• 計畫中文名稱	利用可稀釋性之自行微乳化型預微乳系統爲模板製備奈米級藥物晶體與間質顆粒之技術開發與特質解析		
• 計畫英文名稱	Technology Development and Characterization of Dilutable Self-Microemulsifying Premicroemulsion Systems (SMEPMSs) as the Template for Preparing Nanodrugs and Nanoparticles		
• 系統編號	PC9609-3889	• 研究性質	基礎研究
• 計畫編號	NSC96-2628-B038-001-MY3	• 研究方式	學術補助
• 主管機關	行政院國家科學委員會	• 研究期間	9608 ~ 9707
• 執行機構	臺北醫學大學藥學系(所)		
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• 研究領域	藥學		
• 研究人員	許明照		
• 中文關鍵字			
• 英文關鍵字			
• 中文摘要	本三年期的研究計劃,利用可稀釋性的自行微乳化型預微乳劑作爲模板,使用部分水可混合的製藥級溶媒爲油相以製備三種奈米級藥物顆粒(fenofibrate,griseofulvin,及olanzapine)與三種包覆顆粒(PLGA, Eudragit L100-55,及 EthylCellulose)。以擬三成分相圖的建構爲基礎,尋求可稀釋性的自行微乳化型預微乳劑型所需的界面活性劑/共界面活性劑以及水相/共溶媒的最佳組合種類與比例範圍,並特性解析其相轉移的物理現象。Benzyl alcohol與 butyl lactate將選擇作爲製備奈米藥物顆粒的油相,dichlormethane或 triacetin與丙酮的組合將選爲製備包覆奈米顆粒的油相,而 Tween系列,Pluronic系列,或 Cremophor系列選擇爲製備奈米藥物顆粒與包覆顆粒的界面活性劑/共界面活性劑/共界面活性劑組合的擬三成分相圖。第二年將進行三種模式藥於適宜化之自行微乳化型預微乳劑型的溶解度,以及稀釋過程的溶解度變化與相間界面的物理特質解析。藉此確認製備奈米級藥物顆粒的製程參數條件,並與奈米藥物顆粒之物理特質進行相關影響性解析。第三年將以相同模式進行三種包覆材質之奈米級包覆顆粒的製備,並以前述三種模式藥爲包覆標的。除了進行三種模式包覆材質於適宜化之自行微乳化型預微乳劑型的溶解度測定,以及稀釋過程的溶解度變化與相間界面的物理特質解析。除了進行三種模式包覆材質於適宜化之自行微乳化型預微乳劑型的溶解度測定,以及稀釋過程的溶解度變化與相間界面的物理特質解析。外,並於三種模式藥之存在與否比較其對相轉移與溶解度之影響。由此將確認可達較佳包覆率的自行微乳化型預微乳劑型,並適宜化其製備奈米級包覆顆粒的製程參數條件,最後再將奈米包覆顆粒之物理特質與包覆率進行相關影響性解析。最終期望建構以可稀釋性的自行微乳化型預微乳劑作爲模板製備奈米級藥物顆粒與包覆顆粒的技術平台。		

## In this three-year proposal, the utilization of dilutable SMEPMSs to form microemulsions as the template for preparing three model nanodrugs (fenofibrate, griscofulvin, and olanzapine) and three model nanoparticles (PLGA, Eudragit L100-55, ethylcellulose) will be developed with the use of partially water miscible and pharmaceutically acceptable solvents as the oil phase and the pseudo-ternary phase diagrams will be constructed to characterize and optimize surfactants, cosurfactants, and cosolvents for the respective solvents in the production of three model nanodrugs and nanoparticles. Benzyl alcohol, triacetin, and butyl lactate will be selected as the partially miscible solvent as the internal phase for preparing nanodrugs and dichloromethane and acetone for nanoparticles. Tween series (20-80), Pluronic series (L-44, F-68, and F-127), and Cremophor series (EL, RH-20, RH-40, RH-60) will be selected as surfactants for both preparations of nanodrugs and nanoparticles. Cosurfactants will select from short-chain alcohols (ethanol, propanol, and butanol) and glycols (glycerol and propylene glycol) for both preparations of nanodrugs and nanoparticles. The pseudo-ternary phase diagram will be constructed for optimal combinations of each selected solvents for nanodrugs and nanoparticles with surfactants/cosurfactants and water/cosolvents in the first year period. The solubilization capacity of three model drugs in these systems will be examined and process parameters will be optimized in the second year period. The solubilization capacity of three model polymeric materials in the corresponding optimized SMEPMS systems for preparing nanoparticles will be evaluated and process parameters will be validated in the third year period. In the final, optimized formulations of SMEPMS and process parameters can be

defined with respective to the physical characteristics of model drugs and polymeric materials.