香　港　標　準　及　檢　定　中　心
Hong Kong Standards and Testing Centre

Date: 2003-08-07

TEST REPORT

NO: HC123036

APPLICANT: (Code: SHN005)

Shanghai No.1 Medicine (HK) Co Ltd
Flat 1304 13/F Sup Tower
75-83 King's Road
HK

Attn: Denise Suen

SUPPLIER/MANUFACTURER:

Yunnan Crystal Natural Medicine Pharmaceutical Co

DESCRIPTION OF SAMPLE(S):

One submitted sample said to be 恆古骨傷愈合劑 .
Dosage Form : In Dark Brown Liquid
Pack Size : 25 ml/瓶
Country of Origin: 中國雲南
Batch No./Lot No.: 國药准字 Z20025103

Sample(s) Received Conditions:
In original package

Sample Delivery Condition:
Ambient temperature

Sample Original Storage Condition:
Ambient temperature

SAMPLE(S) RECEIVED DATE:

2003-07-23

Anne Chuah, Ch
For Chief Executive

香港新界大埔工業邨大宏街10號
10 Dai Wang Street,
Taipo Industrial Estate,
N. T., Hong Kong

NO: HC123036

TESTED DATE:

2003-07-26 to 2003-07-30

INVESTIGATION(S) REQUESTED:

1. Heavy Metals or Toxic Elements Test 重金屬或有毒元素測試
   - Arsenic content 砷含量
   - Cadmium content 鎘含量
   - Lead content 鉛含量
   - Mercury content 汞含量
2. Microbial Limit Test 微生物限度測試
   - Aerobic plate count 需氧微生物總數
   - Molds and yeasts count 霉菌及酵母菌
   - *Escherichia coli* 大腸桿菌

METHOD(S) USED:

1. Inductively Coupled Plasma – Atomic Emission Spectrophotometry
2. Pharmacopoeia of the People' s Republic of China (2000 Volume 1)

TEST RESULT(S):

1. Heavy Metals or Toxic Elements Test 重金屬或有毒元素測試

Test item(s) 測試項目	恆古骨傷愈合劑	Upper Limit 上限 (服量計)#	Conclusion 結論
Arsenic content 砷含量	每日 <0.1 微克	每日 1500 微克	Pass 合格
Cadmium content 鎘含量	每劑 <0.1 微克	每劑 3500 微克	Pass 合格
Lead content 鉛含量	每日 <0.1 微克	每日 179 微克	Pass 合格
Mercury content 汞含量	每日 <0.1 微克	每日 36 微克	Pass 合格

Calculated as recommended : 25 ml per dose, once per 2 days consumption
以每日建議服量計算: 每 2 日服食 1 次, 每次 25 毫升

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2. Microbial Limit Test 微生物限度測試

Test item(s) 測試項目	恆古骨傷愈合劑	Microbial Limit 微生物限度#	Conclusion 結論
Aerobic plate count 需氧微生物總數	<10 CFU/ml	100 CFU/ml	Pass 合格
Moulds and yeasts count 霉菌	<10 CFU/ml	100 CFU/ml	Pass 合格
Escherichia coli 大腸桿菌	Not Detected in 1ml	Absent in 1ml	Pass 合格

Notes: # Data based on Technical Guidelines for Testing the Safety of Proprietary Chinese Medicines (pCm) (updated version), sanctioned by the Department of Health of the Government of the HKSAR.
資料是根據香港特別行政政區政府 - 衛生署所制定之[中成藥註冊]安全性資料技術指引(修訂本).
< denotes less than
CFU/ml denotes Colony Forming Unit per milliliter

SUMMARY:

1. Test results of the submitted sample **complied** with the Heavy Metals or Toxic Elements Limit stipulated in the Technical Guidelines for Testing the Safety of Proprietary Chinese Medicines (pCm) (updated version), sanctioned by the Department of Health of the Government of the HKSAR.
根據測試結果, 所提供之樣本符合香港特別行政區政府-衛生署所制定之[中成藥註冊]安全性資料技術指引(修訂本) 之中成藥重金屬或有毒元素限度.

2. Test results of the submitted sample **complied** with the Microbial Limit Stipulated in the Technical Guidelines for Testing the Safety of Proprietary Chinese Medicines (pCm) (updated version), sanctioned by the Department of Health of the Government of the HKSAR.
根據測試結果, 所提供之樣本符合香港特別行政區政府-衛生署所制定之[中成藥註冊]安全性資料技術指引(修訂本)之中成藥微生物限度 (煎膏劑、糖漿劑、合劑、露劑、流浸膏劑及浸膏劑).

REMARK:

微生物限度#

劑型	需氧微生物的總數	霉菌及酵母菌	大腸桿菌
煎膏劑、糖漿劑、合劑、露劑、流浸膏劑及浸膏劑	100 CFU/ml	100 CFU/mlg	Absent in 1ml

Data based on Technical Guidelines for Testing the Safety of Proprietary Chinese Medicines (pCm) (updated version), sanctioned by the Department of Health of the Government of the HKSAR.
資料是根據香港特別行政政區政府 - 衛生署所制定之[中成藥註冊]安全性資料技術指引(修訂本)

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