



TECHNOLOGY AVAILABLE FOR TRANSFER

A Novel, Broad spectrum, Clinically Proven Antimicrobial Herbal Formulation

Key Features

- Herbal formulation effective against bacterial, fungal and viral pathogens infecting the female genital tract
- Prophylactic and therapeutic
- Possesses bio-adhesive properties
- Free from local and systemic side effects
- Helpful in regression of vaginal infections
- Pleasant fragrance and soothing to the skin

State of Development

- Phase II clinical trial confirming safety and efficacy of the product has been successfully completed in 80 women
- Phase III trials to be undertaken
- NBA approval obtained

Applications

- Broad spectrum antimicrobial for female genital pathogens with proven treatment of Vaginosis

Intellectual Property

- Patent Pending in India
- PCT application filed

Inventor

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Background

Carcinoma cervix is a major cancer of women killing 510,000 women every year worldwide. Human papilloma virus (HPV) infection of cervical cells initiates the transformation of the cervical cells to malignant stage. HPV-16 is the most frequent type of HPV causing these changes. Vaginosis is another widely prevalent syndrome. According to a study conducted by the Indian Council of Medical Research (ICMR), the prevalence of this syndrome is about 30% in women attending the antenatal clinics in urban Delhi. Its incidence was 80% in slums of Delhi in a survey conducted by the inventors along with Safdarjung Hospital and Population Foundation of India[1]. Its prevalence in the United States is estimated to be 29.2% in women of 14-49 age [2].

Currently available solutions are mostly specific to either vaginosis or HPV. Vaccines in case of HPV prevent the entry of the virus only. The antibodies generated by these vaccines fail to eliminate the virus from the infected cervical cells. Vaginosis is treated using antibacterial or antifungal formulations. Therefore, there is a need for a single formulation with bio-adhesive properties and broad-spectrum activity against multiple bacterial, viral and fungal pathogens for treatment and protection from vaginosis, cervical cancer and transmission of HIV.

Validation

The technology has been validated at various National and International Institutes. Table 1 below summarizes results of Validation studies of this technology.

Institute	Strain	Results
National Institute of Health (NIH)	HPV16	Prevents entry in HeLa cells
Medical College, Aligarh (159)	HPV 16/18	30 daily intra-vaginal intakes of capsules caused the elimination of HPV 16/18. Their Pap smear also became normal.
University of Oregon, USA	CCR5 and CCR4 tropic HIV 1	Effective against both the strains
AIIMS & Sir Gangaram Hospital	Phase II Clinical trials (80)	Formulation in combination with three strains of lactobacillus were effective in 19 out of 20 women.
National Institute of Virology, Pune	HIV-1 subtypes	Inhibits various HIV-1 subtypes at non cytotoxic concentration. Also inhibits HIV-1 replication in the Epi Vaginal explants model.

Technology

The present invention provides a novel antimicrobial polyherbal formulation with lubricating character and has bio-adhesion property to cover the vaginal mucosa with a molecular film. This novel composition is useful against bacteria, fungi and virus causing sexually transmitted diseases.

The antimicrobial composition has been formulated both as a cream and as powder encapsulated in easily dispersible cellulose capsules. It was tested and found effective against WHO strains and clinical isolates of *Neisseria gonorrhoeae*, including those resistant to penicillin, tetracycline, nalidixic acid and ciprofloxacin. The formulation has also pronounced inhibitory action against various genital pathogens as specifically detailed in Table 2. Thus, this Polyherbal microbicide has a wide spectrum action on a variety of genital pathogens, including HIV and can be used for prophylactic as well as therapeutic measures.

Table 2-Genital Pathogens inhibited by the Formulation

Pathogen Class	Strain	Tested Strains
1 Bacteria	N. gonorrhoeae WHO-C, N. gonorrhoeae WHO-G, N. gonorrhoeae WHO-K, N. gonorrhoeae WHO-L6	N. gonorrhoeae 1586, 1669, 1794, 2182, 2436, 2482, 267, and all strains isolated from patients at the STD centre, New Delhi.
		<i>Chlamydia trachomatis</i> CT231, CT233, CT 239, CT272, CT279, CT244, tested free and in infected cells
2 Fungi	<i>Candida-C. glabrata</i> , <i>C. glabrata</i> (7 clinical isolates), <i>C. glabrata</i> (2 clinical isolates), <i>C. albicans</i> ATCC 36082, 5 clinical isolates, <i>C. tropicalis</i> (2 clinical isolates)	
3 Virus	Human Immunodeficiency Virus (HIV) Inhibition of virus production by BASANT in HIV-1 NL4.3-infected CEM-GEP and P4 cells	Both CCR5 and CXCR4 tropic HIV-1 lab-adapted strains and primary isolates from different clades
		Human Papilloma Virus (HPV) Inhibition of entry of HPV-16 in HeLa Cells

Market

Most women will have a vaginal infection, characterized by discharge, itching, or odor, during their lifetime. With the availability of complementary and alternative therapies and over-the-counter medications for candidiasis, many symptomatic women seek these products before or in addition to an evaluation by a medical provider. This formulation is first of its kind which provides broad spectrum activity against three classes of pathogens. It is expected to replace the antifungal, antibacterial and antiviral products for genital pathogens. The target market is women in adolescent to middle age group (15-64). In India 30-50% of the women suffer from Vaginosis. Considering the existing disease incidence and customer segments, this novel technology offers itself as a unique opportunity to capitalize on the unmet need in the area of antimicrobials for genital pathogens.

1. Bang RA, Bang AT, Baitule M, Sarmukaddam S, Choudhary Y, et al. (1989) High prevalence of gynecological diseases in rural Indian women. *The Lancet* 333: 85-88.
2. Rauh VA, Culhane JF, Hogan VK (2000) Bacterial vaginosis: a public health problem for women. *J Am Med Womens Assoc* 55: 220-224.