直打用間質性控釋材質之開發研究

Development of matrix materials for direct compression of controlled release dosage forms

中文摘要

本實驗即針對直接壓錠法所顯現之優點，嘗試找出可用的直打用間質性材質．採用的方式爲利用濕式造粒法將常用的賦形劑如乳糖，磷酸二鈣,以乙基纖維素的水性分散液 (Surelease 25 % w/w) 製備成間質性材質進行包覆，再將此材質和藥物混合後，以直接壓錠法壓成錠，所選用的藥物爲水溶性良好的 Captopril.實驗變因有：賦形劑種類，高分子材料之用量，水性塑化劑添加量,在此測定包覆顆粒的物化性質，及壓錠後錠片之特性，並藉體外溶離試驗來評估水溶性藥物 Captopril 的緩釋效果，且找出適當的分析方法來偵測此間質性錠片服用後的血中濃度.實驗結果顯示，製成之直打錠片的物理性質再現性皆良好，而隨著包覆之高分子物質 (Ethylcellulose 的 25% 水性分散液之商品 Sure-lease) 的添加由 1% 至 10% 之增加，緩釋效果愈好，用乳糖及磷酸二鈣之結果皆相同，在血中濃度的偵測方面，採用 HPLC 分析，和市售錠劑相比，此劑型確可延緩藥物釋出，且所得緩釋效果和體外溶離結果具有一致性．由此知，此直打用間質性控釋材質的開發有其正面的意義．

英文摘要

The results indicated that the physical properties of the tablets are good. Larger amount of Surelease (The aqueous dispersion of 25% ethylcellulose) used in the formulation (1% to 10%) would result in slower drug dissolution. There shows no significant difference of characteristics between lactose and dicalcium phosphate. Compared to commerical product, the controlled release dosage forms developed in this study present a slower release rate and higher extent of AUC. Above all, it is proved to be developing matrix materials for direct compression of controlled release dosage forms using two common-used excipients of lactose and dicalcium phosphate