

Australian Government

Department of Health and Ageing Therapeutic Goods Administration



Please be advised that GMP Clearance is approved for the following manufacturer:

ScinoPharm Taiwan Ltd Number 1 Nan-Ke 8th Rd Tainan Science-Based Ind Park Shan-Hua Tianan 74144 Taiwan - Republic of China

Manufacturer Client ID: 44852

API Name	Manufacturing Step
Gemcitabine HCL	Active material manufacture
Irinotecan HCL	Active material manufacture
Anastrazole	Active material manufacture
Galantamine Hbr	Active material manufacture
Docetaxel	Active material manufacture
Paclitaxel	Active material manufacture

This Clearance remains current until 23/10/2011 unless otherwise revoked.

You are advised to submit a new electronic GMP Clearance application with updated GMP evidence prior to the expiry date to avoid delays in the registration/listing of new products and maintain products on the Australian Register of Therapeutic Goods (ARTG). Expired GMP Clearance could result in affected product(s) being removed from the ARTG.

THIS CLEARANCE LETTER SHOULD BE USED FOR FUTURE LISTING/REGISTRATION OF THE PRODUCT TYPES SPECIFIED ABOVE.

For further information please refer to the Therapeutic Goods Administration website: http://www.tga.gov.au/manuf\gmpsom.htm alternatively you may contact the undersigned.

Yours sincerely

Colleen Trotter

GMP Clearance Unit

Office of Manufacturing Quality

Therapeutic Goods Administration

17/05/2010