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***Preparation and In Vitro
Evaluation of Prednisolone
Conventional and Hollow-Type
Suppositories***

A thesis

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Abstract

Prednisolone is a corticosteroid derivative used in the treatment of many diseases including ulcerative colitis and Crohn's disease. This investigation concerned with preparation of prednisolone as conventional and hollow-type suppositories for rectal administration to achieve rapid and complete release of the drug.

The influence of suppository type on the *in vitro* release of the drug and the physical properties of the prepared suppositories were demonstrated using conventional and hollow-type suppositories. Two kinds of hollow-type suppositories were prepared. The first type was hollow-type suppositories containing mixture of prednisolone and lactose 5 % W/W, while the second type contains prednisolone solutions in their cavities. A 400 μ L of prednisolone solution was prepared by dissolving 5mg of the drug in aqueous solution of 4 % V/V tween 80, then this solution was mixed with propylene glycol in a percentage of 50 % V/V and used for hollow-type suppositories prepared from oleaginous bases. For hollow-type suppositories prepared from water soluble bases, a 400 μ L of solution prepared by dissolving prednisolone in ethyl oleate followed by mixing with tween 80 in a ratio of (70:30 W/W).

The effect of base type was also studied using various hydrophilic and oleaginous bases. Two types of oleaginous bases (Witepsol H 35 and Witepsol H 37) and three kinds of water soluble bases (polyethylene glycols PEG 400:4000 (70:30), PEG 1000:4000 (70:30) and Glycerinated gelatin base (glycerin, gelatin and water) (4:2:4, W/W) were used.

Furthermore, the effect of storage period and temperature was also studied. Four formulas with high release percentages were selected and stored at 4 °C and 25 °C for 1, 15, 30 and 45 days.

The results showed that the release of the drug was faster from hollow-type suppositories containing solution in their cavities compared with both conventional and hollow-type ones containing powder prepared from water soluble bases. On the other hand, there was a great enhancement in the release of prednisolone from hollow-type suppositories that contain prednisolone solution formulated by using fatty bases compared with the remainder two types.

In addition, the release of the drug was found to be higher from conventional and hollow-type suppositories containing powder prepared from hydrophilic bases compared to those prepared from oleaginous bases. Concerning hollow-type containing solution suppositories prepared from water soluble bases, the results revealed that the release was faster from ones prepared from polyethylene glycol mixtures compared with glycerinated gelatin base. For fatty based hollow-type suppositories containing solution, it was found that changing the base type insignificantly affect the in vitro release of the drug.

Also, the physical properties of the prepared suppositories were found to be significantly affected by changing suppository type or base "in most cases".

Finally, the shelf life of prednisolone in hollow-type suppositories prepared from Witepsol H 35 and contain the drug in solution form was determined at 25 °C and found to be 2.85 years.