

ABSTRACT

**THE EFFECT OF ERITRITOL CONCENTRATION ON
CO-PROCESS COMBINATION OF MICROCRYSTALLINE
CELLULOSIC PH101 AND ERITRITOL MICROCRISTALINE AS
CUSHIONING AGENT IN METFORMIN HCl MULTIPLE UNIT
PELLET SYSTEM (MUPS) TABLET**

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MUPS tablet consists of sustained released pellets which are compacted into tablet. The main problem of MUPS tablet is the rupture of the pellet coating layer due to the compression force. Thus, a material that could protect pellet from compacting energy is needed. This material is so called cushioning agent. The ideal cushioning agent could protect pellet coating layer as well as provide a fast disintegration process with a drug dissolution profile similar to the uncompacted pellets. Microcrystalline cellulose PH101 (MCC PH101) is an excipient that can be used as a cushioning agent because it has good plasticity. However, theoretically, cushioning agent should have good combination of plastic and elastic material. One of elastic material is erythritol. In this study, 3 different formulas of cushioning agent were investigated: MCC PH101:Erythritol with ratio 10:1, 10:3, and 10:5. The co-process was begun with wet ball milling to reduce the particle size of the combined materials followed by spray drying. The co-processed cushioning agents were characterized using FTIR, DTA, MC, SEM, XRD, and calculation of P_y value. MUPS tablets were obtained by compressing pellets containing metformin HCl layered in ethyl cellulose : cushioning agents at ratio 1 : 1 (w/w). Compaction force applied was 2 kN using the NP-RD 10A-1520 Natoli Hand Press. MUPS tablets were then characterized for their size uniformity, hardness, disintegration time and dissolution. dissolution profiles of compacted pellets-cushioning agent were analyzed using the difference factor (f_1) method and similarity factor (f_2) to asses their similarity and difference with the uncompacted pellets. The dataobtained showed that all combinations of co-processed MCC PH101-Erythritol had higher dissolution profiles than the uncompacted pellet. This showed that the combination of cushioning spray dried agent MCC PH101-Erythritol with a ratio of 10: 1, 10: 3, and 10: 5 could not protect the pellets during the compaction process.

Keyword : MUPS tablet, Cushioning agent, Microcrystalline cellulose PH10, Erythritol