liquid paraffin	-	-	1 ml	-	-	-	0.6 ml	0.6 ml	0.6 ml	-	-	-
Methylparaben	-	-	0.01 g	-	-	-	0.01 g	0.01 g	0.01 g	-	-	-
Propylparaben	-	-	0.01 g	-	-	-	0.01 g	0.01 g	0.01 g	-	-	-
Water	-	-	3.2 ml	-	-	-	4.2 ml	4.2 ml	4.2 ml	-	-	-
Carbopol934	-	-	-	1.5 g	1.5 g	-	0.02 g	0.02 g	0.02 g	-	-	-
Vitamin E	-	-	-	-	-	-	-	-	-	-	-	-
Aerosil	-	-	-	-	-	0.6 ml	-	-	-	-	-	-
Glycerine	-	-	-	-	-	-	1 ml	1 ml	1 ml	-	-	-
Propylene glycol	-	-	-	-	-	-	-	-	-	-	-	-
Ethanol	-	-	-	-	5 ml	-	-	-	-	-	-	-
TEA	-	-	-	-	-	-	0.02 ml	0.02 ml	0.02 ml	-	-	-
Quantity obtained	12 g	15 g	7 g	8 g	7.5 g	8.2 g	7.9 g	7.9 g	7.9 g	8.2 g	8.2 g	8.2 g

PGT: *Panchaguna taila*, TEA: Triethanolamine

Table 3: Preliminary analysis of formulations

Parameter	PGT	PGT ointment	PGT cream	PGT gel	PGT physiowax
Color	Greenish brown	Brownish, and brownish cream	Creamish brown	Brownish, and brownish cream	Yellowish brown
Odor	Characteristic aromatic	Characteristic aromatic	Characteristic aromatic	Characteristic aromatic	Characteristic aromatic
Touch	Greasy	Greasy	Greasy	Greasy	Greasy
Consistency	Soft, smooth, homogeneous	Soft, smooth, homogeneous	Soft, smooth, homogeneous	Soft, smooth, homogeneous	Soft, smooth, homogeneous
Texture	Smooth, liquid, opaque	Smooth, opaque non-gritty	Smooth, creamy, thick non-gritty	Smooth, jelly, non-gritty, opaque	Smooth, non gritty

PGT: *Panchaguna taila*

Table 4: Physicochemical analysis of PGT

S. No.	Parameters	Standard (API)	1 st sample	2 nd sample	3 rd sample
1.	RI at 40°C (Abbe refractometer)	1.4703-1.503	1.481	1.482	1.481
2.	Specific gravity at 40°C	0.9106-0.9259	0.9118	0.9177	0.9208
3.	Saponification value	160-184	151.46	163.15	164.08
4.	Iodine value	104-107	103.80	104.37	106.13
5.	Acid value	NMT 2	2.0	2.02	2.0
6.	Peroxide value	NMT 6	6.1	5.89	5.57
7.	Moisture content (Karl Fischer) (%)	-	1.25	1.25	1.25
8.	Rancidity test	-	Negative	Negative	Negative
9.	Mineral oil test	Absent	Absent	Absent	Absent
10.	pH (digital pH meter)	-	3.75	3.75	3.75

PGT: *Panchaguna taila*Table 5: Phytochemical identification of PGT (*Taila* ointment, gel, cream, and physiowax)

S. No.	Active constituent	Chemical test	PGT	PGT ointment	PGT gel	PGT cream	PGT physiowax
1	Alkaloid	Mayer's reagent	+	+	+	+	+
		Wagner's reagent	+	+	+	+	+
		Hager's reagent	+	+	+	+	+
		Dragendorff's reagent	+	+	+	+	+
2	Tannin	Ferric chloride test (FeCl ₃)	+	+	+	+	+
		Lead acetate test	+	+	+	+	+
3	Sterol	For digitoxose	+	+	+	+	+
4	Flavonoid	Shinoda test	+	+	+	+	+
5	Glycoside	Bortrager's test	+	+	+	+	+
6	Fixed oil	Spot test	+	+	+	+	+
7	Steroids	Liebermann Burchard's test	+	+	+	+	+
8	Triterpenoids and phytosterol	Liebermann Burchard's test	+	+	+	+	+
		Salkowski test	+	+	+	+	+
9	Amino acid and proteins	Ninhydrin reagent	-	-	-	-	-
10	Carbohydrates	Benedict's reagent	-	-	-	-	-
11	Saponin	Foam test	-	-	-	-	-

+: Present, -: Not present

Table 6: Physicochemical analysis of PGT (ointment, gel, cream, and physiowax)

Parameter	Ointment Batch			Gel Batch			Cream Batch			Physiowax Batch		
	I	II	III	I	II	III	I	II	III	I	II	III
Solubility												
Cold water	--	--	--	--	--	--	+	+	+	--	--	--
Hot water	--	--	--	--	--	--	++	++	++	--	--	--
Ethanol	--	--	--	--	+	+	+	+	+	--	--	--
Toluene	++	++	++	++	++	++	++	++	++	++	++	++
Skin feeling	++	++	+	+	++	++	++	++	++	++	++	++
Film formation	---	---	+	---	---	---	---	---	---	++	++	++
Cooling sensation	-	-	-	-	-	-	-	-	-	-	-	-
Washability	+	+	+	+	+	+	+	+	+	+	+	+
Homogeneity	++	++	++	+	++	++	++	++	++	++	++	++
Grittiness	---	---	--	---	---	---	---	---	---	---	---	---
Presence of lumps	---	---	---	---	---	---	---	---	---	---	---	---
pH	6.8	6.6	6.6	5.5	5.6	5.5	7.4	7.4	7.4	7.40	7.42	7.42
Viscosity (cps)	481800	480600	445800	152970	156700	158766	158200	158200	123600	482800	482850	482768
Spreadability (cm)	6	6	6	5	5	5	5	5	5	6	6	6
Phase separation	---	---	---	---	---	---	---	---	---	---	---	---
Melting point (°C)	58	60	58	-	-	-	-	-	-	52	50	50

-: Not found, --: Not soluble, ---: Not present, +: Good, ++: Very good

- Stationary phase - Silica gel G.
- Spraying reagent - Liebermann Burchard's reagent.
- Visualization - Under visible light and ultraviolet light (at 254 nm).

Observation

The thin layer chromatography study of PGT and its dosage forms were performed and the R_f observed in between the range of 0.21 to 0.84 as given in the standard monograph. In PGT, PGT ointment and PGT physiowax 10 spots were found, and in PGT gel and PGT cream 7

spots were found. 0.11, 0.15, and 0.34 spots were found in the PGT gel, PGT cream, and PGT physiowax, respectively, that can be given by the excipients or base used for their preparation.

Methods

Stability study was performed by keeping the prepared samples at accelerated temperature conditions. Nine samples of the polyherbal medicated oil (PGT) were taken in an amber-colored glass bottle and kept it at accelerated temperature of 4°C and room temperature of

47°C. The samples were tested for the physicochemical properties like color, odor, pH, specific gravity, etc., at the interval of 24, 48, and 72 hrs to observing the changes.

RESULTS

The present work formulation and evaluation of PGT and its conventional dosage forms were aimed to formulate dosage form using PGT as base

(active pharmaceutical ingredient [API]) with a hope to minimize the inconveniences and to increase the customer acceptability and compliance of PGT. Final quantity obtained of processed PGT and its dosage forms are cited in Tables 2 and 3 and in Figs. 1-5. Macroscopic or organoleptic study of all the prepared formulations is performed, and they comply with the some of the characters with the PGT as shown in Table 4. All the samples of PGT were subjected to the various physicochemical parameters, and all the values comply with the official monograph value. Physicochemical



Fig. 1: Panchaguna taila



Fig. 4: Panchaguna taila cream



Fig. 2: Panchaguna taila ointment



Fig. 5: Panchaguna taila physiowax



Fig. 3: Panchaguna taila gel

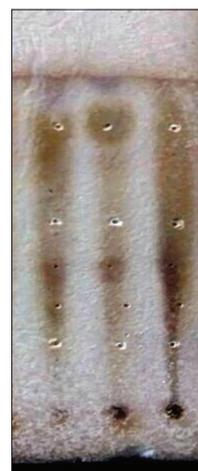


Fig. 6: Panchaguna taila and dosage forms (visible light)

analysis of PGT ointment, PGT gel, and PGT physiowax was performed and all show good results as cited in Tables 6. The PGT, PGT ointment, and PGT gel TLC study shows spots at R_f 0.21, 0.27, 0.38, 0.42, 0.71, 0.81, and 0.84 and cited in Figs. 6 and 7. Spreadability (cm) of prepared dosage forms was performed. PGT ointment and PGT physiowax show 6 cm, and PGT gel and PGT cream show 5 cm spreadability as given in the Figs. 8-11. Phytochemical screening of PGT and its dosage forms was performed,



Fig. 7: *Panchaguna taila* and dosage forms (ultraviolet light at 254 nm)

and all they show positive results for the various phytochemical constituents as given in Table 5. Stability study of PGT performed at accelerated conditions by keeping samples of prepared dosage forms for 3 days. During the stability study, various physicochemical parameters were performed within the specific interval of time. After the comparison between the observed values, there was no significant variation found as cited in Table 7.

DISCUSSION

PGT was prepared by classical principles of Ayurveda and converted into ointment, gel, cream, and physiowax. Precautions were taken during the processing of PGT and the temperature was never exceeded 70°C while preparing ointment, cream, and physiowax. Spreadability of ointment and physiowax was relatively higher than cream and gel (Figs. 8-11). Melting point of physiowax was less than ointment. TLC was performed for PGT, PGT ointment, and PGT cream, and the R_f values were observed in the range of 0.21-0.84. Pharmacognostic, physicochemical, and phytochemical study of formulations was studied, and it showed that all the chemical compounds that were in the prepared oil were also present in the other developed dosage forms. Stability study of PGT was done for 3 days. During the stability study, the various physicochemical studies were done within the specific interval of time of 24, 48, and 72 hrs. The results obtained during the stability study were compared, and no significant variation was found in the results.

CONCLUSION

PGT is polyherbal medicated oil used externally for treating wounds, cut, and burns and used for massaging in rheumatoid arthritis, muscular

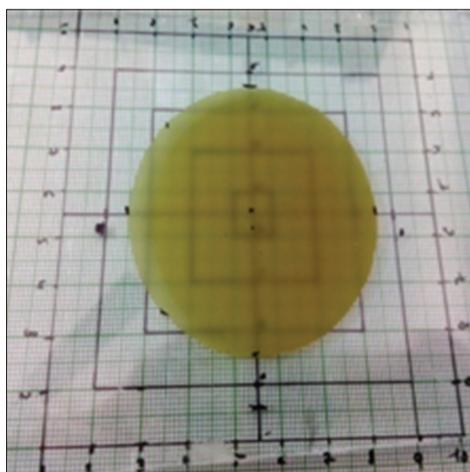


Fig. 8: Spreadability of ointment

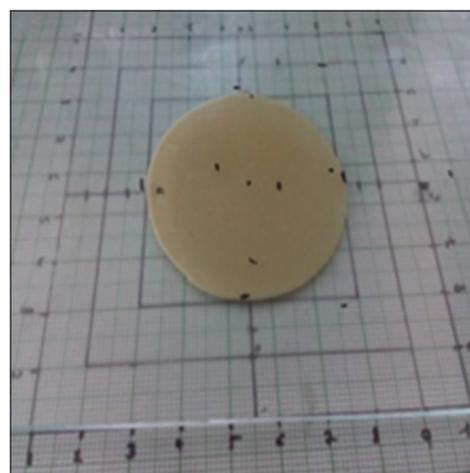


Fig. 10: Spreadability of cream

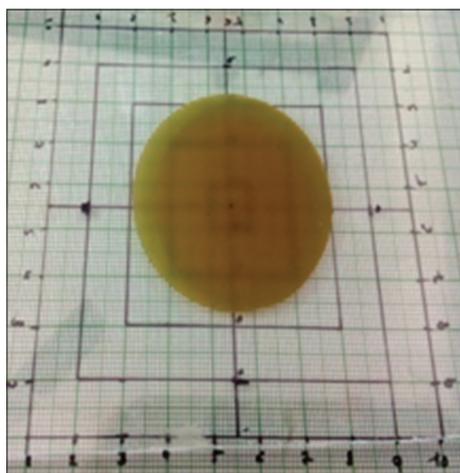


Fig. 9: Spreadability of gel

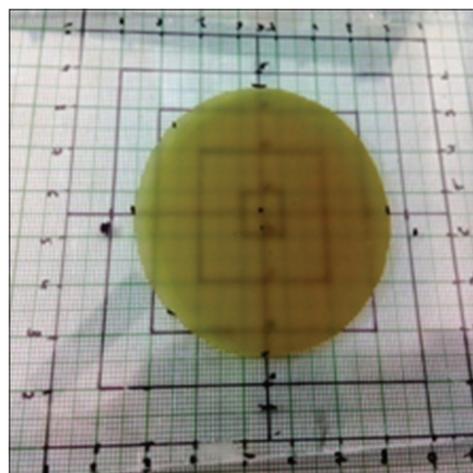


Fig. 11: Spreadability of physiowax

Table 7: Stability study of *Panchaguna taila* was done for the duration of 3 days at accelerated temperature conditions [15]

Sample	Time duration in hour	Temperature °C	Physiochemical parameters					
			Color	Odor	Form	pH	Wt/ml at 25°C	Specific gravity at 40°C
1A	24	4°C	NC	NC	Viscous	3.75	1.094 g	0.9175 g/ml
1B		Room temperature	NC	NC	NC	3.75	1.094 g	0.9177 g/ml
1C		47°C	NC	NC	Less viscous	3.75	1.094 g	0.9177 g/ml
2A	48	4°C	NC	NC	Viscous	3.75	1.094 g	0.9175 g/ml
2B		Room temperature	NC	NC	NC	3.75	1.094 g	0.9177 g/ml
2C		47°C	NC	NC	Less viscous	3.75	1.094 g	0.9177 g/ml
3A	72	4°C	NC	NC	Viscous	3.75	1.094 g	0.9175 g/ml
3B		Room temperature	NC	NC	NC	3.75	1.094 g	0.9177 g/ml
3C		47°C	NC	NC	Less viscous	3.75	1.094 g	0.9177 g/ml

NC: No change

pain, sprains, and joint pains. Using standard PGT as active API, various dosage forms were prepared such as PGT ointment, PGT gel, PGT cream, and PGT physiowax. PGT is greenish brown in color and other dosage forms are brownish and cream in color with characteristic aromatic odor. Analytical standards for PGT such as acid value, saponification value, iodine value, and peroxide value were performed, and obtained results were respectively under the prescribed limit in official monograph. Various physicochemical parameters such as homogeneity, spreadability, pH, and melting point were performed for PGT ointment, PGT gel, PGT cream, and PGT physiowax. Stability study of PGT was done for 3 days under the accelerated conditions. During the stability study of PGT, various physicochemical parameters were performed on the interval of 24, 48, and 72 hrs, and no significant variation found in their physicochemical properties when observed values were compared. PGT ointment, PGT gel, PGT cream, and PGT physiowax containing PGT as active API with various suitable excipients and base are easy to formulate and convenient to apply over the affected area. Exact references for the PGT ointment, PGT gel, PGT cream, and PGT physiowax are not reported earlier, and on trial and error basis, various dosage form was developed. As these, conventional prepared dosage forms non-irritant and possess good spreadability can be replaced the classical oil forms. The prepared dosage form also has elegance that other bases lack an important aspect from patient compliances and customer satisfaction. The wider therapeutic potential of such dosage forms may motivate the researchers for further exploitation of their commercial feasibility.

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