

Testing for toxins in medicinal cannabis products being supplied via SAS B in Australia

TGA Laboratories testing report

Version 1.0, August 2021



Copyright

© Commonwealth of Australia 2021

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <tga.copyright@tga.gov.au>.

Contents

Introduction	4
Testing	4
Conclusion	4
Appendices	5

Introduction

The levels at which toxins and impurities must be controlled in medicinal cannabis plant products are defined in *Therapeutic Goods Order No. 93* (Standard for Medicinal Cannabis) (TGO93). The survey described in this report was conducted to test for the presence of selected toxins as specified in subsection 12(1) of TGO93 for medicinal cannabis plant products.

Testing

Products that met the description of dried cannabis, floss or buds were targeted in this survey. Details of the samples received for testing are outlined in **Appendix A**. At the time of requesting, samples for two of the requested products were not provided. This is due to one product been discontinued and no stock being available for the other. Sample details and the reasons for not providing a sample are given in **Appendix B**.

A total of six medicinal cannabis floss products were tested by an accredited third-party testing laboratory. Testing on each of the received medicinal cannabis products assessed the quality, and conformance with selected tests in subsection 12(1) of TGO 93. Samples were tested for the presence and quantity of aflatoxins, ochratoxin A, heavy metals and pesticides.

The limits for the specified toxins are outlined in **Table 1**.

Table 1 - TGO 93 Limits for selected toxins

Parameter	Test Method	Limit
Aflatoxins	Ph Eur ¹ 2.8.18	Not more than 2 µg/kg of aflatoxin B1 and not more than 4 µg/kg for the sum of aflatoxins B1, B2, G1, G2
Heavy metals	Ph Eur 2.4.27	Not more than 3.0 mg/kg of arsenic, Not more than 0.5 mg/kg of cadmium, Not more than 5.0 mg/kg of lead, Not more than 0.5 mg/kg of mercury
Ochratoxin A	Ph Eur 2.8.22	Not more than 20 μg/kg
Pesticides	Ph Eur 2.8.13	Not more than the limits specified in Ph Eur 2.8.13

¹ European Pharmacopoeia

Conclusion

All six samples met the requirements of TGO93 for aflatoxins, ochratoxin A, heavy metals and pesticides.

Appendices

Appendix A: Details of samples received for testing

Appendix B: Details and reasons for not proving a sample

Appendix C: Summary of Assay Results Pesticides, Aflatoxins, Ochratoxin A and Heavy Metals

Appendix A: Details of samples

Product Name	Batch Number	Expiry Date	Supplier
Cannatrek T15 Flower (Sativa Acadia) 15.0% THC Flos for Inhalation	9415(3)	30 November 2021	Cannatrek Medical Pty Ltd
Bedrocan Dried Cannabis Flos for Inhalation (22% THC OAB ² , < 1% CBD OAB)	20E04EY20G22	07/2021	Novachem Pty Ltd
Beacon Medical "THC+F" Dried Flower Bud (THC 20% w/w, <0.1% w/w CBD)	935SI22302	Jun 2022	Burleigh Heads Cannabis Pty Ltd
MEDCAN CC01 Dried Cannabis Flower (THC 22%, CBD 0.07%)	MCA-AGM- CC01-B2	19 August 2021	Medcan Australia
Tilray Whole Flower Dried Cannabis THC 25 (THC 25%, CBD NMT 0.5%)	N0000010614	10/2021	Tilray Inc.
Tilray THC10: CBD10 Whole Flower Dried Cannabis (THC9.9%, CBD9.6%)	N0000010076	07/2021	Tilray Inc.

² On as is basis

Appendix B: Details and reasons for not providing a sample

Supplier	Requested Sample	Reason for not being provided
Cannatrek Medical	Cannatrek T20 Flower (Indica Mongolian) 18.5% THC, less than 0.07% CBD	Product has been discontinued, and no stock available
Althea Company Pty Ltd	Althea Henik (Tetrahydrocannabinol 18% Cannabidiol less than 1%)	Product not supplied as awaiting supply, pending import.

Appendix C: Summary of Assay Results - Aflatoxins, Ochratoxin A and Heavy Metals

Product Name	Pesticides	Aflatoxins and Ochratoxin A (μg/kg)				Trace Elements (mg/kg)				
		Aflatoxin B1	Aflatoxin B2	Aflatoxin G1	Aflatoxin G2	Aflatoxins B1+B2+G1+G2	Arsenic	Cadmium	Lead	Mercury
Tilray THC10: CBD10 Whole Flower Dried Cannabis (THC9.9%, CBD9.6%)	<lor,3,4< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td>0.15</td><td><0.05</td></lor,3,4<>	<2	<2	<2	<2	<4	<0.05	<0.05	0.15	<0.05
Cannatrek T15 Flower (Sativa Acadia) 15.0% THC Flos for Inhalation	<lor< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td><0.05</td><td><0.05</td></lor<>	<2	<2	<2	<2	<4	<0.05	<0.05	<0.05	<0.05
Bedrocan Dried Cannabis Flos for Inhalation (22% THC OAB, < 1% CBD OAB)	<lor< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td><0.05</td><td><0.05</td></lor<>	<2	<2	<2	<2	<4	<0.05	<0.05	<0.05	<0.05
MEDCAN CC01 Dried Cannabis Flower (THC 22%, CBD 0.07%)	<lor< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td><0.05</td><td><0.05</td></lor<>	<2	<2	<2	<2	<4	<0.05	<0.05	<0.05	<0.05
Beacon Medical "THC+F" Dried Flower Bud (THC 20% w/w, <0.1% w/w CBD)	<lor< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td><0.05</td><td><0.05</td></lor<>	<2	<2	<2	<2	<4	<0.05	<0.05	<0.05	<0.05
Tilray Whole Flower Dried Cannabis THC 25 (THC 25%, CBD NMT 0.5%)	<lor< td=""><td><2</td><td><2</td><td><2</td><td><2</td><td><4</td><td><0.05</td><td><0.05</td><td>0.14</td><td><0.05</td></lor<>	<2	<2	<2	<2	<4	<0.05	<0.05	0.14	<0.05

³ Limit of Reporting

 $^{^{\}rm 4}$ All pesticides stated in Ph Eur. 2.8.13 were < LOR

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Laboratories	August 2021

Therapeutic Goods Administration

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

Reference/Publication #