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Investigation of digoxin solubility in different cosolvent systems

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Background and Aims: Digoxin is a drug with very low aqueous solubility, low therapeutic dose and low therapeutic index. Soft gelatin capsule is an ideal dosage form to formulate low soluble drugs that provides faster dissolution, higher bioavailability and higher content uniformity. The purpose of the present study is to enhance digoxin solubility using appropriate vehicles to prepare digoxin soft gelatin capsule core formulation.
Methods: Solubility of digoxin in different solvents, including water, ethanol, polyethylene glycol 400, propylene glycol, transcutol and binary and/or ternary solvent systems were investigated using shake-flask method. Saturated solutions of these solvents and solvent mixtures were shaken at 25°C for 48h. After equlibrium, the supernatant layer was withdrawn and passed through 0.45µm filter. Concentrations of drug in solutions were determined by HPLC and UV. The mathematical mixture design was used to design the solvent systems.
Results: The obtained results indicated that best co-solvent for increasing the solubility of digoxin is ethanol. Digoxin solubility in other co-solvents also was more than its aqueous solubility. Using cosolvency method, the solubility was increased up to 14.5 times more than its aqueous solubility.
Conclusions: It is concluded that digoxin solubility could be increased using co-solvent method to achieve appropriate formulations for designing soft gelatin capsules.

Keywords: Digoxin; Solubility; Cosolvency; Soft gelatin capsule; Mixture design