• 計畫中文名稱	開發 Gliclazide 體外體內相關性之關鍵性溶離試驗		
• 計畫英文名稱	Critical Dissolution Tests of Gliclazide in the Development of in vitro/in vivo Correlation		
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• 研究領域	藥學		
• 研究人員	許明照		
• 中文關鍵字	體外體內相關性；體外溶離試驗；體內吸收		
• 英文關鍵字	in vitro/in vivo correlation；in vitro dissolution；in vivo input		
• 中文摘要	在本研究中將藉由體外溶離試驗與體內血中濃度變化建立 Gliclazide 之體外體內相關性。體外體內相關性（in vitro/in vivo correlation，IVIVC），是指建立體外溶離（in vitro dissolution）與體內吸收（in vivo input）的關係。體外溶離試驗常用來當做藥物製劑的品質管制或是建立臨床表現的依據，而藉由體外溶離試驗來代替體內的生體相等性（bioequivalence）試驗，是近來新興的研究方向。而 FDA 在 1997 年也制定了 A、B、C 等數種等級，來幫助建立口服藥物的體外體內相關性。Gliclazide 爲一難溶性藥物，因此將藉由添加不同比例之 SLS 來增加其溶解度，並利用充填入控釋膠囊來控制其釋放速率，以建立快、中、慢三種不同處方之溶離速率曲線。之後將這三種處方在 18 名健康受試者進行人體試驗，以得到血中濃度曲線與藥物動力學參數，並經由適當的計算建立 A 等級（level A）和 C 等級（level C）之體外體內相關性，並對建立之相關性進行內部預測力（internally predictability）的檢定，以確定所建立的相關性合於規定的標準。而所建立出的相關性對於日後 Gliclazide 的處方修飾或是製程改變，將可提供體外溶離與體內血中濃度變化的參考依據，進一步代替生體相等性的試驗。		
• 英文摘要	The purpose of this research project is to establish in vitro /in vivo correlation (IVIVC) of Gliclazide. IVIVC refer to relationships between in vitro dissolution and in vivo input rate. As is well known, in vitro dissolution testing is a powerful and useful method for determining product quality and sometimes to evaluate the clinical performance of dosage forms. The utility of in vitro dissolution as a surrogate for in vivo bioavailability is very attractive and has been demonstrated for several products. Four categories ?]Level A,		

	Level B, Level C and Multiple level C ? ^of IVIVCs have been described in the 1997 FDA guidance. Gliclazide is an insoluble drug, in this study SLS or other proper solubility enhancer will be used to improve its solubility and then use the osmotic pump capsules to control the drugs release rate. Finally, three release rate formulations which dissolution profiles are fast, medium and slow will be established. The three formulations will be ingested with 18 volunteers in a three-way cross over design to get plasma concentration profiles, from which the pharmacokinetic data will be deduced. Through the appropriate methods, the dissolution rate and plasma concentration profiles will be established to construct Level A or Level C in vitro/in vivo correlation. An IVIVC shall be verified to demonstrate that the predictability of the in vivo performance of a drug product from the in vitro dissolution characteristics of the drug product formulations. In cases where a meaningful IVIVC can be developed, this can be used as a surrogate for bioequivalence and can minimize the number of the bioequivalence studies needed.