Abstract

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Title of Thesis: Influence of fillers' and disintegrants' type on properties

of tablets with high dose drug

The work engages in the study of fillers' and extragranular superdisintegrants' influence on properties of tablets with high dose drug. Two types of granulate with lactose or microcrystalline cellulose were produced in high shear granulator. Eleven tablets groups with different type and amount of superdisintegrants were prepared from the granulates. Tablets contained 2 %, 3.7 %, 5.4 % of sodium croscarmellose or 2 % and 5.4 % of crospovidone. The tested parameters of tablets were friability, hardness, disintegration time and density. Accelerated stability studies lasting 6 months at temperature of 40 °C and relative humidity 75 % were done. The tablets were evaluated after 1.5, 3 and 6 months.

All tablets had adequate friability, hardness, disintegration and density at T₀. Increasing concentration of superdisintegrant decreased disintegration time. Tablets containing microcrystalline cellulose and sodium croscarmellose disintegrated faster than tablets containing lactose or crospovidone. Tablets with sodium croscarmellose had higher density than tablets with crospovidone.

The stability testing proved that the friability of all tablets did not significantly change over time. Hardness of all tablets increased with time. Density of all tablets initially increased and then decreased but never reaches the same value as at T₀. Disintegration time of tablets containing sodium croscarmellose increased and then decreased with time. Tablets containing microcrystalline cellulose and 3,7 % and 5,4 % of croscarmellose sodium had the smallest changes in disintegration time throughout the stability testing. Tablets containing crospovidone did not disintegrate within 15 min at T_{3M} and thus they were excluded from the study.