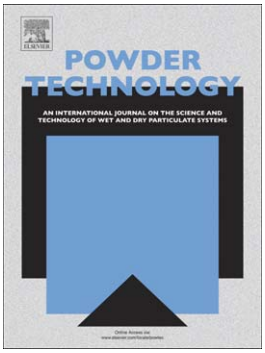

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INTERFACIAL STRENGTH OF BILAYER PHARMACEUTICAL TABLETS

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ABSTRACT

The oral drug delivery system using bilayer (or multilayer) tablets has become more commonly used in therapeutic strategies. However, one of the most common problems associated with bilayer tablets is the insufficient interfacial strength between layers, which leads to product failure during manufacturing. Therefore, it is important to better understand the interfacial strength of bilayer pharmaceutical tablets. For this purpose, in this study, the interfacial strength of bilayer tablets made of microcrystalline cellulose (MCC PH 102) at various manufacturing conditions was systematically examined. Three cases were considered: (1) the effect of interfacial curvature on the interfacial strength, for which the interfaces between two layers with different curvatures were produced using flat, convex and concave punches. (2) The effect of water content on the interfacial strength, for which the powder was conditioned at various relative humidity before being used to produce bilayer tablets. (3) The effect of the particle size of the powder used in first layer on the interfacial strength, for which the feed powder was sieved to obtain powders with specific particle sizes that were then used to produce the first layer of the bilayer tablets. For all cases considered, direct tensile tests were performed to measure the tablet interfacial strength. It is found that the interfacial curvature, the water content and the particle size in the first layer affected the interfacial strength significantly. It is also shown that the tablet interfacial strength was increased when larger particles were used in the first layer, or when curved punches (i.e. either convex or concave

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