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Physico-chemical characterization and *in vitro* dissolution behavior of reserpine - hydroxypropyl-β cyclodextrin inclusion compounds

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The objectives of this research were to prepare, characterize inclusion complexes of reserpine with hydroxypropyl-βcyclodextrin (HP-βCD) and to study the effect of complexation on the dissolution rate of reserpine, an indole alkaloid having antipsychotic and antihypertensive effect that has been used for the control of high blood pressure and for the relief of psychotic symptoms. The phase solubility profile with HP-βCD was classified as Ap-type, indicating the formation of 2:1 stoichiometric inclusion complexes with respect to cyclodextrin. Gibbs free energy ($\Delta G tr^{o}$) values were all negative, indicating the spontaneous nature of reserpine solubilization and they decreased with increase in the HP-βCD concentration, demonstrating that the reaction conditions became more favorable as the concentration of HP-βCD increased. Complexes of reserpine were prepared with HP-βCD using various methods physical mixture, kneading, spray drying and lyophization. The complexes were characterized by differential scanning calorimetry and fourier-transform infrared spectroscopy. These studies indicated complex prepared using spray drying and lyophization methods showed successful inclusion of the reserpine molecule into the HP-βCD cavity. The complexation resulted in a marked improvement in the solubility and wettability of reserpine. The complexes exhibited faster and higher rates of dissolution compared to that of reserpine. The complex prepared with HP-βCD by lyophilization method has fastest and highest *in vitro* dissolution rate when compared to the tablets of pure of reserpine. Physical mixture of cyclodextrin-reserpine also showed significant improvement in the dissolution rate compared to pure reserpine. The findings of this research work suggested that the drawback of poor dissolution profile of reserpine could be overcome by preparing its inclusion complexes with HP-βCD by lyophilization method.