

Abstract

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Title of Thesis: Study of excipients' influence on the drug dissolution
from tablets

The aim of this work was to study the influence of excipients on the dissolution of the high-dose active substance from tablets. The tablets were compressed from the granules prepared by wet-granulation method. 11 batches of tablets which contained two different fillers: either lactose or microcrystalline cellulose, respectively; and extragranularly added disintegrant: either croscarmellose or crospovidone, respectively, in three concentration levels of 2 %, 3,7 % or 5,4 % were prepared. Tablets were packed into aluminium/PVC blisters. The paddle dissolution test was used to determine the release of the active substance into phosphate buffer pH 7,2 at the time of preparation (time 0) and at the time points 1.5, 3 and 6 months of stability assay at 40 °C and 75 % relative air humidity.

The results show that the drug release from tablets containing microcrystalline cellulose was generally faster than from those containing lactose. The same was true for tablets to which croscarmellose was extragranularly added when compared with the addition of crospovidone. Moreover, the visible defects were observed on the surface of crospovidone tablets. The fastest drug release was generally observed for the tablets with the highest concentration of the disintegrant.