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• 中文關鍵字	間質性圓粒；擠壓搓圓法；包覆賦型劑；緩釋劑型藥物；乳糖		
• 英文關鍵字	Matrix pellet；Extrusion spherization；Coated excipient；Controlled release drug form；Lactose		
• 中文摘要	以擠壓搓圓法製備多重顆粒或圓粒的口服控釋劑型,近來在藥界有逐漸普遍的趨勢。擠壓搓圓法中圓粒的性質與處方中起始物質的選擇相當有關,有些材質非常適用於搓圓法,有些則不易成功。然而除了材質的特性之外,搓圓的速度,搓圓的時間,與造粒團塊的水分含量,都可使圓粒具備不同的性質。本報告對搓圓轉速、團塊水分含量及處方中的微晶纖維素比例於搓圓過程和結果的影響作出比較與討論;並且比較所製備的包覆型賦形劑與無包覆的賦形劑對搓圓過程和結果的影響。實驗結果顯示隨著轉速的增加,圓粒粒徑的分布縮小。在水量不足所搓出的圓粒小且形狀不規則,適當含水量所搓出的圓粒大小適中且形狀較圓,而高含水量時因表面有過多的水而使顆粒產生聚集。隨微晶纖維素比例的增加,可產生適當大小圓粒所能選用的水量範圍較大。被聚合物包覆的乳糖、磷酸二鈣與微晶纖維素混合後搓圓所需的水量較無包覆的乳糖、磷酸二鈣與微晶纖維素混合後搓圓所需的水量爲高。		
• 英文摘要	Application of the extrusion/spheronization technique in the manufacture of multigranules or pellets as controlled-release oral dosage forms is becoming popular in the pharmaceutical area. The properties of the pellets prepared by extrusion/spheronization is closely related to the materials selected to be used in the formulation. Some materials are very suitable for the spheronization technique while some are prone to failure. Other than the inherent properties of the materials selected in the formulation, the speed and dwelling time of the spheronization step as well as the quantity of water used in the preparation of the wet mass may also result in pellets with different properties. In this report, the influence of speed, water content, and the ratio of microcrystalline cellulose (MCC) in the		

formulation on the spheronization conditions and the resulting products were compared and discussed. Coated excipients were also prepared, tested for the preparation of pellets, and the properties of these pellets were compared to the uncoated ones. It was found that as the spheronization speed was increased, the size of the pellets were more evenly distributed. When water content was insufficient, irregular and smaller pellets were formed. When optimal water was used in the preparation, round pellets were formed. When much water was added, excessive of water retained on the surface of the wet mass induced the aggregation of pellets. As the proportion of MCC was increased, larger range of water content could be used in the preparation of optimum pellets. When MCC was mixed with coated or uncoated excipients and tested in the preparation of pellets, much water was needed for the polymeric coated lactose or dicalcium phosphate.