ABSTRACT

Charles University, Faculty of Pharmacy in Hradec Králové

Department of: Pharmaceutical Technology

Mentor: Assoc. Prof. PharmDr. Jitka Mužíková, Ph.D.

Student: Iveta Vnučáková

Title of Thesis: Study of tableting materials and tablets from co-processed dry binder based on mannitol and microcrystalline cellulose.

This thesis deals with the study of tableting materials and orally dispersible tablets containing co-processed dry binder F-melt® type M with the drugs domperidone and ibuprofen. All formulations also include the sweetener sucralose in a concentration of 1 %. For placebo tablets and directly pressed tablets, lubricant is added in a concentration of 1%, for granules the lubricant is in a concentration of 1.5%. Domperidone formulations contain magnesium stearate and the tablets are compressed at the compression force of 3 kN and ibuprofen formulations compressed at a compression force of 5 kN contain sodium stearyl fumarate. The flow properties of tablets, the energy profile of compression process, tensile strength, friability, porosity, disintegration time, as well as the time of wetting and water absorption are evaluated.

Placebo tablets showed the highest total compression energy (E_{max}). Due to the influence of drugs and granulation, Emax decreased. The highest tablet tensile strength was achieved by F-melt® placebo tablets. Both drugs reduced the strength, ibuprofen more significantly. Tablet friability correlated with tablet tensile strength. The drugs increased value of friability increased. All formulations with domperidone met the limit up to 1%. In the case of ibuprofen, the friability of directly compressed tablets exceeded the limit, and the friability of granulated tablets was at the limit. Placebo F-melt® tablets showed the shortest disintegration and wetting time. Both drugs prolonged these values, the effect of ibuprofen was more significant. All domperidone formulations met the FDA recommendation and disintegrated within 30 seconds. In the case of ibuprofen, both the directly compressed formulation and the granulated formulation exceeded the European Pharmacopoeia limit of a disintegration time of up to 3 min. The co-processed dry binder F-melt® appears to be the most suitable for the production of ODT with the drug domperidone, compared to the previously tested Ludiflash®, Parteck® ODT and Prosolv® ODT G2.