

Test Report

Date of issue : 17-12-2021

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Castco LRN: 220329-2425

Sample details as supplied by customer:-

Customer: Tin Hee Tong Medicine Factory Ltd

Customer Ref. No.: T017417

Address: Room 612, Honour Industrial Centre, 6 Sun Yip Street
Chai Wan, HK

Contract No.: --

Sample Description: 天喜堂天喜丸

Date Sampled: --

Manufacturer: 天喜堂藥廠有限公司

Exp. Date: 08-12-2024

Pack size: 每盒12瓶, 每瓶10粒。

Dose form: 丸劑

Lot number: ED0325

Sample form: Final product

pCm Registration number: HKP-04055

Laboratory Test Results:-

Date of sample received: 09-12-2021

Test period: 10-12-2021 to 17-12-2021

Test method:

- 1) In-house method FD-TCM-HM4 by employing inductively coupled plasma - optical emission spectrometry
- 2) Pharmacopoeia of the People's Republic of China (2000 Volume 1)
- 3) In-house method FD-TCM-PEST3 by employing gas chromatography with tandem mass spectrometry

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

Test 測試項目	Results 測試結果	Expressed as intake 以服量計算	Upper Limit 上限 (服量計) ²
Arsenic content 砷含量	<2 µg/g	< 1.2 µg/day	每日 1500 微克
Cadmium content 鎘含量	<0.5 µg/g	< 0.2 µg/dose	每劑 3500 微克
Lead content 鉛含量	<2 µg/g	< 1.2 µg/day	每日 179 微克
Mercury content 汞含量	<1 µg/g	< 0.6 µg/day	每日 36 微克

Calculated as dosage: 1 pill(s) per dose, 2 dose(s) per daily use (0.3 g/ pill)
以每日建議用量計算: 每日使用 2 次, 每次 1 粒 (0.3 克/粒)

2) Microbial Limit Test 微生物限度測試

Test 測試項目	Results 測試結果	Microbial Limit 微生物限度 ²
		含原藥材
Aerobic plate count 總細菌數	10 CFU/g	30000 CFU/g
Yeast & Molds count 酵母菌及霉菌數	< 10 CFU/g	100 CFU/g
<i>Escherichia coli</i> 大腸桿菌	Absent in 1 g	Absent in 1g

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Laboratory Test Results (con'd)

3) Residual Pesticides Test 農藥殘留測試

Test 測試項目	Results 測試結果	Maximum Residual Limit 最高殘留量 ³
Aldrin & Dieldrin 艾氏劑及狄氏劑	<0.01 mg/kg	0.05 mg/kg
Chlordane 氯丹 (<i>cis</i> -, <i>trans</i> - & oxy-chlordane)	<0.02 mg/kg	0.05 mg/kg
DDT 滴滴涕 (<i>p,p</i> -DDT, <i>o,p</i> -DDT, <i>p,p</i> -DDE & <i>p,p</i> -TDE)	<0.2 mg/kg	1.0 mg/kg
Endrin 異狄氏劑	<0.01 mg/kg	0.05 mg/kg
Heptachlor 七氯 (heptachlor & heptachlor-epoxide[Isomer-B])	<0.015 mg/kg	0.05 mg/kg
Hexachlorobenzene 六氯苯	<0.02 mg/kg	0.1 mg/kg
Hexachlorocyclohexane 六六六 (α -, β - & δ -BHC)	<0.06 mg/kg	0.3 mg/kg
Lindane 林丹(γ -BHC)	<0.05 mg/kg	0.6 mg/kg
Quintozene 五氯硝基苯 (quintozene, pentachloroaniline & methyl pentachlorophenyl sulphide)	<0.15 mg/kg	1.0 mg/kg

Remark(s):

- Test results only relate to the specimen tested.
- Intake upper limit (Heavy metal), microbial limit and maximum residual limit is based on Application Handbook of proprietary Chinese medicines, sanctioned by the Chinese Medicine Council of Hong Kong.
服量上限(重金屬), 微生物上限及農藥最高殘留量是根據香港特別行政區政府 - 香港中醫藥管理委員會所制定之[中成藥註冊]申請手冊。
- CFU/g denotes Colony Forming Unit per gram.
- mg/kg denotes milligram per kilogram.

Checked by :

Wong Chi Ho
Assistant Technical Manager

Leung Sze Yui, Horasis
Technical Manager

Certified by :

Lo Tim Lun
Senior Manager

End of report

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