Australian Government
Department of Health
Therapeutic Goods Administration

Testing of paediatric medicinal cannabis products being supplied via SAS in Australia

TGA Laboratories testing report

Version 1.0, August 2021

TGA Health Safety Regulation

Contents

Background

Some medicinal cannabis products are used in the paediatric population in the management of a number of different indications. These products are permitted to be supplied in 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 that the average content of each active ingredient in a representative sample of the product must be not less than 90.0 % and not more than 110.0 % of the stated content of that active ingredient for typical samples used in the paediatric population.

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

A total of 9 medicinal cannabis products were requested by the TGA. The samples were targeted based on being in an oral dosage form and intended for use in the paediatric population.

Testing

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

All samples were labelled as containing cannabidiol (CBD) and/or a corresponding acid. The samples were tested for content of total CBD and were reported as a percentage of the stated content as declared to the TGA as part of the SAS application. In all cases the stated content was the same as the declared content on the labels.

Details of the results obtained are included in **Appendix A**.

A sample for one of the nine requested products was not provided upon request. This was due to the product no longer being available. Details of this product are included in **Appendix B**.

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, which would classify the cannabinoid as an ingredient. None of the samples were found to contain other cannabinoids at a level that would constitute it as an active ingredient.

All 8 samples that were received for testing met the TGO93 requirements for content of the active ingredient. The results from an accredited third-party laboratory was accepted for one of the tested products. The labelled content of all of the samples were consistent with the stated content.

Appendix A: Details and results of samples analysed

Product Name	Batch Number	Expiry Date	Supplier	Stated Content	Result (CBD as % of stated content)
Tilray 100 CBD Oral Solution (100mg/mL CBD)	N0000009868	Aug-21	Tilray Inc.	100mg/mL CBD	102.0%
Althea CBD100 (Cannabidiol 100mg/ml, Tetrahydrocannabidiol less than 1mg/mL)	PPP.20.873	07-2021	Althea Company Pty Ltd	Cannabidiol 100mg/ml, Tetrahydrocannabidiol less than 1mg/mL	106.9%[1]
CDA CBD-240 Oil (Cannabidiol 240mg/mL)	0-669	28-Feb-22	Burleigh Heads Cannabis Pty Ltd	Cannabidiol 240mg/mL	100.9%
Entoura CBD 10 Oil (10% CBD, 100 mg/mL)	B1855	2022-06	Entoura Pty Ltd	10% CBD, 100 mg/mL	102.2%
Entoura CBD 20 Oil (20% CBD, 200 mg/mL)	B1856	2022-06	Entoura Pty Ltd	20% CBD, 200 mg/mL	95.7%
GD Cann-C (Cannabidiol 100mg/ml)	GDP280720A3	Jun-22	GD Pharma Pty Ltd	Cannabidiol 100mg/ml	100.9%
LGP Classic CBD 50 (50mg/mL CBD)	P1609	25/10/2021	Little Green Pharma Ltd	50mg/mL CBD	107.7%
MP 100 (CBD 100mg/mL)	D2812	Mar-21	MGC Pharmaceuticals Ltd	CBD 100mg/mL	93.9%

[1] Testing performed by a third-party accredited laboratory

Appendix B: Details of samples not received for testing and reason for not being provided

Supplier	Requested Sample	Reason for not being provided
PharmaCann Holdings Pty Ltd	PharmaCann C1000 Capsules (33.3mg)	Product has been discontinued, and no stock was available

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Section/Office	August 2021

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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