• 系統編號	RC8907-0099
• 計畫中文名稱	新穎靈芝三帖類之製劑研究
• 計畫英文名稱	Formulation Study on the Novel Triterpenoids Isolated from Ganoderma
• 主管機關	行政院衛生署
• 計畫編號	CCMP88-RD-053
• 執行機構	台北醫學院
• 本期期間	8707 ~ 8806
• 報告頁數	0 頁
• 使用語言	中文
• 研究人員	許明照；邱惠苓 Sheu, Ming-Thau；Chiu, Hui-Ling
• 中文關鍵字	靈芝；配方；三？類；安定性試驗；製劑
• 英文關鍵字	Ganoderma lucidum；Formulation；Triterpenoid；Stability；Pharmaceutical preparation
• 中文摘要	本計畫之研究目的在於改善中藥的製劑劑型,以提高其成分的安定性,及增強中藥成分的生體可用率而加強其臨床的治療效果。本實驗選用靈芝單方的三帖類萃取物爲模式中藥成分,使用生體可接受之助溶劑與共溶媒溶解成爲加熱可溶的固體或半固體劑型,而後在熔融狀態下直接充填而製備成膠囊劑型。首先開發完成能有效分析靈芝三帖類及其可能降解產物的高效液相層析法,以進行靈芝三帖類膠囊製劑的安定性試驗。在靈芝三帖類的助溶實驗中發現, Gelucire 44/14,RH40,及 RH60 分別與 PEG600 以一定比例(2:3)組合,再與靈芝三帖類以 1:9 的比例混合後,可使 Ganoderic acid B 及 Ganoderic acid C/sub 2/完全溶解。傳統的固體硬膠囊與錠片以習用的澱粉、微晶纖維素與乳糖吸附熔融狀態的助溶萃取物後製備而得。由溶離試驗確定此些吸附於固體賦型劑的靈芝三帖類皆能迅速的於 10 分鐘內完全溶出,但其所需要的吸附量都相當大,尚須改進。最後調製助溶萃取物組合,趁其熔融時充填於適當膠囊中,以鋁箔包裝後將上述的膠囊劑型儲存於三種溫度下(25,37,45.degree.C),在儲存期間定時取樣,以高壓液相層析法分析其指標成分之含量變化。結果顯示,使用 Gelucire 44/14 及 PEG600 作爲共溶媒的硬膠囊中,其 Ganoderic acid B 及 Ganoderic acid C/sub 2/的含量較其他高些;然而,大多數處方 Ganoderic acid B 及 Ganoderic acid C/sub 2/成分降解 10%所需時間的有效期皆在一至二星期之間而已。
• 英文摘要	The purpose of this study was to improve the dosage form by increasing the stability of active ingredients and enhancing its bioavailability as a way to strengthen clinical efficacy. Triterpenoids isolated from Ganoderma resinaceum were selected as model drugs with the use of pharmaceutically acceptable solubilizers and cosolvents to prepare heat-soluble solid or semi-solid dosage forms such as hard capsules or tablets. Initially, a valided HPLC method was developed to have an acceptable accuracy and precision as a method to assay all samples in the following

study. The solubilization study revealed that when Gelucire 44/14, Cremmorphor RH-40, RH-60 at a ratio of 2:3 with respect to PEG 600 was able to completely solubilize Ganoderic acid B and C2 at a concentration of 10%. Solid dosage forms prepared with the adsorption of above formulation to these commonly-used excipients, such as lactose, starch, or MCC, was only able to become free-flow powder when a large quantity of them was employed. Although the dissolution of both was fast enough, the large quantity of excipient necessary for such a preparation made it become impractical in the application. Results of accelerated stability study using semi-solid filled in capsule as model sample showed that expiration date of Ganoderic acid B and C2 in all samples tested was only 1-2 weeks. Active ingredients carried by Gelucire 44/14 with PEG 600 system showed the best stability among all, but it was still not good enough for practical application.