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# A Novel Polyherbal Formulation BASANT for Keeping Human Vagina Healthy

**Talwar GP***

Talwar Research Foundation, India

***Corresponding author:** GP Talwar, Talwar Research Foundation, New Delhi-110068, Email: gptalwar@gmail.com

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## Abstract

A Short Review article on BASANT, a polyherbal formulation which is effective in curing Abnormal vaginal discharge, fishy odour, and a variety of Vaginal Infections for which it was investigated, N. gonorrhoeae, Chlamydia trachomatis, HIV, and HPV causing Carcinoma of Cervix. Inorder to make it available to Women, it has been passed on to a Company BIPHA PHARMA in Kerala. It is a Mission Oriented Research.

At AIIMS New Delhi, a fairly large number of otherwise healthy women coming to Obstetrics and Gynaecology Department suffered from abnormal vaginal discharge. Their vaginal pH was above normal and vagina had foul odour.

We developed a Polyherbal formulation, named as BASANT. It was composed of 95% purified diferuloyl methane (curcumin), purified extract of Amla (Emblica officinalis), purified extract of Neem (Azadirachta indica) and Aloe vera (Aloe barbadensis). These ingredients were formulated in pharmacopoeially approved excipients: Citric acid, Sorbitol, Microcrystalline cellulose, Sodium starch glycolate, Starlac, Crospovidones and Sodium alginate as a lubricating agent. 250 mg BASANT was dispensed as powder in Cellulose capsules for intra-vaginal use.

We also prepared a formulation of probiotics composed of Lactobacillus fermentum, Lactobacillus gasseri and Lactobacillus salivarius. They were packed in cellulose capsules and named as Pro-Vag-Health.

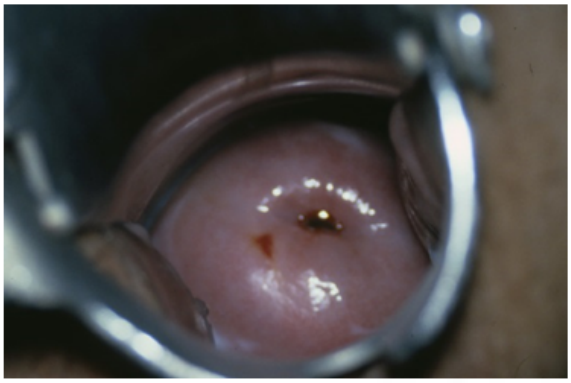
Regression of Vaginosis was studied in ailing women with BASANT, Probiotics and a Combination of the two. Table 1 summarizes the results.

Treatment with a combination of the two cured nearly every women. Fig. 1 given below shows the restoration of a normal Healthy vagina.

**Keywords:** BASANT; Lactobacillus Salivarius

## Abbreviations

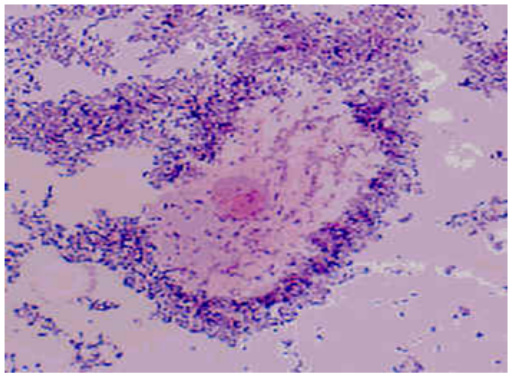
HIV: Human Immunodeficiency Viruses; HPV: Human Papillomavirus; KOH: Potassium Hydroxide; WHO: World Health Organization.

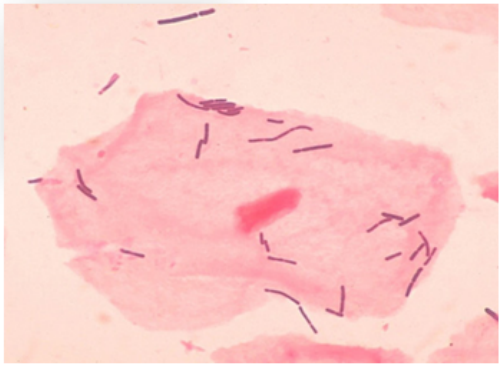


On Enrollment

After Using Basant

**a) Relief from abnormal vaginal discharge**





On Enrollment

After Treatment (Lactobacilli colonised)

**b) Disappearance of Clue cells**

**c) Healing of fishy odour**

Fishy Odour (After KOH addition on slide) On Enrollment → No Fishy Odour (After KOH addition on slide) After Treatment

**d) pH of vagina restored to acidic range**

pH > 5 On Enrollment → pH < 4.5 After Treatment

**Figure 1:** An illustrative representation of a typical woman suffering from recurring episodes of Vaginosis [1].

| Group Name | Improved (%) N=20 | P value Comparison with Placebo | P value Comparison with BASANT+Probiotics |
|---|---|---|---|
| Probiotics | 65% | P<0.001 | P = 0.04 |
| BASANT | 70% | P<0.001 | P = 0.09 |
| BASANT+Probiotics | 95% | P<0.001 | - |
| Placebo | 5% | - | P<0.001 |

*Comparison with Fisher's Exact Test.*

**Table 1:** Table 1. Summary of results of treatment with either Probiotics, BASANT or a Combination of BASANT and Probiotics to cure Vaginosis and restore reproductive health [1].

## Therapeutic Action of BASANT on Genital Infections

According to World Health Organization (WHO), 340 million cases of newly sexually transmitted infections occurred in the year 1999 worldwide, of which 92 million infections were Chlamydia trachomatis and 62 million were Neisseria gonorrhoeae. Cervical cancer caused by HPV (Human Papilloma Virus) is the fifth cause of cancer deaths in women. Approximately 40 million people are infected with HIV (AIDS) virus.

BASANT prevents women from acquiring undesirable genital infections, such as gonorrhea and HIV. Table 2 shows a range of WHO strains of Neisseria gonorrhoeae which are inhibited by the BASANT.

| Standard WHO strains | Antibiotic resistance | Growth at different concentrations (v/v) of Basant after 24 h | | | |
|---|---|---|---|---|---|
| | | 5% | 2% | 1% | 0% |
| N. gonorrhoeae WHO–C | None | - | - | + | + |
| N. gonorrhoeae WHO–G | Tetracycline (TRNG), nalidixic acid | - | - | - | + |
| N. gonorrhoeae WHO–K | Penicillin (PPNG), nalidixic acid, ciprofloxacin, ceftriaxone less sensitive | - | - | - | + |
| N. gonorrhoeae WHO–L | Penicillin (PPNG), nalidixic acid, ciprofloxacin, ceftriaxone less sensitive | - | - | - | + |
| N. gonorrhoeae 1586 | Nalidixic acid, ciprofloxacin | - | - | - | + |
| N. gonorrhoeae 1669 | Nalidixic acid, ciprofloxacin | - | - | + | + |
| N. gonorrhoeae 1794 | Nalidixic acid, ciprofloxacin | - | - | + | + |
| N. gonorrhoeae 2182 | Nalidixic acid, ciprofloxacin | - | - | - | + |
| N. gonorrhoeae 2436 | Penicillin (PPNG), tetracycline (TRNG), nalidixic acid, ciprofloxacin | - | - | - | + |
| N. gonorrhoeae 2482 | Penicillin (PPNG), nalidixic acid, ciprofloxacin | - | - | - | + |
| N. gonorrhoeae 2676 | Penicillin (PPNG), tetracycline (TRNG), nalidixic acid, ciprofloxacin less sensitive | - | - | + | + |

**Table 2:** WHO strains of *Neisseria gonorrhoeae* inhibited by BASANT [2].

Studies on HIV inhibition were conducted by Gustavo Doncel at CONRAD, Eastern Virginia Medical School, Arlington, USA, and Manoj Pastey at the University of Oregon, USA. The findings are presented in Table 3 and Figure 2.

| Basant Dilution | % Inhibition by p24 assay in | |
|---|---|---|
| | CEM-GFP cells | P4 cells |
| 0.736111111 | 98 | 99 |
| 3.513888889 | 89 | Not calculated |
| 1:10000 | 81 | 64 |
| 1:20000 | 51 | 53 |
| 1:40000 | 22 | 45 |
| 1:80000 | Not calculated | 32 |

**Table 3:** Percent inhibition of virus production by Basant in HIV-1 NL4.3-infected CEM-GFP and P4 cells [2].

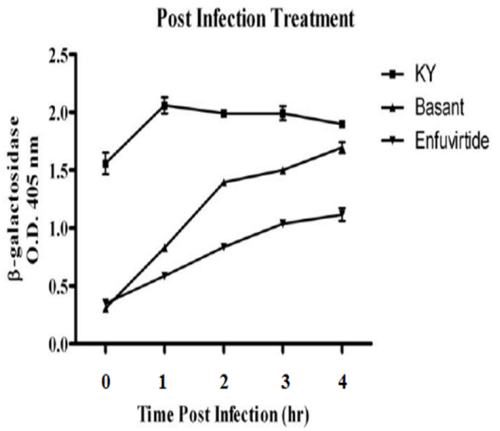



**Figure 2:** Kinetics of HIV-1 Inhibition by BASANT in comparison to KY jelly and Enfuvirtide. TZM-bl cells were infected with HIV-1NL4-3 and then treated with either KY jelly or Basant or Enfuvirtide, hourly for four hours. HIV-1 Tat dependent β- galactosidase activity was measured at 405nm after two days. Treatment of cells with Basant is effective for up to three hours post-infection. Enfuvirtide continues to be effective at four hours post infection [3].

| S.No. | Age | Parity | HPV-16 | HPV-16 |
|---|---|---|---|---|
| | | | Pre-treatment | Post-treatment |
| 1 | 42 | 3+0 | +VE | NEGATIVE |
| 2 | 27 | 4+0 | +VE | NEGATIVE |
| 3 | 35 | 3+0 | +VE | NEGATIVE |
| 4 | 28 | 1+1 | +VE | NEGATIVE |
| 5 | 45 | 3+0 | +VE | NEGATIVE |
| 6 | 35 | 4+0 | +VE | NEGATIVE |
| 7 | 30 | 2+1 | +VE | NEGATIVE |
| 8 | 45 | 2+0 | +VE | NEGATIVE |
| 9 | 38 | 5+2 | +VE | NEGATIVE |
| 10 | 35 | 3+1 | +VE | NEGATIVE |
| 11 | 38 | 3+1 | +VE | NEGATIVE |

**Table 4:** Pre and post treatment with BASANT of HPV-16 positive patients [4].

## Human Papilloma Virus (HPV)

Another highly significant action of BASANT is its effect on HPV-16, a virus that can lead to Carcinoma of Cervix. Table 4 presents the results from a study involving 11 women, all of whom tested negative for HPV after using a vaginal capsule containing 250 mg of BASANT nightly for 30 days.

## Safety of BASANT

BASANT did not cause any abnormalities in the structural integrity of the vaginal epithelium in mature NZW rabbits. Additionally, no systemic effects were observed, as evidenced by blood chemistry and hematology results, after 7 consecutive days of use or twice-daily applications for 3 weeks. Furthermore, no significant changes were detected in cytokine levels (interleukin (IL)-1β, IL-2, IL-6, IL-10, IL-12, tumor necrosis factor-alpha, and granulocyte-macrophage colony-stimulating factor) following intravaginal administration of BASANT.

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