



NAUROZ-A clinically validated, novel technology against Vaginosis

TECHNOLOGY AVAILABLE FOR TRANSFER

UNMET NEED

Carcinoma of cervix is a major cancer of women, killing ~3,40,000 women every year worldwide. Human papilloma virus (HPV) infection of the cervical cells initiates the transformation of these cervical cells to the 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 antenatal clinics in urban Delhi. Its incidence was 80% in the slums of Delhi in a survey conducted by the inventors along with Safdarjung Hospital and Population Foundation of India¹. Its prevalence in the United States is estimated to be 29.2% in women of 14-49 age². 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 formulations 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.

TECHNOLOGY

Nauroz is a combination of a novel polyherbal formulation and three selected probiotic *Lactobacilli* for improving the reproductive health of women.

The first component of this technology is an antimicrobial Polyherbal Formulation, with a lubricating character and a bio-adhesion property, to cover the vaginal mucosa with a molecular film. This novel composition is useful against bacteria, fungi, and virus that cause sexually transmitted diseases. It 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 1. Thus, this Polyherbal microbicide has a wide spectrum of action on a variety of genital pathogens, including HIV, and can be used for prophylactic as well as therapeutic measures.

Table 1-Pathogens tested for inhibition by the formulation		
1	Bacteria	<i>N. gonorrhoeae</i> WHO-C, <i>N. gonorrhoeae</i> WHO-G, <i>N. gonorrhoeae</i> WHO-K, <i>N. gonorrhoeae</i> WHO-L6
		<i>N. gonorrhoeae</i> 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	Candida- <i>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)
		Both CCR5 and CXCR4 tropic HIV-1 lab-adapted strains and primary isolates from different clades
		Human Papilloma Virus (HPV)

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.



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Whereas the second component, Probiotic *Lactobacilli* is the mixture of 3 meritorious *Lactobacilli* strains namely *Lactobacillus fermentum*, *Lactobacillus salivarius* and *Lactobacillus gasserei*. These special probiotic *Lactobacilli* possess arginine deiminase, the enzyme preventing the formation of foul odor derivatives. All of them make and secrete high amounts of lactic acid besides being hydrophobic to enable colonization in the vagina.

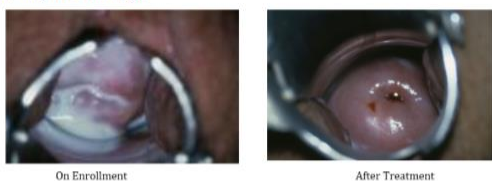
The combined use of antimicrobial Polyherbal Formulation and meritorious probiotic *Lactobacilli* in Nauroz provides the best efficacy results for curing recurrent episodes of vaginosis.

Validation

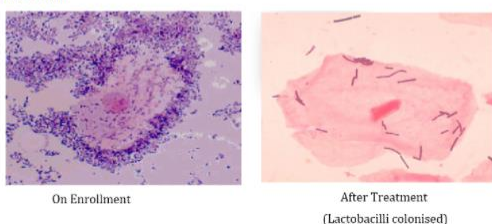
The technology has been validated at various National and International Institutes including at National Cancer Institute/National Institute of Health, Bethesda, MD, USA. Table 2 and the figure below summarizes the results of Validation studies of this technology.

Table 2-Validation results of the 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)	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.

(a) Relief from Abnormal Vaginal Discharge



(b) Disappearance of Clue Cells



(c) Healing of fishy Odour



(d) pH of vagina restored to acidic range



Fig . Representation of a typical woman receiving treatment with NAUROZ



APPLICATIONS

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

UNIQUE SELLING PROPOSITION

- Nauroz is effective against bacterial, fungal, and viral pathogens infecting the female genital tract providing a highly acceptable, fully safe, low-cost, natural remedy.
- Prophylactic as well as a therapeutic effect.
- Bio-adhesive properties.
- All-natural components and free from local and systemic side effects.
- Natural alternative to antibiotics for the elimination of infecting microorganisms.
- Recolonizes the vagina with *Lactobacilli* and restores the acidic pH.
- Helpful in regression of vaginal infections
- Pleasant fragrance and soothing to the skin

OPPORTUNITY

Bacterial vaginosis (BV) disturbs the normal balance of bacteria in the vagina. BV may be asymptomatic; however, it is more commonly associated with vulvovaginal symptoms such as itching, discharge, odour, and discomfort³. The global market for vaginosis drugs will be driven primarily by the increasing demand for OTC products and the rising incidence of vaginosis among women worldwide with a growth of 6.4% of CAGR annually⁴. The developed technology is first of its kind which provides broad-spectrum activity against three classes of pathogens as well as promotes the recolonization of the vagina with *Lactobacilli*. It is expected to replace the existing antifungal, antibacterial and antiviral products for genital pathogens. Globally 30 – 50% of the women in the adolescent to middle age group (15-64) suffer from vaginosis which makes them an ideal target for the use of this product. Considering the existing disease incidence and customer segments, this novel technology offers a unique opportunity to capitalize on the unmet need in the area of antimicrobials for genital pathogens.

STAGE OF TECHNOLOGY

- Clinical trial confirming the safety and efficacy of the product has been successfully completed in 80 women

INTELLECTUAL PROPERTY

- Technology is protected by granted patents in India.

³ Bacterial Vaginosis Treatment Market - Global Industry Analysis, Size, Share, Growth, Trends, and Forecast 2017 – 2025-
<https://www.transparencymarketresearch.com/bacterial-vaginosis-treatment-market.html>

⁴ Global Vaginosis Drug Market by Type (Rx, OTC), By Application (Hospital, Pharmacy, Other) And By Region (North America, Latin America, Europe, Asia Pacific and Middle East & Africa), Forecast To 2028 -
https://dataintel.com/report/global-vaginosis-drug-market/?utm_campaign=copy



BCIL Biotech Consortium India Limited



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LICENSING OPPORTUNITY

BCIL is looking for a suitable industrial partner for the development and commercialization of Nauroz technology for the treatment of vaginal infections.

CONTACT:

BIOTECH CONSORTIUM INDIA LIMITED (BCIL)

Dr. Shiv Kant Shukla,

Head Technology Transfer Office

& Dy. General Manager

V Floor, Anuvrat Bhawan, 210,

Deen Dayal Upadhyaya Marg, New Delhi-110002

Phone (Direct) : +91-11-23219058,

Email: shuklashivkant@biotech.co.in or tto.bcil@biotech.co.in

Website: www.biotech.co.in