Comparative evaluation of the discriminatory power of different dissolution methods for Glibenclamide tablets

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Background

Dissolution methods are designed and optimized for different purposes such as in vivo In vitro correlation and for quality control. As it has been stated by Sauet (2005), the purpose of developing and optimizing dissolution tests –for Quality Control - is to assess the product attributes by monitoring their effects on the rate and extent to which the drug is released from the dosage form.

Objective

The aim of this work was to compare the discriminatory power of a proposed method with that of the Food and Drug Administration (FDA) and other methods suggested for dissolution testing of local and imported brands of Glibenclamide tablets.

Method

A UV-spectrophotometric method has been used in the assay. The calibration curve of standard Glibenclamide was prepared in concentration range 2-10 µg/ml using methanol as solvent (with r²=0.999). Erweka dissolution apparatus paddle DT-6 has been used, with different rotation speed (50, 75 rpm), according to the method employed. The proposed method was developed by determining the solubility of Glibenclamide in different pH values, (1.2-9.5). pH 7.5 was selected and, the addition of 0.1% tween 20 was found to fulfill the sink condition. The method was further optimized by setting the rotation speed at 50 rpm. The dissolution profiles obtained from each method were compared using a simple independent approach model, through the calculation of the similarity factor, f₂ and the difference factor, f₁.

Results and conclusion

The solubility study confirms that, glibenclamide solubility is pH dependent. Higher sink condition in the developed method (7.2) was found to affect the discriminatory power of the method compared to the suggested method by El-Massiket et al. (1996). For two curves to be similar, the acceptance range of f₁ and f₂ values is (0-15) and (50-100) respectively, according to this criterion, the proposed method resulted in almost similar dissolution profiles, while the FDA method was able to discriminate between different brands but with low power compared to the suggested method by El-Massiket al., (1996) method.