

Test Report

Date of issue : 03-06-2024

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Castco LRN: 240521-2774

Sample details as supplied by customer:-

Customer: 漢方醫藥有限公司

Address: 新界葵涌大連排道21-33號宏達工業中心9樓17A室

Sample Description: 【漢立方】五苓散

Manufacturer: 科達製藥股份有限公司

Pack size: 每盒2.5g X 10包

pCm Registration number: HKC-14437

Lot number: 32203302

Customer Ref. No.: --

Contract No.: --

Date Sampled: 16-05-2024

Exp date: 20-04-2026

Dose form: 顆粒劑

Sample form: Final product

Laboratory Test Results:-

Date of sample received: 17-05-2024

Condition when received: Room Temperature

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

Test period: 21-05-2024 to 03-06-2024

Type of container: Original package

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	< 15.0 µg/day	每日 1500 微克
Cadmium content 鎘含量	<0.5 µg/g	< 1.3 µg/dose	每劑 3500 微克
Lead content 鉛含量	<2 µg/g	< 15.0 µg/day	每日 179 微克
Mercury content 汞含量	<1 µg/g	< 7.5 µg/day	每日 36 微克

Calculated as dosage: 2.5 grams(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 2.5 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
		不含原藥材
Aerobic plate count 總細菌數	<10 CFU/g	1000 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 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)	<0.02 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
Quintozone 五氯硝基苯 (quintozone, pentachloroaniline & methyl pentachlorophenyl sulphide)	<0.15 mg/kg	1.0 mg/kg

Remark(s):


- Test results only relate to the specimen tested and as received.
- Intake upper limit (Heavy metal), microbial limit and maximum residual limit are 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。
- CFU/g denotes Colony Forming Unit per gram and mg/kg denotes milligram per kilogram..

Checked by :


 Wong Chi Ho
 Technical Manager


 Tsing Chan Man
 Assistant Technical Manager (Acting)

Certified by :


 Lo Tim Lun
 Senior Manager

End of report

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