Novachem Cannabis Standards

Testing and quality control for medicinal cannabis



Overview

- Testing requirements
- Secondary tests
- The schedules S4, S8, S9 what is what
- Reference materials
- Proficiency testing
- Product quality verification (Vericann®)



Testing requirements

- TGA Order 93
 - THC / THCA and CBD/CBDA
 - +/- 20% of stated content for herbal
 - +/- 10% of stated content for oils
 - Aflatoxins
 - Foreign Matter
 - Heavy Metals
 - Ochratoxin A
 - Pesticides
 - Total Ash

Ph Eur 2.8.18

Ph Eur 2.8.2

Ph Eur 2.4.27

Ph Eur 2.8.22

Ph Eur 2.8.13

Ph Eur 2.4.16



Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)

Therapeutic Goods Act 1989

I, LARRY KELLY, a delegate of the Minister for Health for the purposes of subsection 10(1) of the Therapeutic Goods (ct. 1989, having consulted the Therapeutic Goods Committee in accordance with subsection 10(4) of that Act, make the following order.

Dated 21 March 2017

(Signed by)

LARRY KELLY

Delegate of the Minister for Health

Authorised Version F2017LIXCN6 registered 23/03/20



Testing requirements

- TGA Order 93
 - THC / THCA and CBD/CBDA
 - +/- 20% of stated content for herbal
 - +/- 10% of stated content for oils
 - Method ??

Development of a validated method for the qualitative and quantitative analysis of cannabinoids in plant biomass and medicinal cannabis resin extracts obtained by super-critical fluid extraction

https://doi.org/10.1016/j.jchromb.2019.01.027





Testing requirements

- TGA Order 100
 - Microbiological Standards for Medicines
- TGA Order 101
 - Standard for tablets, capsules and pills

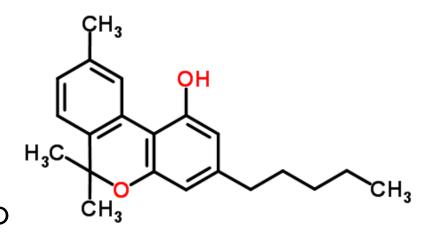
- GMP Compliance
 - Part of Manufacturing PIC/S Guide to GMP





Secondary tests

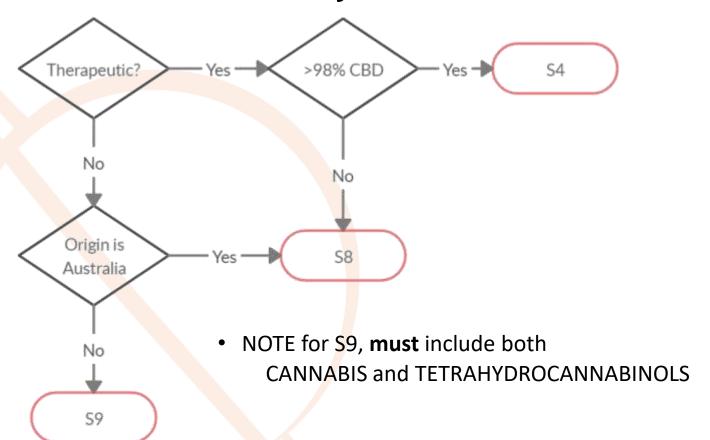
- Cannabinoids
 - Cannabinol (CBN)
 - ** important degradation product of THC and CBD
 - Cannabigerol (CBG)
 - Cannabichromene (CBC)
 - Cannabidivarin (CBDV)
 - (±)-Cannabicyclol (CBL)
 - Tetrahydrocannabivarin (THCV)
 - (-)-delta8-THC
- And respective acid forms (decarboxylation...)
- Terpenes





The schedules S4, S8, S9

• The Poisons Standard June 2019







Reference materials

- Cerilliant
 - Cannabinoids THC, CBD etc.
 - Certified reference materials
 - ISO 17034
 - ISO 9001
 - Tested under ISO 17025
 - Deuterated analogues for quantitation
 - All Australian based stock, next day delivery





ALL SCHEDULE 9 (S9)



Reference materials

- Pesticides
 - Dr Ehrenstorfer / AccuStandard
- Terpenes
 - AccuStandard / Dr Ehrenstorfer
- Ochratoxin A / Mycotoxins
 - LGC Standards
- Heavy Metals
 - LGC / VHG / AccuStandard

Custom mixes for EP / TGA Order 93 Available





Proficiency testing

- For ISO 17025, PT is required
- Currently being developed with LGC Standards
- Initial schemes currently Q1 2020
- Incorporates all TGA tests
- Expressions of interest sought now





Vericann® product certification

- ISO 9001:2015 Quality Assured
- Provide external product labels
- Online batch and serial number tracking
- Visible verification of meeting TGA criteria
- Fully independent verification process
- Find out more vericann.cc



