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CONVERSION OF PANCHANIMBA LEPA IN TO PANCHANIMBA OINTMENT & ITS STANDARDIZATION

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ABSTRACT
The Reference for the *Lepa Kalpana* is available in many classical texts. Since Vedic period, *Lepas* were used as external application and integral parts of treatment. The reference for the external application has been mentioned in Charaka Samhita "*Aragwadhiya Adhaya*". The *Lepa Kalpana* is considered as the secondary *Kalpana* of the *Panchvidh Kasaya Kalpana*.[1] Now- a- days due to hectic lifestyle *lepa Kalpana* seems time consuming as patient needs to wait till *Lepa* get totally dried off. So, there is need of modification of *kalpana*. so here attempt is made to modified *lepa Kalpana* into *Panchanimba* ointment. The present formulation "*Panchanimba* Ointment" is modified formulation from the classical formulation "*Panchanimba* Churna". The formulation "*Panchanimba* Ointment" is combination of *Nimba patra*, *Nimba puspa*, *Nimba phala*, *Nimba tvaka*, and *Nimba moola*. i.e., *Panchanga* of *Nimba* are taken as the main ingredients. *Panchanimba churna* is described in *Kustharogadhikara* as internal medication, but due to its strong bitterness it's not easy for patients to take it orally. If *Panchanimba lepa* used in *kustharoga* than *lepa Kalpana* has some drawbacks like stability, inconvenient to use because it is not available in readymade form and difficult to transportation.[2] So, here invention of new formulation "*Panchanimba* Ointment" has been done with its Standardization.

KEYWORDS: *Lepa kalpana*, *Panchanimba*, Ointment.

INTRODUCTION
Lepa kalpana:
The reference for the *Lepa Kalpana* is available in many classical texts. Since Vedic period, *Lepa*s were used as external application and integral parts of treatment. The reference for the external application has been mentioned in Charaka Samhita "*Aragwadhiya Adhaya*". The *Lepa Kalpana* is considered as the secondary *Kalpana* of the *Panchvidh Kasaya Kalpana*, *Lepa Kalpana* is a form of *Kalka Kalpana*. *Kalka* and *Lepa* both are the same. The purpose for which it is used decides its nomenclature. *Lepa* may be equated with paste or plaster, though these words are not competent to explain *Lepa* in all its aspects elaborately. Drugs in wet form are to be crushed to fine paste form. If the drugs are in dry form, then they should be converted into paste by adding specified amount of liquid. This paste is to be applied externally and is known as *Lepa*.

Lepa should not be followed by another *Lepa*, because the density and compactness of material increases, which causes rise in local temperature, burning sensation and pain. It is suggested that, *Lepa*. The topical formulations should be gently rubbed in an upward or reverse direction of the hairs over the skin to make the action of application quicker and more effective. Because of this, the drug enters into the *Romakupa* and further gets absorbed through *Swedavahi Srotas* and *Siramukh* leading to quicker absorption of medicament and desired effects.

Shelf life for *Lepa*, *Churna* has been mentioned as 2 years in the revised Gazette notification GSR No.789(E) dated on 12 August, 2016 in Drug and Cosmetic Act 1940.

Ointment[3]
Ointments are the soft semisolid preparations meant for external application to the skin or mucous membrane. They usually contain a medicament or medicaments dissolves, suspended or emulsified in the base. Ointments are used for their emollient and protective action to the skin. They may also be used as vehicles or bases for the topical application of medicinal substances.

Ointment bases:
The ointment bases are classified as follows:
1. Oleaginous bases

2. Absorption bases
3. Emulsion bases
4. Water soluble bases

Preparation of ointment:
There are two methods of preparation of ointments for extemporaneous compounding:
1. Trituration method.
2. Fusion method.

Due to inconvenience of *Lepa* application, there is need for pharmaceutical modification of the same for better enhancement of efficacy, shelf life and acceptability. Considering the significance of topical applications, the later works have developed on ointment preparation which has its own benefits in therapeutics.

The present formulation "*Panchanimba* Ointment" is modified formulation from the classical formulation "*Panchanimba Churna*". The formulation "*Panchanimba* Ointment" is combination of *Nimba patra, Nimba puspa, Nimba phala, Nimba tvaka,* and *Nimba moola*. i.e., *Panchanga* of *Nimba* are taken as the main ingredients. *Panchanimba churna* is described in Kustharogadhikara as internal medication, but due to its strong bitterness it's not easy for patients to take it orally. If *Panchanimba churna* used as *Lepa* in *kustharoga* than *Lepa Kalpana* as some drawbacks like stability, inconvenient to use because it is not available in ready-made form and difficult to transportation. As "*Panchanimba* Ointment" is topical formulation and very easy to apply on effected parts with more stability and more conveniency.

Stage 1: Preparation of *Panchanimba Taila.* (PNT)
Stage 2: Preparation of *Panchanimba* ointment. (PNO)
Stage 1: Preparation of *Panchanimba Taila.* (PNT)

Table 1: showing proportion and batch size of PNT

Ingredients	Proportion	Batch 1	Batch 2	Batch 3
Panchanimba kalka (g)	1 Part	83.33	83.33	83.33
Tila taila (ml)	4 Part	333	333	333
Jala (water) (ml)	16 Part	1333	1333	1333

Procedure
Kalka was prepared from the *panchanga* of *nimba* and made it to bolus form with addition of water. *Tila taila* was taken into the S.S. Vessel. Prepared bolus was added in *taila* after 5 minutes followed by *jala* with intermitting stirring. Heating duration was adjusted so as to complete the *Sneha paka* by 3 days and process was carried out till *Sneha siddhi lakshana* achieved. The prepared *taila* was filtered through cotton cloth in warm state and stored in a container after self-cooling.[4]

Observation
- The colour of *taila* turned yellow to dark yellow on heating.
- After addition of *kalka*, the colour of *taila* changed to greenish and mild froth was appeared.
- The characteristic smell of *kalka dravya* was felt during heating process.
- After 90 min of heating, *kalka* could be rolled between fingers easily without sticking and didn't make any sound when put on fire.
- After 120 min of heating, *kalka* started sticking to the bottom of vessel and phenodgama was observed.
- Final colour of *Panchanimba Taila* was dark green.

AIMS AND OBJECTIVES:
1. To modify *Panchanimba Lepa* in to *Panchanimba* Ointment.
2. To develop the SMP of *Panchanimba* Ointment.

MATERIALS AND METHODS
The all reference of *Lepa Kalpana* and Ointment as topical formulation are collected, collated and compiled from *Ayuvedic* classics, authentic research journals and various pharmaceutics books.

Collection of plant material:
For preparation of *Panchanimba* Ointment the *Panchanga* of *Nimba* was collected from the premise of our institute J. S. Ayurveda Mahavidyalaya, Nadiad.

METHOD
The method followed for the preparation of *Panchanimba* Ointment is reference from pharmaceutical book. The Ointment were prepared in the Laboratories of the PG department of Rasashastra and Bhaishajya *Kalpana*, JASM, Nadiad.

Pharmaceutical processing:
To establish pharmaceutical standardization, three batches of *Panchanimba* Ointment were prepared.

The entire pharmaceutical study was carried in two stages as mentioned below,

Table 2: Showing temperature of PNT at different stages.

Temperature (℃) at	Material (℃)			Flame (℃)		
	Batch 1	Batch 2	Batch 3	Batch 1	Batch 2	Batch 3
Starting point	30	34	32	390	400	400
The time when *kalka* added	70	76	68	290	300	300
The time when *jala* added	50	52	48	320	340	310
At the boiling stage	96	98	98	420	430	420
At the time to *phenodgma*	98	96	96	420	400	416
At the time of filtration	34	32	32	-	-	-

Stage 2: Preparation of *Panchanimba* ointment. (PNO)

Three Pilot batch were prepared in order to develop desired characteristics in the product sample.

Ingredients:

Table 3: showing phase wise ingredients with quantity of main batch of PNO.

Sr. No.	Ingredients	Batch 1(g)	Batch 2(g)	Batch 3(g)
1	*Panchanimba taila*	30 ml	30 ml	30 ml
2	Bees wax	20	20	20
3	Lanolin (wool fat)	15	15	15
4	White petroleum jelly	30	30	30
5	Hard paraffin wax	05	05	05
6	Perfume	0.5	0.5	0.5

Table 4: Showing observation of main batch of PNO.

Batch	Time (min)	Temperature ℃	Observation	Consistency
Batch 1	0	30	Starting of heating oil phase on hot water dish	Liquid form
	5	80	Heating continues	Liquid form
	10	75	Adding all ingredients in to *Panchanimba taila*	Liquid form
	12	42	Continues stirring in one direction	Slightly semisolid form
	15	30	Store in container	Ointment like consistency
Batch 2	0	32	Starting of heating oil phase on hot water dish	Liquid form
	5	80	Heating continues	Liquid form
	10	68	Adding all ingredients in to *Panchanimba taila*	Liquid form
	12	44	Continues stirring in one direction	Slightly semisolid form
	15	30	Store in container	Ointment like consistency
Batch 3	0	30	Starting of heating oil phase on hot water dish	Liquid form
	5	80	Heating continues	Liquid form
	10	72	Adding all ingredients in to *Panchanimba taila*	Liquid form
	12	48	Continues stirring in one direction	Slightly semisolid form
	15	30	Store in container	Ointment like consistency

RESULTS

Table 5: showing results of PNO.

Parameters	Batch 1	Batch 2	Batch 3	Average
Initial Quantity (g)	100	100	100	100
Obtained Quantity (g)	94	96	99	96.33
Obtained	94	96	99	96.33

Quantity (%)				
Loss (g)	06	04	01	3.66
Loss (%)	06	04	01	3.66
Reason of loss	Due to sticking to the vessel			

Equipment specification:

Table 6: Showing equipment with their specifications.

Sr. No.	Equipment	Specification
1.	vessel	Material – stainless steel Diameter- 14.5cm, Depth- 7cm, Capacity- 500ml
2.	Stainless steel spatula	Material – stainless steel Diameter- 15cm, Depth- 8cm, Capacity- 700ml
3.	Heating device	Hot water dish bath 10litre capacity, 0-110℃ temperature
4.	Weighing machine	Electronic precision balance model- CTG 602-600 Maximum – 600g, Minimum- 0.02g.
5.	Thermometer	0-150 ℃ mercury filled glass tube 6.5mm diameter x

Unit process of ointment preparation:

- Preparation of *Panchanimba Taila*.
- Heating of emulsion base with *taila* at mild heat up to 80℃.
- Addition of emulsion base into *taila* with continuous stirring.
- Continuous stirring till ointment like consistency.
- Stirring till room temperature.
- Addition of perfume.
- Storage in a clean airtight tube.

Analytical study:

1. Analysis of raw material (All the Ingredients of *Panchanimba Taila*)

Organoleptic characteristics

Table 7: Showing organoleptic characteristics of raw material.

Sr. No.	Ingredients	Colour	Appearance	Touch	Taste	Odour
1	*Nimba patra*	Dark greenish	Powder	Smooth	Bitter	Characteristic
2	*Nimba puspa*	Light greenish	Powder	Smooth	Bitter	Characteristic
3	*Nimba phala*	Dark brown	Coarse Powder	Rough	Bitter	Characteristic
4	*Nimba tvaka*	Brown	Coarse Powder	Rough	Bitter	Characteristic
5	*Nimba mula*	Whitish	Coarse Powder	Rough	Bitter	Characteristic

2. Analysis of intermediate products

Organoleptic characteristic of *panchanimba taila*

Table 8: Showing Organoleptic characteristic of PNT

Sr. No.	Parameters	Results		
		Batch 1	Batch 2	Batch 3
1	Colour	Greenish	Greenish	Greenish
2	Odour	Characteristic	Characteristic	Characteristic
3	Touch	Smooth	Smooth	Smooth
4	Taste	Bitter	Bitter	Bitter
5	Appearance	Reduced translucent	Reduced translucent	Reduced translucent

Physico-chemical analysis of *Panchanimba Taila*

Table 9: Showing Physico-chemical analysis of PNT.[5]

Sr. No.	Parameters	Results			
		Batch 1	Batch 2	Batch 3	Average
1	pH	08	08	08	08
2	Specific gravity kg/m^3	0.938	0.937	0.938	0.937

3	Refractive index m/sec	1.474	1.476	1.476	1.475
4	Saponification value mgKOH/g	186	184	186	185
5	Viscosity sec	30	28	30	29.33
6	Acid value mgKOH/g	3.4	3.3	3.4	3.36

3. Analysis of finished products

Organoleptic characteristic of *Panchanimba* Ointment[6]

Table 10: Showing organoleptic characteristic of PNO.

Sr. No.	Parameters	Results		
		Batch 1	Batch 2	Batch 3
1	Color	Green colored	Green colored	Green colored
2	Odour	Characteristics	Characteristics	Characteristics
3	Touch	Soft	Soft	Soft
4	Appearance	Waxy ointment	Waxy ointment	Waxy ointment

Heavy metal analysis:

Table 11: Showing heavy metal analysis of *panchanimba* ointment.

Sr. No.	Parameters	Instrument detection limit/ permissible limit (mg/L)	*Panchanimba* Ointment
1	Mercury	0.279 ppm	BDL
2	Lead	0.036 ppm	BDL
3	Cadmium	0.001 ppm	BDL
4	Arsenic	0.0279 ppm	BDL

***BDL- Below Detection Limit**

Microbial limit test:

Table 12: Showing microbial limit test of *panchanimba* ointment.

Sr. No.	Parameters	Results
1	Total plate count	645 cuf/g
2	Total yeast and mould count	15 cuf/g
3	*E.coli*	Absent
4	*Salmonella sp.*	Absent
5	*S. aureus*	Absent
6	*P. aeruginosa*	Absent

DISCUSSION

As the *Lepa Kalpana* has some draw back invention of this new formulation has been done i.e., *Panchanimba* Ointment and maintained its SOP to develop the SMP. The pilot batches were prepared for fixing suitable proportion for ointment preparation and to avoid batch to batch to batch variations.[7] There was no fungus growth noted in those batches.

The sample also sent for analysis to develop its Standardization. The organoleptic character of raw material. Intermediate product and final product shows ingredients specific characteristics. There was no considerable difference seen in each parameter.

Physico- chemical analysis was also under ideal suitable range and also the Heavy metal analysis were found to below detection level in all the sample of PNO i.e, Hg, Cd, As, Pb.

On observing Microbial growth, all the microbes were found absent in PNO i.e., *E.coli*, *Salmonella sp.*, *S. aureus*, and *P. aeruginosa.*

Pharmaceutical process of *Panchanimba* Taila

- Figure 1: *Kalka* was prepared from the *panchanga* of *Nimba* and made it to bolus form with addition of water
- Figure 2: *Tila taila* was taken into the S.S. Vessel. Prepared bolus was added in *taila* after 5 minutes followed by *jala* with intermitting stirring
- Figure 3: Heating duration was adjusted so as to complete the *Sneha paka* by 3 days
- Figure 4: Process was carried out till *Sneha siddhi lakshana* achieved
- Figure 5: The prepared *taila* was filtered through cotton cloth in warm state and stored in a container after self-cooling

Pharmaceutical process of *panchanimba* ointment

- Figure 1: Preparation of *Panchanimba Taila*
- Figure 2: Heating of emulsion base with *taila* at mild heat up to 80℃
- Figure 3: Addition of emulsion base into *taila* with continuous stirring
- Figure 4: Stirring till room temperature
- Figure 5: Addition of perfume
- Figure 6: Storage in a clean airtight container.

CONCLUSION

We can conclude that comprehensive description on *Lepa Kalpana* is available in classics regarding their classification, types, methods of preparation, precautions etc. The adopted method for preparation of PNO can be considered as standard. Average loss 3.66 was noted. The heavy metal analysis and microbial count were found below permissible limits in all the sample of ointment indicating their standards and safety as well. On the basis of various analytical parameters, we can conclude that *Panchanimba* ointment is as standard topical formulation and can be easily used to treat the skin disease as well as it's a new dosage form of present era and mode of application is so easy as comparison to *Lepa*.

REFERENCES

1. The Charak Samhita with Ayurved Dipika's Ayushi hindi commentary, edited and translated by Vd. Harish Chandra Singh Kushwaha, Chaukhambha orientalia Varanasi, sutrasthana, 2012.
2. Sharangadhara, Sharangadhara Samhita, 'Dipika' Hindi commentary, commented by Brahamanand Tripathi, Madhyam Khanda madhyama khanda, Choukhamba Surbharti Prakashana, Varanasi, 2010; 172: 2 – 1.
3. Introduction to Pharmaceutics. by- A. K. Gupta . By -CBS Publishers and Distribuyors Pvt.Ltd, 2000; 2, 4: 184.
4. Ayurvedic pharmacopeia of India, 2: 187.
5. Sharangadhar Samhita of Acharya Sharangadhar "Jiwanprada" hindi commentary by Dr. Smt. Shailaja Srivastava, Chaukhambha Orientalia Varanasi, uttarkhanda, 2011; 11: 1- 426.
6. Anonymous, The Ayurvedic Formulary of India. part- B, Paribhasha, New Delhi, Govt. of India, 2000; 1: 2.
7. Hiremath S. G, The text book of Bhaisajya *Kalpana*, IBH Prakashana, Bangalore, 2005; 2: 92.