• 計畫中文名稱	水溶性維生素 E 改善 Estradiol 經皮吸收之研究		
• 計畫英文名稱	The Study of Improving Percutaneous Absorption by Water-Soluble Tocopherol		
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• 研究人員	何秀娥		
• 中文關鍵字	水溶性維生素 E；Estradiol；統計實驗設計法；局部皮膚製劑；溶媒組合		
• 英文關鍵字	Water-soluble Tocopherol；Estradiol；Experimental Statistical Design；Transdermal Delivery		
• 中文摘要	本計畫之目的在於探討具有類似於皮膚角質細胞間之脂質的 mesomorphic 液晶結構的水溶性維生素 E (tocopheryl polyethylene glycol succinate, TPGS) 對於改善停經後症候群治療劑的 ESTRADIOL 之經皮吸收效果， 以提供國內廠商設計開發相關的 ESTRADIOL 局皮膚用產品之參考。本實驗將應用統計實驗設計法有效的 利用較少的實驗組數而能最佳的將水溶性維生素 E 改善 ESTRADIOL 經皮吸收的影響效果適宜化，並探討 在不同溶媒組合時，水溶性維生素 E 影響 ESTRADIOL 經皮吸收效果之程度差異。實驗將以裸鼠皮爲主要 的障礙層模式，於 FRANZ 滲透裝置中進行評估。固定 ESTRADIOL 濃度爲 1%，將添加有不同量水溶性維 生素 E 的不同溶媒組合置於給藥室，於預設的時間由接受室取樣，樣品中 ESTRADIOL 與 TPGS 的濃度將 利用已經確效的液相層析法分析並定量以及計算其通透量。進而將 ESTRADIOL 由不同量水溶性維生素 E 的不同溶媒組合之通透量 (Flux) 作爲應對值 (Response)，對水溶性維生素 E 用量與溶媒組合比率的自變數 進行二次方程式迴歸，由此而將此些自變數對 ESTRADIOL 通透量影響的定量方程式適宜化。此定量方程 式將可應用於設計 ESTRADIOL 局部皮膚製劑之處方參數選擇之依據。		
• 英文摘要	In this study, tocopheryl polyethylene glycol succinate (TPGS) with a mesomorphic structure of liquid crystal similar to that of intercellaric lipid of stratum corneum will be used to explore the possibility of improving the transdermal efficacy of estradiol as a way to treat postmenopause symdroms. The results will provide the local pharmaceutical company as a reference to develop and		

	market the product. An experimental statistical design with a suitable number of experimental sets will be employed to examine and optimize the improvement of TPGS on the transdermal delviery of estradiol in different ratio of solvent systems.The penetration studies will use the hairless mouse skin the principal barrier. Franz type of diffusion cells will be used as a device to assess the percutaneous penetration. At a fixed concentration of 1% for estradiol, different ratios of solvent composition will be added to the donor compartment with different amount of TPGS. At predetermined time intervals , samples will be drawn from the receive compartment and concentration of estradiol and TPGS in the samples will be determined with a validated HPLC method. The flux of estradiol or TPGS will be calculated from the linear portion of the cumulated amount versus time plots. With flux as a response, regression on a second order equation using solvent ratio as indepenedent variable will be processed and statistical significance of coefficient for each terms will be examined. A quantitative equation for the expression of the influence of solvent ratio on the percutaneous penetration of estradiol at a certain amount of TPGS will be constructed. Optimization to maximize the penetration of estradiol with an appropriate flux of TPGS will be proceeded leading to optimally select a solvent ratio for the percutaneous delivery of estradiol.The final equation will be referred as a measurement to select a suitable solvent ratio with a an appropriate 68amount of TPGS for such a water-in soluble drug of estradio l.