

PREPARATION OF NIMBADI YONI VARTI CONVERTED INTO MODERN VAGINAL SUPPOSITORY DOSAGE FORM FOR THE MANAGEMENT OF SHWETAPRADAR

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Abstract

The goal of this study was converted *Ayurveda* well known dosage form into modern dosage form for treatment of *Shwetapradara* (Leucorrhoea) i.e. *Yoni Varti* into modern vaginal suppository dosage form. Suppository form of the drug does not need any special precautionary measures for its administration. Even patient can administer it by herself. The present study is aimed to find out a method of treatment, which will impart a permanent, easy, effective cure and is with no or minimal side effect, which makes it widely acceptable by the modern world. The term leucorrhoea means, strictly speaking, white discharge. It is the most common complaint for which reproductive age women consult the gynaecologist. *Shwetapradara* (Leucorrhoea) is not directly mentioned in classics, but a lot of single as well as compound drugs are described in various contexts for internal as well as external use for it. Out of them *Nimbadi Yoni Varti* - A combination of *Nimba Patra* (*Azadirachta indica* A. Juss.), *Triphala* (*Amalaki* (*Embllica officinalis* Linn), *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.), *Madhu* (*Apis cerana* Fabr. (Source) and *Su. Sphatika* (alum) selected and converted into modern dosage form for management of *Shwetapradara*. The result shows that *Nimbadi Yoni Varti* is highly effective for the management of *Shwetapradara*, and more convenient with no apparent evidence of complications.

Key words: *Nimbadi Yoni Varti*; Vaginal suppository; *Shwetapradara*.

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INTRODUCTION

The term leucorrhoea means, strictly speaking, white discharge.^[1] It is the most common complaint for which reproductive age women consult the gynaecologist. Leucorrhoea (*Shwetapradara*) is the symptom of several reproductive tract infections which is not directly mentioned in classics, but *Shwetavrava* (leucorrhoea) and *Yonivrava* (vaginal discharge) word has been used to indicate abnormal discharge per vagina.

In *Ayurveda Aushadha* (medicine) is considered as one of the four fold constituents of *Chikitsa* (treatment) – *Chatushpada* (four fold) and it has been placed next to the physician.^[2] The drug is “an agent” which a physician employs as an instrument in restoring the equilibrium of the body tissues.^[3] *Ayurvedic* literature contains infinite number of herbs. Their actions have been explained on the basis of their *Rasa* (taste), *Guna* (property), *Virya* (active principal), *Vipaka* (bio transformation) and *Prabhava* (specific action). Out of them *Nimbadi Yoga*^[4] - a combination of *Nimba Patra* (*Azadirachta indica* A. Juss.), *Triphala* (*Amalaki* (*Emblica officinalis* Linn), *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.)), *Madhu* (*Apis cerana* Fabr. (source) and *Su. Sphatik* (alum) selected due to *Tridoshashamaka* (Pacifies all three vitiated humors), *Krimighna* (carminative, germicidal), *Kandughna* (destroys itching), *Stambhana* (stops the secretions), *Shoshana* (absorbent), *Samgrahi* (ceases secretions), *Kledaghna* (ceases harmful infectious phlegm), *Kaphaghna* (destroys excess Phlegm), *Putihara* (decreases septic conditions), *Vranasodhana* (purifies the wound), *Vranaropana* (wound healing) property.

In classics, a lot of single as well as compound drugs are described in various contexts for internal as well as external use for *Shwetapradara* (leucorrhoea). Out of them

Yoni Varti was because it does not need any special precautionary measures for its administration. Even patient can administer it by herself. This makes it widely acceptable by the modern world.

MATERIALS AND METHODS

The Drugs

The raw drugs for *Nimbadi Yoni Varti* (*Nimba Patra* (*Azadirachta indica* A. Juss.), *Triphala* [*Amalaki* (*Emblica officinalis* Linn), *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.)], *Madhu* (*Apis cerana* Fabr. and *Su. Sphatik* (alum) were obtained from Pharmacy of Gujarat Ayurved University, Jamnagar. Glycerin, Gelatin powder, Distilled water, Propyl Paraben Sodium Salt and Paraffin Liquid were obtained from local market from Jamnagar. For preparation of *Nimbadi Varti*, dry water soluble extract of *Nimba* (*Azadirachta indica* A. Juss.), and *Triphala* [*Amalaki* (*Emblica officinalis* Linn), *Haritaki* (*Terminalia chebula* Retz.), *Bibhitaki* (*Terminalia bellirica* Roxb.)] was prepared at Pharmacy of Gujarat Ayurved University, Jamnagar and *Nimbadi Yoni Varti* was prepared at Institute of Ayurvedic Pharmaceutical Sciences, Gujarat Ayurved University, Jamnagar.

Plan of study

Criteria for selection of Drugs

Selection of Drugs

Nimbadi Yoga is *Anubhuta Yoga*^[5] which was used for *Shwetapradara* due to its *Stambhana* (stops the secretions), *Krimighna* (carminative, germicidal), *Kandughna* (destroys itching), *Vranasodhana* (purifies the wound), *Vranaropana* (wound healing), *Putihara* (decreases septic conditions), etc. properties which converted into modern vaginal suppository dosage form for conveniently of the patients and Vaidya also.

Contents of *Nimbadi Yoga* are tabulated in Table 1.

Preparation of Drugs

Nimbadi Yoni Varti :

Ref.: *Anubhuta yoga* ^[12] (formula which resulted followed as a consequence) *Nimbadi Varti* formula was made after many trials from various formulations.

Ingredients of *Nimbadi Yoni Varti* are mentioned in Table 2.

Procedure:

- *Nimbadi Varti* formula was made after many trials from various formulations.
- *Nimbadi* (*Nimba Patra: Triphala Yavakuta-4:1*) *Kashaya* (decoction) was prepared by *Kashaya Vidhi* and then filtered.
- Evaporation of water was done from filtrate *Kwatha* (decoction) by mild heating up to semi liquid stage.
- Then it had kept in oven for complete drying at temp 45–50°, after completely drying, it was scraped and made into fine powder.
- Gelatin powder after being soaked with distilled water was heated until it melted.
- Glycerin was added to molten Gelatin and *Nimbadi Ghana* (dry *Nimbadi* extract) was sprinkled on this Gelato-Glycerin base.
- When it turned into a homogeneous mixture, *Madhu* (honey) was added and the whole mixture was poured into lubricated mould with solution of *Su. Sphatika* (alum) & preservative and allowed to set and chill in refrigerator.
- Finally the *Varti* was packed in Aluminium foil.

Weight: About 3 gm.

Shape: Oviform shape.

Size: About 1.5 " x 0.5"

Physical property of *Nimbadi Yoni Varti*

It is dark black in colour; characteristic in odour; smooth & soft in touch and resemble like soft gelatin capsule. (Figure 1)

Storage

Nimbadi Varti had kept in well closed container and stored in refrigerator.

Pharmacognostical study

Pharmacognostical Study of the raw drugs was carried out at the Pharmacognosy Department of I.P.G.T. & R.A., Jamnagar.

Analytical study

Physico-chemical analysis for *Nimbadi Varti* was carried out at the Pharmaceutics Department of I.P.G.T. & R.A., Jamnagar, and results are as follows:

Data of Physico-chemical Analysis

Quantitative test

Uniformity of weight, Disintegration time and pH Value carried out in quantitative test and results were show on Table 3.

Qualitative test

Test for Carbohydrates, Reducing Sugar, Fats & Oils, Steroids, Glycosides, Cardiac Glycosides, Saponin Glycosides, Flavonoids, Alkaloids and Test for Tannins & Phenolic Compound were carried out in qualitative test and results show in Table 4.

Thin Layer Chromatography (TLC)

Sample: Methanolic extract of *Nimbadi Varti*

Adsorbent layer: Silica gel G pre-coated plates

Solvent System: Toluene: Ethylacetate (6.5:4.0)

Solvent Front: 6.0 cm

Spray: 10% Feric chloride (aqu.)

Thin Layer Chromatography (TLC) of *Nimbadi Yoni Varti* is mentioned in Table 5. Thin Layer Chromatography (TLC) of *Nimbadi Yoni Varti* - Before spray shown in Figure 2 and After spray shown in Figure 3.

Antimicrobial study

As the drug possesses the property to cure the leucorrhoea -It is important to know whether it is to inhibit the growth of micro-organisms which are responsible for the infection in genital tract.

The sample was sent to ISO 9001:2008 certified Shrey Pathology laboratory situated in Jamnagar.

Observations and Results as follow

Antibacterial activities of *Nimbadi Yoni Varti*, *Nimbadi Kwatha* and *Nimbadi Ghana* are tabulated in Table 6.

Antifungal activities of *Nimbadi Yoni Varti*, *Nimbadi Kwatha* and *Nimbadi Ghana* are tabulated in Table 7. Posology is mentioned in Table 8. The Antibiogram report is shown in Figure 4.

Treatment protocol

Method of administration of *Yoni Varti*

- Patient was advised to empty the bladder
- Then asked to lie on her back with thighs flexed and *Yoni Varti* was inserted deep in vagina (Posterior Fornix).

Advice

- To avoid intercourse during the course of treatment.
- To avoid spicy, fried, bakery items and fermented items and over eating.
- To avoid mental stress.
- To take green leafy vegetables, simple food and milk.

Follow up

After completion of course patients were advised to report every 15 days for follow up study which was carried out for 1 month. During the follow up study further recurrence in the signs & symptoms were recorded.

OBSERVATION AND RESULTS

Overall Effect of Therapies on 58 patients of *Shwetapradara* is tabulated in Table 9. ^[13] ADR during course of treatment on 58 patients of *Shwetapradara* is mentioned in Table 10.

DISCUSSION

Leucorrhoea (*Shwetapradara*) is the most common complaint for which reproductive age women consult the gynecologist. The term leucorrhoea means a running of flow of white substances.^[14] The management of leucorrhoea should be conducted according to the causative factors. Physiological leucorrhoea needs no treatment but only proper counseling.

Table 1: Contents of Nimbadi Yoga

No.	Drug	Latin Name	Family	Part used
1.	<i>Nimba</i> ^[6]	<i>Azadirachta indica</i> A. Juss.	Meliaceae	Leaf
2.	<i>Amalaki</i> ^[7]	<i>Embllica officinalis</i> Linn.	Euphorbiaceae	Fruit
3.	<i>Haritaki</i> ^[8]	<i>Terminalia chebula</i> Retz.	Combretaceae	Fruit
4.	<i>Bibhitaki</i> ^[9]	<i>Terminalia bellirica</i> Roxb.	Combretaceae	Fruit
5.	<i>Madhu</i> (honey) ^[10]	<i>Apis cerana</i> Fabr.(source)	Apidae	-
6.	<i>Sphatika</i> ^[11]	-Potassium alum $K_2SO_4(Al_2SO_4)_3 \cdot 24 H_2O$	-	-

Table 2: Ingredients of Nimbadi Yoni Varti

Ingredients	For 1 tab. of 3 gm.
1. Dry extracts of <i>Nimba</i> and <i>Triphala</i>	1.5gm
2. <i>Madhu</i>	0.06ml
3. <i>Su. Sphatika</i>	0.1gm
4. Gelatin powder	0.9gm
5. Glycerin	2.4ml
6. Distilled water	0.5ml
7. Propyl Para Ben Sodium Salt	0.01gm
8. Paraffin Liquid	as lubricant

Table 3: Quantitative test results of Nimbadi Varti

Parameters	Nimbadi Varti
Uniformity of weight (gm)	
Maximum weight	3.793
Minimum weight	3.014
Average weight	3.552
Disintegration time	14 minutes
pH Value (By pH meter)	4.16

Table 4: Qualitative test results of Nimbadi Varti

Name of Test	Result
Test For Carbohydrates	+ve
Test For Reducing Sugar	+ve
Test For Fats & Oils	+ve
Test For Steroids	-ve
Test For Glycosides	-ve
Test For Cardiac Glycosides	-ve
Test For Saponin Glycosides	+ve
Test For Flavonoids	+ve
Test For Alkaloids	+ve
Test For Tannins & Phenolic Compound	+ve

Table 5: Thin Layer Chromatography (TLC) of Nimbadi Yoni Varti

Before Spray				After Spray	
UV-366nm		UV-254nm		UV-366nm	
No. of Spot	Rf Value	No. of Spot	Rf Value	No. of Spot	Rf Value
1	0.08	1	0.16	1	0.41
2	0.13	2	0.33	2	0.58
3	0.16	3	0.41	3	0.75
4	0.33				
5	0.41				
6	0.91				

Table 6: Antibacterial activities of Nimbadi Yoni Varti, Nimbadi Kwatha and Nimbadi Ghana

Antibacterial agent	Bacteria			
	Streptococci	Staphylococcus Aureus	E. Coli	Klebsiella
Nimbadi Varti	++/(3mm)	++/(3mm)	++/(3mm)	++/(3mm)
Nimbadi Kwatha	++/(3mm)	++/(3mm)	Resistant	Resistant
Nimbadi Ghana	++/(3mm)	++/(3mm)	++/(3mm)	++/(3mm)

*+++ = Highly sensitive, ++= Moderately sensitive, += Poorly sensitive

Table 7: Antifungal activities of Nimbadi Yoni Varti, Nimbadi Kwatha and Nimbadi Ghana

Antibacterial agent	Fungus	
	Candida Albicance	Aspergillus Flavus
Nimbadi Varti	+/(1mm)	+/(1mm)
Nimbadi Kwatha	+/(1mm)	+/(1mm)
Nimbadi Ghana	+/(1mm)	+/(1mm)

*+++ = Highly sensitive, ++= Moderately sensitive, += Poorly sensitive

Table 8: Posology

Group	Drug	Method	Route	Dose	Duration
A	Nimbadi Yoga	Yoni Varti	Vaginal	1 tab. of 3gm	7 days

Table 9: Overall Effect of Therapies on 58 patients of Shwetapradara^[13]

Status	Nimbadi Yoni Varti	
	No. of patients	%
Complete remission	51	87.93
Markedly Improved	07	12.07
Improved	00	00.00
Unchanged	00	00.00

Table 10: ADR during course of treatment on 58 patients of Shwetapradara

ADR	Number of patients	%
Burning sensation in vagina	02	1.87

Figure 1: *Nimbadi Yoni Varti*

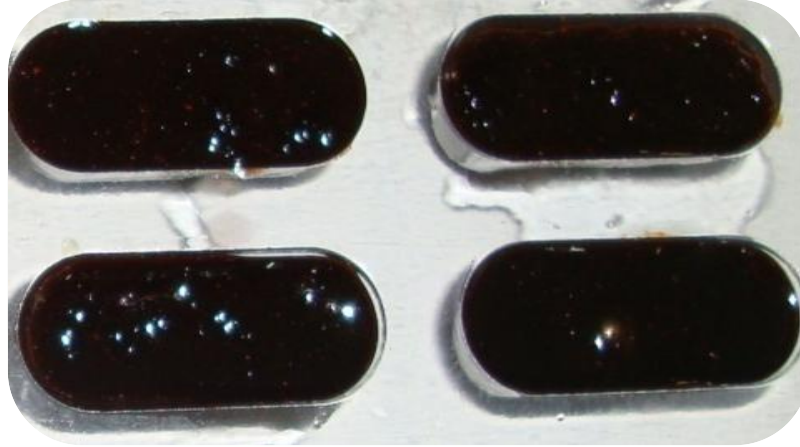


Figure 2: Thin Layer Chromatography (TLC) of *Nimbadi Yoni Varti*- Before spray

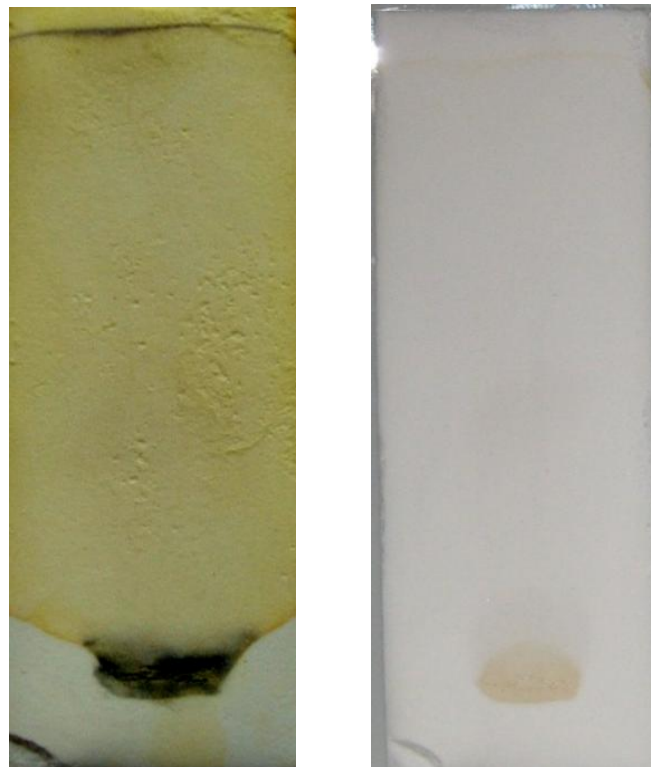


Figure 3: Thin Layer Chromatography (TLC) of *Nimbadi Yoni Varti*- After spray

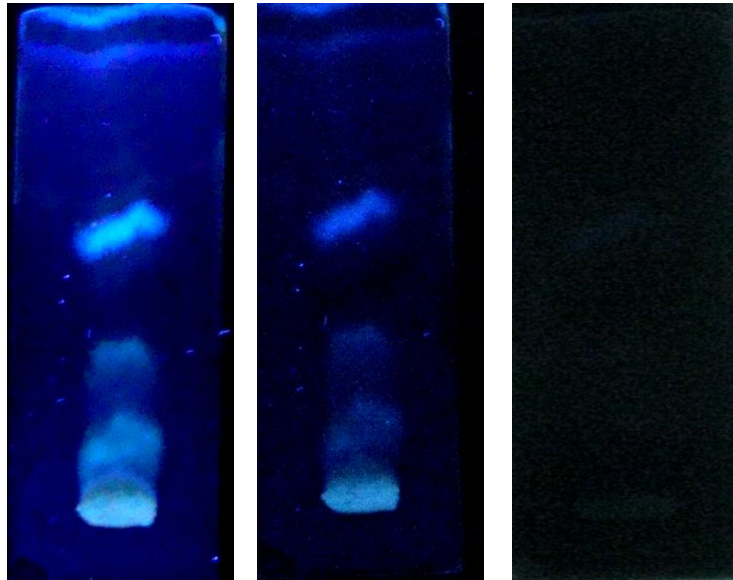
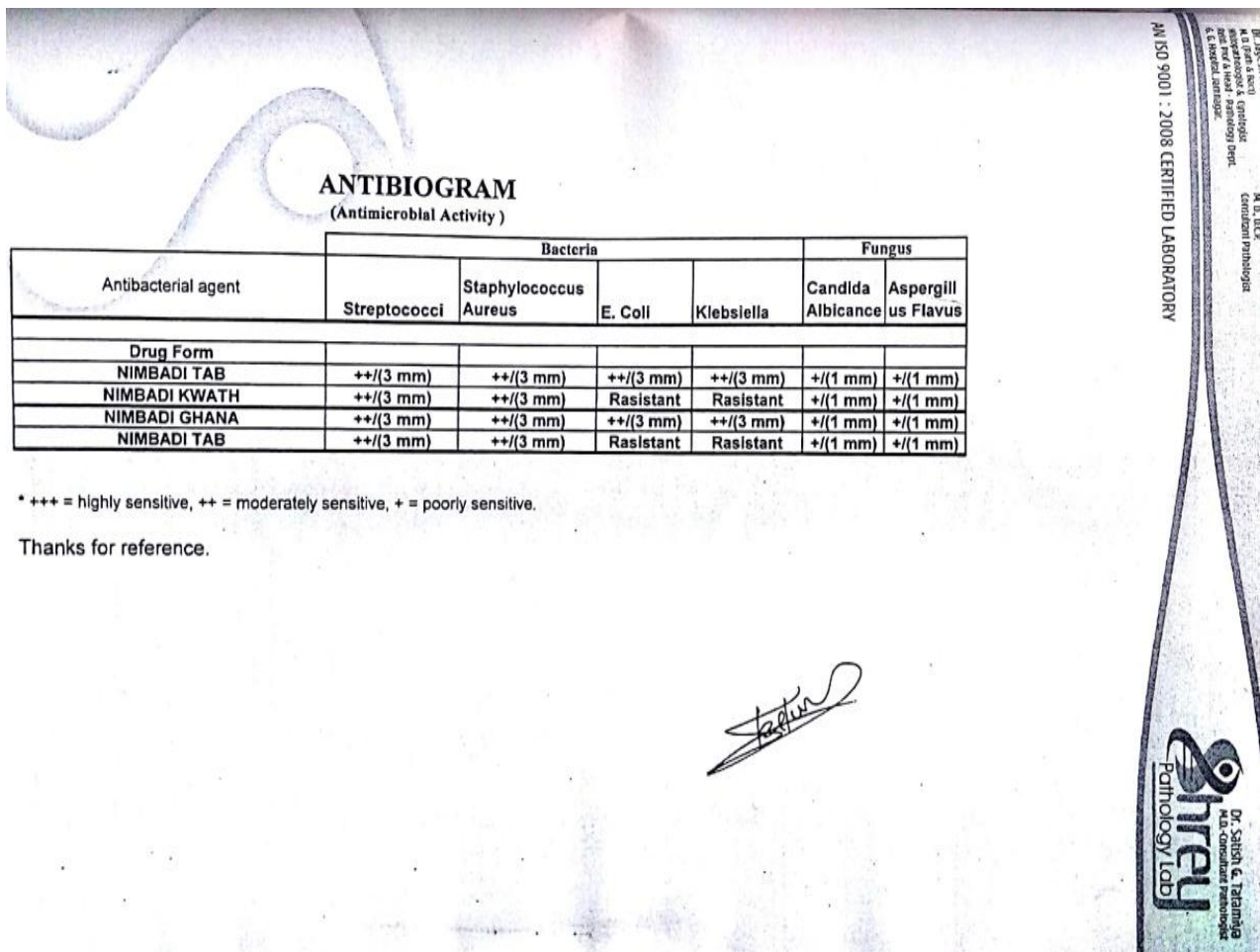


Figure 4: Antibigram report



In *Ayurveda* many pharmaceutical preparations have been mentioned for the treatment of *Shwetapradara*. From such recipes, *Nimbadi Yoga*^[15] - a combination of *Nimba Patra*, *Triphala*, *Madhu* and *Su. Sphatika* selected due to *Tridoshashamaka* (Pacifies all three vitiated humors), *Krimighna* (carminative, germicidal), *Kandughna* (destroys itching), *Stambhana* (stops the secretions), *Shoshana* (absorbent), *Samgrahi* (ceases secretions), *Kledaghna* (ceases harmful infectious phlegm), *Kaphaghna* (destroys excess Phlegm), *Putihara* (decreases septic conditions), *Vranasodhana* (purifies the wound), *Vranaropana* (wound healing) as well as antimicrobial, antifungal, antibacterial properties which lead to *Samprapti Vighatana* (breakdown pathology) and successfully control & cure *Shwetapradara* (leucorrhoea). One of the reasons behind the selection of this *Yoga* (formulation) is that its drugs are easily available in sufficient quantity, non controversial, economical and also effective by experience.

In classics, a lot of single as well as compound drugs are described in various contexts for internal as well as external use for *Shwetapradara* (leucorrhoea). *Acharya Charaka* has mentioned to use *Madhuyukta Varti* of *Kashaya Rasa Dravyas* in *Shwetapradara Chikitsa*.^[16]

So we were selected *Nimbadi Yoni Varti* and converted into modern vaginal suppository dosage form for the present study because it does not need any special precautionary measures for its administration. Even patient can administer it by herself. This makes it widely acceptable by the modern world.

A vaginal suppository provides targeted relief from conditions affecting the vagina. They also tend to be fast acting due to their rapid absorption. They become liquid within the vagina as they warm to the body's temperature. Suppositories usually require

fewer dosages than others form and tend to provide symptom relief sooner.

Effect of therapy

Probable mode of action of *Nimbadi Yoga*

Nimbadi Yoga^[17] (*Nimba Patra*, *Triphala Yavakuta*, *Su. Sphatika* and *Madhu*) has *Tridoshashamaka* (Pacifies all three vitiated humors), *Krimighna* (carminative, germicidal), *Kandughna* (destroys itching), *Stambhana* (stops the secretions), *Shoshana* (absorbent), *Samgrahi* (ceases secretions), *Kledaghna* (ceases harmful infectious phlegm), *Kaphaghna* (destroys excess Phlegm), *Putihara* (decreases septic conditions), *Vranasodhana* (purifies the wound), *Vranaropana* (wound healing) *Rasayana* (rejuvenating) as well as antimicrobial, antifungal, antibacterial, antiviral, antioxidant, Immunomodulator properties.

So, Probable mode of action of *Nimbadi Yoga* can be understood as:

- *Yoni Shodhan*- Clean the vagina- by *Vrana Shodhana* (purifies the wound) Property
- Restrain *Srava* - *Kashaya* (astringent), *Tikta* (bitter) and *Katu* (pungent) *Rasa* (taste) *Laghu* (light) and *Ruksha* (dry) *Guna* (property).
- Kill causative microorganism – *Krimighna* (diminishes worms and germs), antimicrobial, antibacterial, anti fungal, antiviral properties
- Rejuvenate the epithelium - *Rasayana Prabhava* (rejuvenating), antioxidant and *Madhura Rasa* (sweet taste) property like *Prinana*, (*nourishing the life*), *Jivana* (life giving) etc.
- Improving the body defense system - Immunomodulator property

CONCLUSION

Vaginal tablets/suppository is the most popular and convenient form for curing vaginal infection and this is the first and primary work to convert classical *Varti* into convenient modern vaginal suppository dosage form. Hence further more work should be carried out to develop a more stable and convenient form. This is also the first effort to manage *Shwetapradara* with easily adaptable form of *Nimbadi Yoni Varti*. *Nimbadi Yoni Varti* highly effective modalities for the management of *Shwetapradara*. It is also is more convenient with no apparent evidence of complications. Hence further more work should be carried out to develop a more stable and convenient form.

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