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Evaluation of the effect of agents and optimization of vaginal gel of progesterone

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Objectives: Progesterone is a hormonal drug which its vaginal gel formulation because of low adverse effects nowadays has a vast use in menopausal and postmenopausal periods in the treatment of secondary amenorrhea and ART. It has more patient acceptance for the reason of ease in application and its once daily use. Unfortunately this product is not available in Iranian market. In world market, progesterone vaginal gel is marketed under the trade name of CRINONE and there are two forms 4% and 8%. **Methods:** First the solubility of progesterone in different solvents was evaluated, then formulations were prepared using gelling agent (Carbomer 934p), pH of the formulations was adjusted according to the pH of vagina. The stability of gels was evaluated in three different temperatures, refrigerator, room temperatures and 40°C oven. The in vitro release of drug was assessed using static diffusion cell and dialysis membrane. The concentration of drug was analyzed by means of UV spectrophotometer at 241 nm. **Results:** Our findings showed that increasing the amount of gelling agent, decreased the drug release mean while decreasing the amount of paraffin and increasing the amount of glycerin increased the release of drug. Concomitant increasing of the amount of carbomer and glycerin didn't change the release of drug. The results showed that release of drug follows zero order release mechanism. **Conclusion:** These findings show that bioadhesive polymers such as carbopol in the formulation prolonged contact, residence time and zero order release. ART = Assisted Reproductive Techniques. **Key words:** progesterone, vaginal gel, hydrogenated glyceride of palm oil, sorbic acid, release.

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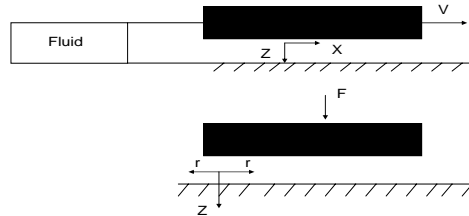
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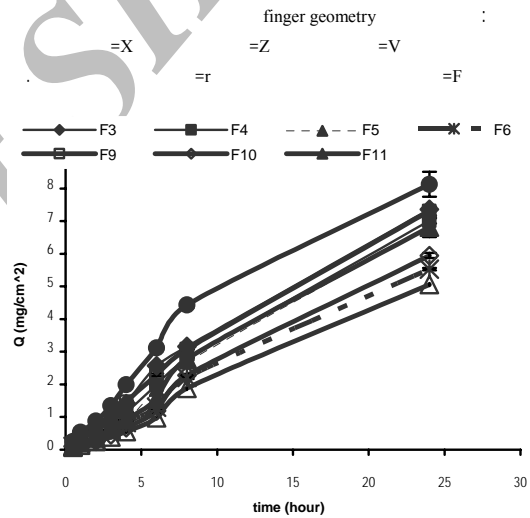
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