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Dissolution enhancement of Ursodeoxycholic acid by complexation with Glucosyl-β-Cyclodextrin

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The objective of the present investigation is to study the *in vitro* dissolution effects of glucosyl-β-cyclodextrin (G1-β-CD) on ursodeoxycholic acid (UDCA) .The molecular inclusion complexes of UDCA with Gl-β-CD were prepared using different methods. Physicochemical characterization and *in vitro* dissolution of pure drug, physical mixtures and inclusion complexes were carried out. Phase solubility studies of UDCA-Gl- β-CD systems in water at 25°C exhibited typical AL-type solubility curve. Low values of standard deviation in drug content of cyclodextrin inclusion complexes indicated uniform drug distribution. The average particle size of the Gl-β-CD complexes was found to be within the range of 58.1 μm to 74.3μm. The scanning electron microscopy revealed the appearance of binary systems as agglomerates, exhibiting the amorphous nature of the multi-component systems. FT-IR spectroscopy and DSC studies indicated no interaction between UDCA and Gl-β-CD. Molecular inclusion complexes of ursodeoxycholic acid with Gl-β-CD showed considerable increase in the dissolution rate in comparison with physical mixture and pure drug in 0.1N HCl, pH 1.2 and phosphate buffer, pH 7.4. Dissolution enhancement was attributed to the formation of water soluble inclusion complexes with the Gl-β-CD. The *In vitro* release from all the formulations was best described by first order kinetics followed by Higuchi release model. In conclusion, due to the formation of stable molecular inclusion complex of UDCA with Gl-β-CD, the dissolution profile was enhanced significantly, which in turn have potential to produce a faster onset of action and assists in dose reduction.

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