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 (1 part 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