



Australian Government

Department of Health

Therapeutic Goods Administration

Testing of medicinal cannabis products being supplied via SAS in Australia

TGA Laboratories testing report

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TGA Health Safety
Regulation

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Background

Medicinal cannabis products are products intended for therapeutic use that contain or are derived from any part of the *Cannabis* plant. They generally contain the components cannabidiol (CBD) and/or tetrahydrocannabinol (THC) or their corresponding acids.

Medicinal cannabis products are permitted to be supplied into Australia under the Special Access Scheme (SAS), Authorised Prescriber scheme, and clinical trial schemes. Products supplied under these schemes are required to comply with *Therapeutic Goods Order No. 93 (Standard for Medicinal Cannabis)* (TGO93). In particular, Section 12(2) specifies the following assay limits:

- in relation to a medicinal cannabis product in herbal final form - the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 80.0 per cent and not more than 120.0 per cent of the stated content of that active ingredient
- in relation to a medicinal cannabis product in tablet or capsule form, where that product is not included on the Australian Register of Therapeutic Goods (ARTG) - the average content of each active ingredient, together with any corresponding acid, in a pooled sample of not fewer than 20 tablets or capsules must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient
- in relation to a medicinal cannabis product in any other dosage form - the average content of each active ingredient, together with any corresponding acid, in a representative sample of the product must be not less than 90.0 per cent and not more than 110.0 per cent of the stated content of that active ingredient.

The survey described in this report was conducted to assess compliance with TGO93 for medicinal products being supplied via SAS in Australia.

A total of 22 medicinal cannabis products were tested by the TGA. The samples were targeted based on the top 25 supplied medicinal cannabis products by volume.

Testing

Content of cannabinoids by Ultra High Performance Liquid Chromatography (UHPLC)

Each of the samples received were tested for compliance against TGO93, specifically, the *stated content of each active ingredient*.

An active ingredient for the purposes of TGO93 (whether or not specified) is defined as:

- any THC (together with any corresponding acid) present in the product greater than or equal to 1.0% w/w or w/v
- any other cannabinoid present (together with any corresponding acid) in the product greater than or equal to 2.0% w/w or w/v.

All samples were labelled as containing either THC (together with any corresponding acid), CBD (together with any corresponding acid), or a combination of both.

The samples were tested for content of total CBD and/or total THC and were reported as a percentage of the stated content as declared to the TGA as part of the SAS application. Where samples contained any corresponding THC and CBD acids, the content of the acid was converted to the equivalent base (either THC or CBD) and included in the calculation of total THC and CBD contents.

Details of the results obtained are included in [Appendix A](#).

Samples for three of the 25 requested products were not provided upon request. In all cases this was due to the product no longer being available.

An assessment of all samples was made for the presence of any other cannabinoids present in a concentration greater or equal to 2% w/w or w/v. None of the samples were found to contain other cannabinoids at a level that would constitute an active ingredient.

Of the 22 samples that were received for testing, three samples failed to meet the TGO93 requirements for content of the active ingredient. All three samples failed to meet the lower limit requirement.

The sample of ***Bedrocan Dried Cannabis Flos for Inhalation*** imported by Novachem Pty Ltd returned a low result of 74.9% of the stated content for total THC. Subsequent communication with the supplier has identified that their stated content was declared in terms of an anhydrous basis. When the moisture content of the product was taken into account the TGA result against this value would be 79.9% on an anhydrous basis. The requirements for content, for plant material finished products, are 80.0 – 120.0% of the stated content.

The sample of ***Spectrum Blue Cannabis Oil*** imported by Anspec Pty Ltd returned a moderately low result of 87.3% of the stated content for total THC. Analysis of the sample by an accredited third party laboratory returned a result of 90.7% of the stated content. The requirements for content, for oil finished products, are 90.0 – 110.0% of the stated content.

The sample of ***LGP Classic 20:5 Cannabis Oil (Tetrahydrocannabinol (THC) 20 mg/mL and cannabidiol (CBD) 5 mg/mL)*** supplied by Little Green Pharma returned a moderately low result of 88.3% of the stated content for total CBD. Analysis of the sample by an accredited third party laboratory returned a result of 89.1% of the stated content.

A further two samples were initially found to be marginally above the higher limit when compared with the declaration made to the TGA regarding content.

The samples of ***Althea Jasper Cannabis Oil (labelled as 5.39mg/mL THC, THCA; 10.26mg/mL CBD, CBDA, stated content 5 mg/mL THC, THCA; 10 mg/mL CBD, CBDA)*** and ***Althea Capilano Cannabis Oil (labelled as 10.72mg/mL THC, THCA; 12.79mg/mL CBD, CBDA, stated content 10 mg/mL THC, THCA; 12.5 mg/mL CBD, CBDA)*** supplied by Althea Pty Ltd returned high results of 111.2% and 110.1% of the stated content for total CBD. It was noted that these two products had a declared stated content that was lower than the amount included on the product label. The testing results found the amount of CBD present was lower than 110% of the label claim, but marginally exceeded the 110% upper limit for the stated content. The inconsistencies in the label claim and declared stated content were highlighted as a concern with the supplier. Subsequent analysis by a third party laboratory returned results for total CBD that were below the upper limit of 110.0% for the stated content, meeting the requirements of TGO93.

Inconsistencies in testing results from different laboratories were observed during the survey. A number of factors can lead to differences in results including: variability within the batch – particularly problematic for plant samples; the precision of the method used – this can be affected by non-representative sample size and extraction; and accuracy of the method – this can be affected by poor/incomplete extraction and the accuracy of the reference material used. These factors can contribute to unacceptably high measurement uncertainty relative to the acceptance limits.

The accuracy of some commercial reference standards supplied as dilute solutions in methanol is questionable as they were observed to give significantly different results to other standards. While these dilute reference solutions are provided as certified reference standards, the TGA has concern that they are not reproducible or stable. This inconsistency could lead to significant differences in results between laboratories and is a factor any testing facilities conducting this

work should consider carefully. The TGA utilised a solid state certified reference standard of CBD as the primary reference and used response factors calculated from validation studies to calculate the content of the other cannabinoids (e.g. THC).

It is well known that the content of active ingredients of medicinal cannabis decline with time, as such the reported results only represent the content measured at the time of analysis. Medicinal cannabis products supplied through the SAS must meet the requirements of TGO93 for the duration of their shelf lives.

All suppliers of the products failing to meet the requirements were notified of the testing results and reminded of the requirements of TGO93 and the provisions of penalties if they supply a good that does not conform to the standard.

Responses from the suppliers of failing products included evidence to demonstrate that the products had met the requirements at the time of manufacture, and for products with unacceptably low levels of active ingredient, an assurance that any remaining stock would not be supplied under the current TGO93 declaration until the matter had been resolved to the satisfaction of TGA. TGA has subsequently written to advise that supply of any remaining stock under the current TGO93 declaration would constitute an offence under the Act.

The remaining 17 products tested met the requirements for the content of active ingredients.

Packaging – Child resistant closures

Products not included on the ARTG (such as products supplied under the SAS or Authorised Prescriber scheme) and not declaring child-resistant packaging are not required to adhere to the packaging requirements of *Therapeutic Goods Order No. 95 - Child resistant packaging requirements for medicines 2017* (TGO95).

Despite not being legally required, the majority of samples received were enclosed in child resistant packaging. Three samples were observed to not be packaged using child-resistant closures (CRC). These products were *Nanabis Cannabis Oil Extract*, *Bedrocan Dried Cannabis Flos for Inhalation* and *CDA CBD-240 Oil*.

The TGA has written to the suppliers of these products regarding the lack of child-resistant packaging. Information was provided to the suppliers outlining the risks of not utilising CRCs, and a recommendation was made to incorporate a CRC into their products packaging.

To date as a result, one of the suppliers has indicated that they are in the process of implementing a child-resistant closure.

Appendix A: Details and results of samples analysed

Product Name	Batch Number	Expiry Date	Supplier	Stated content (label claim where different)	TGA Assay Result (total THC &/or CBD as % of stated content)
Satipharm CBD 50 Gelpell Cannabidiol 50 mg Capsules	0980011	11/2020	Health House International	50 mg CBD/cap	CBD: 95.8%
Nanabis Cannabis Oil Extract 8.33mg/mL of THC & 8.33mg/mL of CBD	PPP.19.1542	05/12/2021	Medlab Clinical Ltd (VIC)	CBD 8.33 mg/mL THC 8.33 mg/mL	CBD: 107.9% THC: 103.5%
MXP 100 CBD 100mg/mL Oral, drops, solution	4072/1119	08/06/2020	Health House International	100 mg/mL CBD	CBD: 100.6%
Medicabilis 5% CBD 50mg CBD & <2mg THC per mL Oral Solution	74719004-A	07/2021	Bod Australia Ltd	50 mg/mL CBD, <2 mg/mL THC	CBD: 93.5% THC: < 2 mg/mL
T15 Flower for Vaporisation 10g 15.0% THC, <1.0% CBD	5089(3)	30/08/2020	Cannatrek Medical Pty Ltd	15% THC, <1.0 % CBD	THC: 92.5%
Tilray 100 CBD Oral Solution (100mg/mL CBD)	N0000007946	06/2020	Pharmaceutical Packaging Professionals Pty Ltd	100 mg/mL CBD	CBD: 102.1%
Tilray 10 THC 10 CBD Oral Solution (10mg/mL THC, 10mg/mL CBD)	N0000008421	12/2020	Pharmaceutical Packaging Professionals Pty Ltd	10 mg/mL CBD; 10 mg/mL THC	CBD: 97.6% THC: 90.8%
Tilray 25 THC 25 CBD Oral Solution (25mg/mL THC, 25mg/mL CBD)	N0000008633	07/2020	Pharmaceutical Packaging Professionals Pty Ltd	25 mg/mL CBD; 25 mg/mL THC	CBD: 107.4% THC: 91.9%
Tilray Purified CBD 25 (Cannabidiol 25mg/mL)	N0000008894	03/2021	Pharmaceutical Packaging Professionals Pty Ltd	25 mg/mL CBD	CBD 102.1 %

Product Name	Batch Number	Expiry Date	Supplier	Stated content (label claim where different)	TGA Assay Result (total THC &/or CBD as % of stated content)
Bedrocan Dried Cannabis Flos for Inhalation (22% THC, < 1% CBD)	19I30EY19K05	11/2020	Novachem Pty Ltd	22% THC; <1% CBD	THC 74.9% THC 79.9% (on anhydrous basis)
GD Cann C Purified Cannabidiol 100mg/mL	GDP161019A1	09/2020	GD Pharma Pty Ltd	CBD 100 mg/mL	CBD: 100.8%
Spectrum Therapeutics Yellow Cannabis Oil (CBD 20mg/mL, THC less than 1mg/mL)	1900005816	11/2020	Anspec Pty Ltd	20 mg/mL CBD; <1 mg/mL THC	CBD: 95.3% THC: < 1 mg/mL
Spectrum Blue Cannabis Oil (CBD 15 mg/mL, THC 10 mg/mL)	1900013049	05/03/2021	Anspec Pty Ltd	15 mg/mL CBD; 10 mg/mL THC	CBD: 98.8% THC: 87.3% (THC: 90.7%) ¹
CDA Health Cannabidiol 240mg/mL Oil	0-605	08/2021	Burleigh Heads Cannabis	240mg/mL CBD	CBD: 95.5%
Althea Capilano Cannabis Oil (10.72mg/mL THC, THCA; 12.79 mg/mL CBD, CBDA)	6985-8649	07/08/2020	Althea Company Pty Ltd	12.5 (12.79) mg/mL CBD, CBDA; 10 (10.72) mg/mL THC, THCA	CBD: 110.1% (CBD: 107.6%) ¹ THC: 104.8%
Althea Rideau Cannabis Oil (CBD, CBDA 24.57 mg/mL, THC, THCA 0.98 mg/mL)	7264-8652	08/08/2020	Althea Company Pty Ltd	25 (24.57) mg/mL CBD, CBDA; >2 (0.98) mg/mL THC, THCA	CBD: 107.2%; THC: 0.96 mg/mL

¹ Analysis by a third party accredited laboratory

Product Name	Batch Number	Expiry Date	Supplier	Stated content (label claim where different)	TGA Assay Result (total THC &/or CBD as % of stated content)
Althea Henik Dried Cannabis for Vaporisation 10g (18.54% w/w THC, THCA; <0.07% w/w CBD, CBDA)	3101718719-8764	03/03/2021	Althea Company Pty Ltd	18 (18.54) %w/w THC, THCA; <1 (<0.07) %w/w CBD, CBDA	87.3% total THC CBD not detected
Althea Jasper Cannabis Oil (5.39mg/mL THC, THCA; 10.26mg/mL CBD, CBDA)	6988-8650	07/08/2020	Althea Company Pty Ltd	10 (10.26) mg/mL CBD, CBDA; 5 (5.39) mg/mL THC, TCHA	CBD: 111.2% (CBD: 106.9%) ¹ THC: 108.3%
Althea Champlain Cannabis Oil Champlain (20.19mg/mL THC, THCA; 0.00 mg/mL CBD, CBDA)	7632-8656	12/08/2020	Althea Company Pty Ltd	<1 (0.00) mg/mL CBD, CBDA; 20 (20.19) mg/mL THC, THCA	CBD not detected THC: 101.8%
Althea CBD100 (Cannabidiol 100mg/ml, Tetrahydrocannabidiol less than 1mg/mL)	PPP.20.597	05/2021	Althea Company Pty Ltd	100 mg/mL CBD; <1 mg/mL THC	CBD: 106.5% THC: not detected
LGP Classic 10:10 (Tetrahydrocannabinol 10mg/mL:Cannabidiol 10mg/mL)	P1339	03/04/2021	Little Green Pharma Pty Ltd	10 mg/mL CBD; 10 mg/mL THC	CBD 94.2% THC 96.7%
LGP Classic 20:5 (Tetrahydrocannabinol (THC) 20 mg/mL and cannabidiol (CBD) 5 mg/mL)	P1338	02/04/2021	Little Green Pharma Pty Ltd	5 mg/mL CBD; 20 mg/mL THC	CBD 88.3% (CBD: 89.1%) ¹ THC 99.1%

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Laboratories	September 2020
V1.1	Testing results updated	TGA Laboratories	October 2020
V1.2	Testing results updated	TGA Laboratories	November 2020
V1.3	Testing results updated	TGA Laboratories	December 2020

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