ABSTRACT

THE EFFECT OF PVPK30 ADDITION ON MICROCRYSTALLINE CELLULOSE PH101 AND MALTITOL COMBINATION CO-PROCESSED AS CUSHIONING AGENT IN METFORMIN HCL MULTIPLE-UNIT PELLET SYSTEM (MUPS) TABLETS

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The aim of this research was to investigate the effect of PVP K30 addition on the co-processed combination of microcrystalline cellulose (MCC) PH101 and maltitol combination co-processed as cushioning agent and discover optimum ratio of MCC PH101:maltitol:PVP K30 that could protect pellets. Thus, good physical characteristics of tablet MUPS was produced. Hydrophilic polymer PVP K30 was plastic material that could used as binder. Two different formulas ratios of MCC PH101:maltitol:PVP K30 (5:1:0.3 and 5:1:0.7 w/w) were optimized. These cushioning agents were made by co-process which include wet ball milling and spray drying. Cushioning agents were evaluated for their physicochemical and mechanical characteristics. Mechanical characteristics was analyzed using Heckel-plot to obtained p_y value. Result showed that addition of PVP K30 couldn't increase its plasticity of the co-process obtained. MUPS tablets were evaluated to determine its physical properties of tablet. Moreover, dissolution studies was used to determine the optimum cushioning agent that could protect pellets from damaged caused by compaction. Differential factor (f_1) and similarity factor (f_2) were applied to evaluate dissolution profiles of MUPS tablets. The f_1 dan f_2 values of MUPS tablet with MCC PH101:maltitol:PVP K30 5:1:0.3 combination were 12.25 and 56.84. It showed that dissolution studies of those combination had the most similar value with dissolution profile of uncompacted pellets as control. However, dissolution profile MUPS tablet compacted with MCC PH101:maltitol:PVP K30 5:1:0.7 showed difference compared to the dissoultion profile of uncompacted pellets as control. In conclusion, increasing level of PVP K30 did not affect plasticity hence failed to protect pellets from damaged.

Keywords: Tablet MUPS, cushioning agent. MCC PH101, maltitol, PVP K30