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• 中文關鍵字	調胃承氣湯；加速安定性試驗；毒性試驗
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• 中文摘要	中藥科學化最大的瓶頸是如何有效的控制其品質及穩定性？而定量的困難，在於不知何組成含有多少量，可以代表此一製劑之有效性。且方劑以科學化之劑型生產時，因其組成複雜，與古代給藥經驗亦不相同，新劑型與給藥方式是否產生毒性，皆應該依新藥上市之辦法評估其安定性。因而如何進行中藥製劑之安定性品管，是迫切待解決之問題。目前各 GMP 中藥廠已依衛生署中醫藥委員會規定，皆自行訂定指標成分之標準，進行安定性試驗，計算出有效貯存時間，但各廠間並無統一之標準，導致市售製劑各家效果不一。故本研究根據西藥之安定性進行調胃承氣湯之安定性試驗，結果發現大黃之指標成分 Sennosides A 及 B 在藥用大黃中含量比錦紋大黃高，且於調胃承氣湯中之移行率爲 50%以下，但在加速安定性試驗中發現成分消長不明顯，無一規則性，顯示中藥製劑不適合用加速安定性試驗方法，宜採用貯存性安定試驗監測。另已利用 HPLC 建立三承氣湯之指紋圖譜，且發現調胃承氣湯之 Sennoside B 及 Aloe-emodin 含量較大、小承氣湯多，而大、小承氣湯之差異在於 Rhein 與 Mangnolol 之含量比例不同。
• 英文摘要	It is important to control the quality of Chinese medicine products. However, Chinese medicine included complex compounds; it is difficult to identify which is an active principle. The purpose of this research is to establish the normal quality-controlling process through determining the chemical markers of Chinese medicine products by HPLC system. In this study, we investigated the safety and toxicity of Tiao-Wei-Cheng-Qi Tang (TWCQ). The prescriptions of Tiao-Wei-Cheng-Qi Tang are Rhubarb, Licorice and Mirabilitum, and Rhubarb is the major active component among them. Therefore, sennosides A and B were used as substance markers in TWCQ. The results showing: (1) Sennosides A and B content in commercial TWCQ were very difference between pharmaceutical companies. (2) High content of sennosides A, B in R. officinale is a characteristic different

from R. palmatum. (3) Sennosides A and B content in commercial TWCQ were stable in stress conditions, temperatures. However, TWCQ was suitable in aqueouse solution of pH 4~5. In according to the above results, we suggested that the stability analysis of Chinese medicine products did not suitably use the stress stability test. The other hand, the HPLC fingerprint spectrum of Tiao-Wei-Cheng-Qi Tang was compared with the other similar prescriptions, Da Cheng-Qi Tang (DCQ) and Xiao Cheng-Qi Tang (XCQ), that was identified the special principle, sennoside B and aloe-emodin in Tiao-Wei-Cheng-Qi Tang. The content ratio of rhein and mangnolol was difference between DCQ and XCQ.