

Thesis Title The in vitro Release Profiles of Ibuprofen
with Fusible Excipients in Hard Gelatin
Capsules.

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Date of Graduation 9 May B.E. 2537 (1994)

ABSTRACT

This study was to solve the problem on dissolution of ibuprofen solid dosage form and explore feasibility of making prolonged-release formulation. Ibuprofen capsules were prepared as semisolid matrix or liquid-filled in hard gelatin capsules. The drug was incorporated with fusible excipients which were 11 grades of Gelucires^R products and polyethylene glycol 6000 (PEG 6000). Good uniformity of drug content and weight variation of ibuprofen capsules were obtained. The effect of fusible excipients on release profiles of ibuprofen capsules were studied and classified into 3 groups. First, fast release formulations, the excipients were Gelucire 44/14, Gelucire 42/12 and Gelucire 35/10 at ibuprofen:Gelucire weight ratios of 1:1.5 and 1:1. Second, medium release formulations where the excipients were Gelucire 50/13,

Gelucire 37/02, Gelucire 33/01, PEG 6000 at the weight ratios of 1:1.5, 1:1 and 1:0.5, Gelucire 44/14, Gelucire 42/12 and Gelucire 35/10 at the weight ratio of 1:0.5. Third, slow release formulations where the excipients were Gelucire 53/10, Gelucire 48/09, Gelucire 46/07, Gelucire 62/05 and Gelucire 50/02 at all weight ratios. The mechanism of release was governed by erosion process and followed a first order kinetics. The release of ibuprofen capsules for fast delivery were slow down after prolonged storage at room temperature for 4 and 6 months, but the release rate lied within the limit of the USP. The differential scanning calorimetry was studied. It was shown that the interaction might occur between the drug and excipients and could be defined as the eutectic mixtures. PEG 6000 was the excipient that provided the required release profile, but there were some limitation for ibuprofen prolonged-release formulation. However, the rapid release ibuprofen capsules were found to be satisfactory. This is one of the choices to solve the problem of ibuprofen tablets.