

化銀白色沉澱，並與標準品高效液相層析圖譜比對，判定為磷酸氯林絲菌素。25件檢體之pH值、含水量及抗生素力價檢測結果均符合藥典規定（表二），本調查結果除了可以瞭解目前氯林絲菌素原料藥品質現況外，更提供衛生主管機關作為藥政管理之參考。

參考文獻

1. 蔡美麗、邱怡寧、邱進益、林嘉伯。2006。抗生素Cephalexin原料藥之品質調查。藥物食品檢驗局調查研究年報，24: 57-64。
2. 蔡美麗、羅瀚倫、許家銓、連淑華、邱怡寧、許鳳麟、葉美伶、邱進益、林嘉伯。2007。四環素類 (Tetracyclines) 原料藥之品質調查。藥物食品檢驗局調查研究年報，25: 46-52。
3. 行政院衛生署中華藥典編修委員會。2006。中華藥典。第六版。行政院衛生署，台北市。
4. The United States Pharmacopeia Convention, Inc., 2006, The Pharmacopeia of United States of America XXIX. United States Pharmacopeia Convention, Inc., Rockville, U.S.A.
5. The Directorate for Quality of Medicines of the Council of Europe (EDQM), 2005, European Pharmacopoeia Fifth Edition, France.
6. British Pharmacopoeia Commission, 2000, British Pharmacopoeia 2000, the Stationery Office under license from the controller of Her Majesty's Stationery Office for the Department of Health on Health Ministers, U.K.

Quality Survey of Clindamycins Active Pharmaceutical Ingredient in Taiwan

JIA-CHUAN HSU, TZU-HUI WANG, MEI-LIE TSAI, FONG-LING HSU,
MEI-LING YEH, SHU-HWA LIAN, YU-HSUAN CHEN AND CHIA-PO LIN

Drug Biology Division

ABSTRACT

In order to survey the quality of clindamycin active pharmaceutical ingredient (API), 25 samples were collected by local health authorities from March to August, 2007 and analyzed according to the methods described in the Ch.P. VI, USP 29, EP 5.0 and BP 2000. The results showed that all samples including 12 clindamycin hydrochloride samples and 13 clindamycin phosphate samples met the pharmacopeia requirements.

Key words: clindamycin hydrochloride, clindamycin phosphate, Active Pharmaceutical Ingredient (API)