

Two Valuable Products for Healthy Vagina

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Abstract

Described are 2 Products developed by us for improving the reproductive health of women. These are: (1) 3 strains of Lactobacilli (Pro-vag-Health) that possess arginine deiminase, the enzyme preventing the formation of foul odour derivatives, make and secrete high amounts of lactic acid besides being hydrophobic to enable colonization in the vagina, and (2) a Polyherbal formulation BASANT with inhibitory action on a wide spectrum of genital pathogens. The combined use of BASANT and Pro-vag-Health, has the highest efficacy for curing recurrent episodes of Vaginosis.

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I. Pro-vag-Health Probiotics

Vagina is a unique organ. While the pH of the human body is strictly regulated at 7.4, a healthy vagina has an acidic pH of around 4.5. This is materialized by co-existence on the vagina of a family of microorganisms called Lactobacilli. Lactobacilli make and secrete lactic acid which render the local pH acidic. There are many species of Lactobacilli and each species has strains that differ in their capacity of making lactic acid. Some make high amounts, others are low secretors, as was reported by us [1]. Figure 1 is a representation of this phenomenon.

On the basis of their ability to make and secrete high amounts of lactic acid, hydrophobicity which enables their colonization, and possession of the enzyme arginine deiminase, which prevents the formation of foul odor derivatives, we selected 3 worthy strains of lactobacilli. These are (1) *L. salivarius* TRF # 30 (2) *L. fermentum* TRF # 36 and (3) *L. gasseri* TRF # 8. These have been patented and deposited in the International Depository. These have also been passed on to Industry, M/s Microbax Hyderabad, who have a set-up to culture probiotics on a mass-scale, lyophilize these along with stabilizer and pack in cellulose capsules that are easily insertable in the vagina. Vikas Rajurkar of M/s Microbax (India) Ltd can be contacted for these probiotic strains.

II. Polyherbal formulation BASANT

We developed a polyherbal formulation, which we have named as BASANT. It contains 95% pure curcumin (diferuloyl methane), purified extracts of Amla (*Embllica officinalis*), Aloe Vera (*Aloe barbadensis*) and Neem (*Azadirachta indica*) leaves along with pharmacopoeially approved excipients. BASANT has action on a wide spectrum of genital pathogens. It inhibits all strains of *Neisseria gonorrhoeae* tested, including those resistant to various antibiotics and drugs. It inhibits *Candida glabrata*, *Candida albicans* and *Candida tropicalis* including drugs-resistant strains isolated from women suffering from vulvo-vaginal candidiasis [2].

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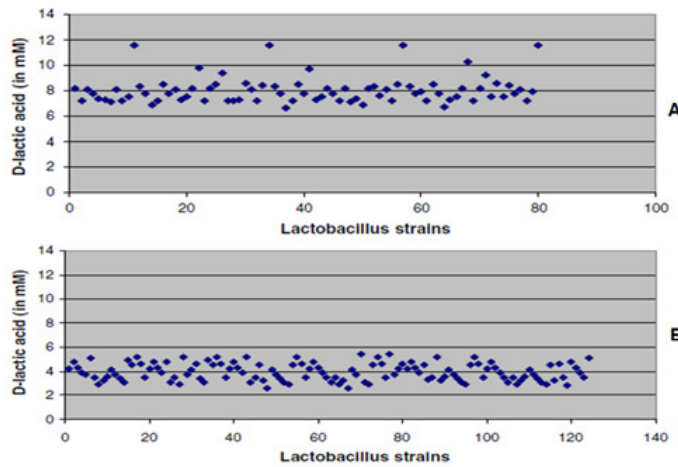


Figure 1A: D-lactic acid production by 80 *Lactobacillus* strains from women with healthy vagina.

Figure 1B: D-lactic acid production by 124 *Lactobacillus* strains from women with Bacterial Vaginosis (BV) [1]

BASANT inhibits *Chlamydia trachomatis* *in vitro*, as well as when present in infected cells [3]. BASANT inhibits all strains of HIV (Human Immunodeficiency Virus) tested, which enter the blood lymphocytes employing either CXCR4 or CCR5 receptors as reported by Manoj Pastey at the University of Oregon, USA [4]. Of special interest is the ability of BASANT to inhibit Human Papilloma virus 16 (HPV-16), the virus which causes Carcinoma of Cervix, a major killer of women. What is further impressive is its ability to eliminate HPV-16 from infected cells at early CIN1 stage.

Table 1 shows data from a trial conducted in 11 women by Professor Sharma at the Jawaharlal Nehru Medical College Aligarh, Uttar Pradesh. 11 women whose cervical cells were infected with HPV-16, and whose Pap smear was abnormal, were asked to insert a capsule of BASANT in the vagina every night for 30 days, excluding the days of menstruation. Treatment with BASANT was effective in every woman. Not only the infected cervical cells became HPV-16 negative but also the Pap smear returned to normalcy [5].

Patient No.	Age	Parity	HPV-16 Pre-treatment	HPV-16 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 1: Pre and post treatment with BASANT of HPV-16 positive patients [5].

Synergistic action of BASANT and Pro-vag-Health in treatment of Vaginosis

Vaginosis is prevalent in 30-50% of women in urban and rural localities in India. Even in USA, its prevalence has been reported to be 29% [6]. A Phase II clinical trial conducted at the All India Institute of Medical Sciences, New Delhi and Sir Gangaram Hospital, New Delhi in 80 women suffering from recurring episodes of Vaginosis, showed that 7 night intake of either the 3 selected probiotics or BASANT cured 65-70% of such patients, but the combination of the 2 had remarkable efficacy of curing 95% of women suffering from Vaginosis manifested as abnormal vaginal discharge, presence of Clue cells loaded with aerobic, anaerobic micro-organisms and elevated ph. Figure 2 is a representation of a typical case before and after the treatment. Table 2 summarizes the results of this trial.

Group Name	Women enrolled	Women Improved	P value Comparison with Placebo	P value Comparison with BASANT + Probiotics
Probiotics	20	13 (65%)	P < 0.001	P = 0.04
BASANT	20	14 (70%)	P < 0.001	P = 0.09
BASANT+ Probiotics (NAUROZ)	20	19 (95%)	P < 0.001	-
Placebo	20	1 (5%)	-	P < 0.001

Table 2: Summary of results of treatment with either Probiotics, BASANT or a combination of BASANT and Probiotics to cure Vaginosis and restore reproductive health [7].

Comparison with Fisher’s exact test

It was observed that while both Probiotics and BASANT restored healthy vagina, the combination of 2 cured Vaginosis in nearly every woman, 19 out of 20 women were cured [7]. This is the highest efficacy so far observed and reported in world literature. Metronidazole and other antibiotics currently employed attain only an efficacy of about 65%.

(a) Relief from Abnormal Vaginal Discharge

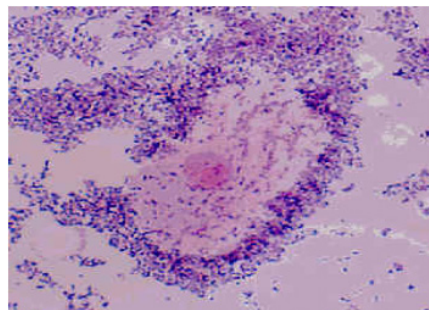


On Enrollment

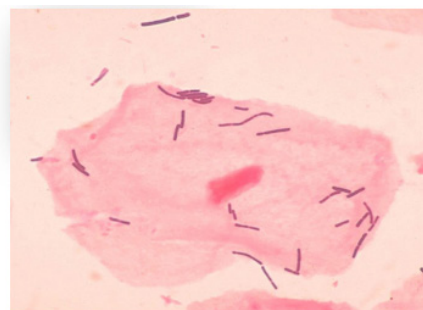


After Treatment

(b) Disappearance of Clue Cells



On Enrollment



After Treatment
(Lactobacilli colonised)

