

Abstract

Formulation and evaluation of mucoadhesive vaginal tablet for the treatment of bacterial vaginosis

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The primary purpose of this study was to formulate a mucoadhesive vaginal tablet of clindamycin phosphate. It developed to achieve an excellent therapeutic effect and patient compliance in the treatment of bacterial vaginosis. The formulation has a sustained-release effect with good mucoadhesion due to mucoadhesive polymers like Polycarbophil and Carbopol 971P NF, which decreases dose frequency. The mucoadhesive vaginal tablets were prepared by the direct compression method. FTIR was employed to study drug excipient incompatibility. The analytical method performed using HPLC. Optimization of the formulation was done by 32 full factorial designs using DOE. The mucoadhesive vaginal tablet was evaluated for % swelling index, Mucoadhesive strength, drug content, % drug release, and ex-vivo mucoadhesion time. The ex-vivo mucoadhesion time of the optimized batch was up to 9 h, 97.24% drug content, $88.34 \pm 0.97\%$ drug release observed at 8 h. Stability study shows developed mucoadhesive intravaginal tablets were stable at $30\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ at $65 \pm 5\%$ RH (Room temperature) and $40\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ at $75 \pm 5\%$ RH condition after three months. This study may prove potential vaginal formulation of clindamycin phosphate against bacterial vaginosis.

Keywords: *Bacterial vaginosis, Mucosal drug delivery, Vaginal tablet, Polymeric drug delivery*