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#### Evaluation of fenofibrate-cyclodextrin complexes prepared by co-grinding method

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Cyclodextrins (CD-s), and CD derivatives are widely used for the improvement of the physicochemical properties of poorly water soluble active pharmaceutical ingredients (API-s). Several methods (e.g., co-precipitation, kneading) require organic solvents to prepare these complexes. Nevertheless, complexation can be achieved via mechanochemical activation by co-grinding method. Generally, complexation with amorphous CD-derivatives requires shorter grinding time and results stable amorphous products.

Our aim was to prepare API-CD complexes by co-grinding and use analytical techniques to describe the complexation process as a function of grinding time. In this study heptakis(2,6-di-O-methyl)- $\beta$ -cyclodextrin (DIMEB), an amorphous CD-derivative was used as a complexation agent, and fenofibrate (FEN), a BCS II. API was chosen as a model drug. FEN-DIMEB physical mixture was prepared in 1:1 molar ratio. Co-grinding was performed in a mortar for 60 minutes, and samples were taken at predetermined intervals. Original components and samples were characterized by DSC, XRPD, FTIR methods. Dissolution properties of API, physical mixture, kneaded product, and co-grinded samples were also investigated.

DSC investigation showed that the endothermic peak indicating the melting point of the API decreased continuously with increasing co-grinding time. Meanwhile, a new, continuously growing exothermic peak appeared at a higher temperature after 30 minutes of grinding time. XRPD studies showed a linear trend of decreasing peaks with the increasing grinding time, after 60 minutes the product was totally amorphous. Based on FTIR results, presence of molecular interactions was detected between the host and guest molecules. The product obtained by co-grinding showed similar dissolution property compared to the kneaded product due to the presence of stable amorphous molecular complex.

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