"DEVELOPMENT AND EVALUATION OF PUSH-PULL OSMOTIC TABLET OF NITROFURANTOIN"

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<u>Abstract</u>

Nitrofurantoin has a relatively short elimination half life of 1 hour, there by requiring four times daily dosing in patients, which may lead to non-compliance. The objective of this study was to develop and evaluate push-pull osmotic tablet of Nitrofurantoin for the treatment of urinary tract infection. Push-pull osmotic tablet were prepared by direct compression method. From the preliminary trial batches polyethylene oxide 100-K and sodium chloride were selected as a suspending agent and osmotic agent respectively to achieve controlled drug release. The FTIR result revealed that drug & polymers were chemically compatible. Effects of all the polymers, with different concentrations, on physical properties of push-pull osmotic tablet were investigated. To evaluate the effect of polyethylene oxide 100-K and sodium chloride concentrations, 3^2 full factorial design was employed. The optimization of push-pull osmotic tablet was done by optimizing the concentration of polyethylene oxide 100-K and sodium chloride as well as by drug release. 25% polyethylene oxide and 15% sodium chloride was optimized. Drug content was found to be 97.41% and in-vitro drug release was found to be 90.31% with coating solution 5% w/v and 0.6mm orifice size. From regression value it revealed that optimized formulation followed zero order kinetic model, indicating controlled drug release. Stability study at $40^{0}C\pm2^{0}C/75\pm5$ % RH revealed no significant changes. As, the developed push-pull osmotic tablet releases the drug in controlled manner up to 12 hours, decreasing the dosing frequency and improved patient compliance, it may be effectively used orally in case of urinary tract infection.

Key words: Nitrofurantoin, Controlled release, Push-pull osmotic pump.