

Test Report

Date of issue: 06-07-2021

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Castco LRN: 220329-2408

Sample details as supplied by customer:-

Customer: 恒昌隆藥品有限公司

Customer Ref. No.: --

Address: 葵涌永業街14-20號華榮工業大廈16樓D室

Date Sampled: 25-06-2021

Job Title: --

Exp. Date: 25-06-2024

Sample Name: 【恒昌隆】人參歸脾丸

Preparation: 水蜜丸劑

Manufacturer: 恒昌隆藥品有限公司

Batch No.: 250792

Pack size: 每盒1瓶，每瓶100克

Sample form: 製成品

Laboratory Test Results:-

Date of sample received: 25-06-2021

Test period: 25-06-2021 to 06-07-2021

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	< 30.0 µg/day	每日 1500 微克
Cadmium content 鎘含量	<0.5 µg/g	< 2.5 µg/dose	每劑 3500 微克
Lead content 鉛含量	<2 µg/g	< 30.0 µg/day	每日 179 微克
Mercury content 汞含量	<1 µg/g	< 15.0 µg/day	每日 36 微克

Calculated as dosage: 5 gram (s) per dose, 3 dose(s) per daily use
以每日建議用量計算: 每日使用 3 次, 每次 5 克

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
Molds count 霉菌數 ³	<10 CFU/g	100 CFU/g
<i>Escherichia coli</i> 大腸桿菌	Absent in 1 g	Absent in 1g
<i>Salmonella</i> 沙門氏菌	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 ²
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)	<0.03 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])	<0.02 mg/kg	0.05 mg/kg
Hexachlorobenzene 六氯苯	<0.05 mg/kg	0.1 mg/kg
Hexachlorocyclohexane 六六六 (α -, β - & δ -BHC)	<0.15 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):

1. Test results only relate to the specimen tested.
2. 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.
服用上限(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。
3. According to Application Handbook of proprietary Chinese medicines, sanctioned by the Chinese Medicine Council of Hong Kong, solid preparations should be examined for moulds.
根據香港中醫藥管理委員會所制定之[中成藥註冊]申請手冊, 固體制劑應檢查霉菌。
4. CFU/g denotes Colony Forming Unit per gram.
5. 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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