

Evaluation of Probiotic Vanishing Cream as Potential Treatment for Bacterial Vaginosis

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Abstract

Objective: To develop a vanishing cream containing potential probiotic bacteria for treating bacterial vaginosis which may help in the release of lactic acid for a prolonged period to restore the acidic pH of the vaginal lumen and also to study sub-acute vaginal toxicity on animal models using this cream.

Methods: The probiotic culture in the present study viz., *Lactobacillus helveticus* (V3) MTCC 5463 was used which was obtained from Anand Agricultural University. Comparison of readymade emulsion from market and laboratory made emulsion with different concentrations of selected strain (1part emulsion: 0.5 culture pellet; 1 part emulsion: 0.8 part culture pellet and 1 part emulsion: 1 part culture pellet) was done by determining viscosity, pH, viability and rate of freeze thaw stability. The optimized vanishing cream (stearic acid 37% and KOH 0.6%) was further compared with market cream using different *in vitro* tests. The shelf-life study of optimized cream was done at 40 °C ± 2 °C and 7 °C ± 2 °C, at 75% humidity for a period of three months. Sub-Acute Vaginal Toxicity on "Guinea-pig" was assessed to study the toxicological profile of the test item at high dose when topically applied on vagina daily for 28 days.

Results: The market cream formulations had pH value ranging from 3.69-6.95 while laboratory made probiotic cream had pH value ranging between 4.4 - 5.38. The maximum viability of probiotic culture was seen in formulation having 1:1 concentration (10.20 log cfu/ml) followed by 1:0.8 concentration (9.83 log cfu/ml) and 1:0.5 concentration (9.69 log cfu/ml). The market cream formulation had viscosity in the range 31.2-48.11 Pa at 6 rpm while the viscosity of Laboratory made Probiotic cream was in the range 38.69-54.61 Pa. The minimum pH was seen in cream made of concentration of stearic acid 37% and 0.6% KOH. The final optimized cream (37 % stearic acid and 0.6 % KOH) showed best results for different *in vitro* tests when compared with four different market creams also this cream was able to inhibit indicator organisms *G. vaginalis*, *Candida albicans*, *E. faecalis*, *S. aureus*, *E. coli* for bacterial vaginosis. The initial average viable count of dosage forms (10.20 ± 0.20 log cfu/g) got reduced up to 5.67 ± 0.06 log cfu/g after storage of 30 days. A significant ($P < 0.05$) difference in pH was observed in first week of storage. The initial pH of cream was 4.15 ± 0.13 which increased to 4.24 ± 0.06 on 30th day when stored at 40 °C ± 2 °C. At 7 °C ± 2 °C, the initial average viable count of cream (10.76 ± 0.31 log cfu/g) got reduced up to 7.32 ± 0.07 log cfu/g after storage of 90 days. A significant ($P < 0.05$) difference was observed in first week of storage. The initial pH of cream was 4.14 ± 0.13 which almost remained same i.e. 4.17 ± 0.03 on 90th day. The cream stored at both temperatures was found to be thermodynamically stable. The sub-acute vaginal toxicity study showed that cream made was giving no side effects and is safe for human clinical trials.

Conclusion: The probiotic cream developed is safe and can be used by humans after clinical trials are done. The *in vitro* test proved that this probiotic cream can be a potential treatment for treatment of Bacterial Vaginosis.

Keywords: Anand Agricultural University, *Lactobacillus helveticus*, Bacterial Vaginosis
