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Novel Approach in Formulation of Low Soluble Drugs: Gliclazide as Model Substance

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The study demonstrates two approaches in formulation of solid self-emulsifying drug delivery systems (SSEDDS) of gliclazide (BCS class II drug). Self-emulsifying (SE) formulations can improve oral bioavaiability of poorly water-soluble and lipophilic drugs. Traditional SE formulations are liquids, having some disadvantages such as high production cost, low stability, low drug loading and few choices of dosage forms. To address these problems solid SEDDS are being investigated [1].

The aim of the study was formulation of solid oral self-emulsifying gliclazide preparations - hard capsules and tablets.

Twelve formulations have been prepared with varying type of solubilizer (Labrafil® M2130CS, Cremophor® RH40, Labrafil® M 1944CSCG, Labrafil® M2125CS), ratio gliclazide:solubilizer (1:1 to 1:20), presence of adsorbent (Neusilin® UFL2), as well as the ratio of gliclazide solution:adsorbent (1:1 and 2:1) and presence of disintegrator (Ludiflash®) in concentration of 10–50%. Formulations have been filled in hard capsules or compressed into tablets using excenter tablet press. Determination of gliclazide release from prepared capsules or tablets has been conducted in rotating basket apparatus (Erweka DT600, pH=7.5, 100 rpm, 900 ml, 45 minutes).

It has been demonstrated that gliclazide has the highest solubility in Cremophor® RH40, at ratio 1:20. Gliclazide release studies have demonstrated that capsules filled with gliclazide solution adsorbed on adsorbent, with ratio solution:adsorbent 1:1, show the fastest gliclazide release rate. Addition of disintegrator in formulations having ratio of solution:adsorbent 1:1, slows down gliclazide release rate. On the other hand, disintegrator enhances gliclazide release in formulations having ratio of solution:adsorbent 2:1. Gliclazide release studies from tablet formulations containing adsorbed solution (in ratios 1:1 and 2:1) and Ludiflash® demonstrate faster onset of drug release in first minutes followed by more sustained gliclazide release, in comparison to capsules.

Obtained results demonstrate the possibility to formulate solid self-emulsifyng gliclazide formulations, once appropriate emulsifier, adsorbent and disintigator, in adequate ratio, are selected.

[1] Tang B, Cheng G, Gu JC, Xu CH. Development of solid self-emulsifying drug delivery systems: preparation techniques and dosage forms. Drug Discov Today. 2008; 13: 606–612. doi:10.1016/j.drudis.2008.04.006