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Formulation of Extended-Release Gliclazide Tablet Using a Mathematical Model for Estimation of Hypromellose

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Abstract : Formulation of gliclazide in the form of extended-release tablet in 30 and 60 mg dosage forms was performed using hypromellose (HPMC K4M) as a retarding agent. Drug-release profiles were investigated in comparison with references Diamicron MR 30 and 60 mg tablets. The effect of size of powder particles, the amount of hypromellose in formulation, hardness of tablets, and also the effect of halving the tablets were investigated on drug release profile. A mathematical model which describes hypromellose behavior in initial times of drug release was proposed for the estimation of hypromellose content in modified-release gliclazide 60 mg tablet. This model is based on erosion of hypromellose in dissolution media. The model is applicable to describe release profiles of insoluble drugs. Therefore, by using dissolved amount of drug in initial times of dissolution and the model, the amount of hypromellose in formulation can be predictable. The model was used to predict the HPMC K4M content in modified-release gliclazide 30 mg and extended-release quetiapine 200 mg tablets.

Keywords : Gliclazide, hypromellose, drug release, modified-release tablet, mathematical model
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