Therapeutic Goods (Standard for Psilocybine) (TGO 113) Order 2024

I, Tracey Duffy, as delegate of the Minster for Health and Aged Care make the following Order.

Dated 19 August 2024

Tracey Duffy
First Assistant Secretary
Medical Devices and Product Quality Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Psilocybine) (TGO 113) Order 2024*.

(2) This instrument may also be cited as TGO 113.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	6 January 2025.	6 January 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 10 of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) batch;
(b) container;
(c) European Pharmacopoeia;
(d) label;
(e) manufacture;
(f) Secretary;
(g) sponsor;
(h) standard;
(i) therapeutic goods;
(j) United States Pharmacopeia-National Formulary.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active ingredient has the same meaning as in the Regulations.

batch number means a number, or a combination of letters, numerals, or symbols, which is given by the manufacturer to a batch of synthetic psilocybine, plant derived psilocybine or a psilocybine product to uniquely identify that batch.

Note: The batch number may be used to trace the batch through all stages of manufacture and distribution.

batch number prefix means the prefix which precedes the batch number, and consists of any words or symbols that clearly indicate that the information following those words or symbols is the batch number.

Note: Common forms of the batch number prefix include (either in capital letters, lower case letters, or a combination of capital and lower case letters):

(a) Batch number;
(b) Batch no.;
(c) Batch;
(d) B;
(e) (B);
(f) B/N;
(g) Lot number;
(h) Lot No.;
(i) Lot.

capsule has the same meaning as in the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*.

Note: The *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

contact details of the sponsor means information to enable a person to contact the sponsor that:

(a) includes an address that is:
  (i) the sponsor's physical address in Australia; and
  (ii) not a post office, cable, telegraphic or code address; and
(b) may also include a telephone number, website or email address.

expiry date has the same meaning as in the Regulations.

expiry date prefix means the prefix which precedes the expiry date, and consists of any words or symbols that clearly indicate that the information following those words or symbols is the expiry date (other than words indicating that the goods may be used after that date, including 'Best by' and 'Best before').

Note: Common forms of the expiry date prefix include (either in capital letters, lower case letters, or a combination of capital and lower case letters):

(a) Expiry date;
(b) Expiry;
(c) Expires;
(d) Exp. Date;
(e) Exp;
(f) Use by;
(g) Use before.

ICH Q3D guideline document means the ICH Harmonised Guideline: *Guideline for Elemental Impurities Q3D*, as in force from time to time.

Note: The ICH Q3D Guideline is published by the International Council of Harmonisation at www.ich.org.

manufacturing licence has the same meaning as in subsection 38(1B) of the Act.

Ph Eur means the European Pharmacopoeia.

plant derived psilocybine means the following substances:

(a) psilocybine extract;

(b) psilocybine isolate.

plant derived psilocybine product means a therapeutic good that is:

(a) a psilocybine extract product; or

(b) a psilocybine isolate product.

plant material means the dried or fresh fruiting body of the psilocybine mushroom that has not been homogenised.

psilocin means the substance with the chemical formula $C_{12}H_{16}N_2O$.

psilocybine means the substance with the chemical formula $C_{12}H_{17}N_2O_4P$.

psilocybine extract means a substance that is extracted from the psilocybine mushroom and that:

(a) contains psilocybine and psilocin; and

(b) may contain other components, including tryptamines.

psilocybine extract product means a therapeutic good that:

(a) contains psilocybine extract as the active ingredient; and

(b) is manufactured in a dosage form for human therapeutic use.

psilocybine isolate means psilocybine that is isolated from the psilocybine mushroom.

psilocybine isolate product means a therapeutic good that:

(a) contains psilocybine isolate as the active ingredient; and

(b) is manufactured in a dosage form for human therapeutic use.

psilocybine mushroom means a mushroom, or part of a mushroom, of the species *Psilocybe cubensis*, including, but not limited to, the fruiting body or mycelium.

psilocybine product means a therapeutic good that is:

(a) a psilocybine extract product; or

(b) a psilocybine isolate product; or

(c) a synthetic psilocybine product.

quantity of the psilocybine product means the stated number of units in the container.

Regulations means the *Therapeutic Goods Regulations 1990*.

stated content means the amount or quantity of each substance that is stated on the label to be present in a psilocybine product.

synthetic psilocybine means psilocybine that is produced using precursor ingredients, rather than compounds obtained from the psilocybine mushroom.

synthetic psilocybine product means a therapeutic good that:

(a) contains synthetic psilocybine as the active ingredient; and

(b) is manufactured in a dosage form for human therapeutic use.

tryptamines mean the group of monoamine alkaloids, excluding psilocybine and psilocin, derived from the amino acid tryptophan.

USP means the United States Pharmacopeia-National Formulary.

5 Standard

The matters specified in this instrument constitute a standard for the following:

(a) plant derived psilocybine;

(b) plant derived psilocybine products;

(c) synthetic psilocybine;

(d) synthetic psilocybine products.

6 Application

(1) Subject to subsection (2) this instrument applies to:

(a) plant derived psilocybine; and

(b) plant derived psilocybine products; and

(c) synthetic psilocybine; and

(d) synthetic psilocybine products.

(2) This instrument does not apply to:

(a) therapeutic goods that are the subject of an approval under paragraph 19(1)(b) of the Act; or

(b) therapeutic goods mentioned in item 1 of Schedule 5 to the Regulations; or

(c) therapeutic goods mentioned in items 3, 4, 8, 10, 11 or 12 of Schedule 5A to the Regulations, subject to compliance with the conditions specified in those items.

Part 2—Requirements for plant derived psilocybine

7 Application of this Part

This Part applies to plant derived psilocybine.

8 Assay limits

(1) The following assay limits apply in relation to psilocybine extract:

(a) the purity of psilocybine in psilocybine extract must be not less than 90.0% and not more than 110.0%, calculated on a dried basis;

(b) the purity of psilocin in psilocybine extract must be not less than 80.0% and not more than 120.0%, calculated on a dried basis;

(c) the purity of any tryptamines in psilocybine extract must be not less than 80.0% and not more than 120.0%, calculated on a dried basis.

(2) The following assay limits apply in relation to psilocybine isolate:

(a) the purity of psilocybine in psilocybine isolate must be not less than 98.0% and not more than 102.0%, calculated on a dried basis;

(b) any psilocin that is present in psilocybine isolate must be at a level that is not more than 2.0%, calculated on a dried basis.

9 Identification

Psilocybine mushroom used in the manufacture of psilocybine extract or psilocybine isolate must be able to be positively identified using each of the following identification methods:

(a) macroscopic examination;

(b) microscopic examination;

(c) chromatographic procedures.

10 Tests

For each item in the tables in Parts 1 and 2 of Schedule 1, plant derived psilocybine must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

Part 3—Requirements for plant derived psilocybine products

11 Application of this Part

This Part applies to plant derived psilocybine products.

12 General

(1) Psilocybine extract or psilocybine isolate used in the manufacture of a plant derived psilocybine product must be obtained from the psilocybine mushroom.

(2) A plant derived psilocybine product that is a psilocybine extract product must:
  (a) contain psilocybine extract as the only active ingredient; and
  (b) be manufactured in the dosage form of a capsule for oral administration.

(3) A plant derived psilocybine product that is a psilocybine isolate product must:
  (a) contain psilocybine isolate as the only active ingredient; and
  (b) be manufactured in the dosage form of a capsule for oral administration.

13 Assay limits

(1) The following assay limits apply in relation to psilocybine extract products:
  (a) the average content of psilocybine in a pooled sample of not fewer than 20 capsules must be not less than 90.0% and not more than 110.0% of the stated content of psilocybine;
  (b) the average content of psilocin in a pooled sample of not fewer than 20 capsules must be not less 90.0% and not more than 110.0% of the stated content of psilocin;
  (c) the average content of any nominated tryptamines in a pooled sample of not fewer than 20 capsules must be not less than 90.0% and not more than 110.0% of the stated content of the nominated tryptamine.

(2) The following assay limits apply in relation to a psilocybine isolate product:
  (a) the average content of psilocybine isolate in a pooled sample of not fewer than 20 capsules must be not less than 90.0% and not more than 110.0% of the stated content of psilocybine isolate.

14 Tests

Psilocybine extract products

(1) Subject to subsection (2), for each item in the table in Part 1 of Schedule 2, a psilocybine extract product must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

(2) This section does not apply to an extemporaneously compounded psilocybine extract product where:

(a) the psilocybine extract used in the manufacture of that product has been tested in accordance with the requirements specified in section 10 of this instrument; and

(b) the testing was conducted at a site that is covered by a manufacturing licence granted by the Secretary under Part 3-3 of the Act.

Psilocybine isolate products

(3) Subject to subsection (4), for each item in the table in Part 2 of Schedule 2, a psilocybine isolate product must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

(4) This section does not apply to an extemporaneously compounded psilocybine isolate product where:

(a) the psilocybine isolate product used in the manufacture of that product has been tested in accordance with the requirements specified in section 10 of this instrument; and

(b) the testing was conducted at a site that is covered by a manufacturing licence granted by the Secretary under Part 3-3 of the Act.

Part 4—Requirements for synthetic psilocybine

15 Application of this Part

This Part applies to synthetic psilocybine.

16 Assay limits

The following assay limits apply in relation to synthetic psilocybine:

(a) the purity of psilocybine in synthetic psilocybine must be not less than 98.0% and not more than 102.0%, calculated on a dried basis;

(b) any psilocin that is present in synthetic psilocybine must be at a level that is not more than 2.0%, calculated on a dried basis.

17 Tests

For each item in the table in Schedule 3, synthetic psilocybine must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

Part 5—Requirements for synthetic psilocybine products

18 Application of this Part

This Part applies to synthetic psilocybine products.

19 General

A synthetic psilocybine product must:

(a) contain synthetic psilocybine as the only active ingredient; and

(b) be manufactured in the dosage form of a capsule for oral administration.

20 Assay limits

The average content of synthetic psilocybine in a pooled sample of not fewer than 20 capsules must be not less than 90.0% and not more than 110.0% of the stated content of synthetic psilocybine.

21 Elemental impurities

A synthetic psilocybine product must comply with the requirements for elemental impurities specified in the ICH Q3D guideline document.

22 Tests

(1) Subject to subsection (2), for each item in the table in Schedule 4, a synthetic psilocybine product must comply with the requirements specified in column 4 using the test method specified in column 3, in relation to the test specified in column 2.

(2) This section does not apply to an extemporaneously compounded synthetic psilocybine product where:

(a) the synthetic psilocybine used in the manufacture of that product was tested in accordance with the requirements specified in section 17 of this instrument; and

(b) the testing was conducted at a site that is covered by a manufacturing licence granted by the Secretary under Part 3-3 of the Act.

Part 6—Labelling requirements

23 Application of this Part

This Part applies to psilocybine products.

24 Information to be included on the label

(1) The label of a psilocybine product, other than a psilocybine product that is extemporaneously compounded by a pharmacist for a particular patient, must contain all of the following information:

(a) the name of the psilocybine product;
(b) the name of the active ingredient;
(c) the quantity of the active ingredient in mg;
(d) the dosage form;
(e) the quantity of the psilocybine product;
(f) the batch number, preceded by the batch number prefix;
(g) the expiry date, preceded by the expiry date prefix;
(h) the name of the sponsor;
(i) the contact details of the sponsor;
(j) the storage conditions applicable to the psilocybine product;
(k) for a psilocybine extract product—all of the following:
(i) the quantity of psilocybine in mg;
(ii) the quantity of psilocin in mg;
(iii) the quantity of each nominated tryptamine in mg (if any);
(iv) the quantity of the psilocybine extract and the minimum dry weight or fresh weight of the plant material from which it was prepared, including the word “minimum”;
(v) the words “*Psilocybe cubensis*”;
(vi) the plant part;
(vii) the preparation type.

(2) All of the information that is required to be included on the label of a psilocybine product must be:

(a) in English; and
(b) legible, clearly visible and not obscured; and
(c) durable.

Schedule 1—Specified tests for plant derived psilocybine

Note: See section 10.

Part 1—Psilocybine extract

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for aflatoxins	Ph Eur 2.8.18	not more than 4 ppb for the sum of aflatoxins B1, B2, G1 and G2
2	test for heavy metals	Ph Eur 2.4.27	not more than the limits specified in the ICH Q3D guideline document
3	test for pesticide residue	Ph Eur 2.8.13	not more than the limits specified in Ph Eur 2.8.13
4	test for purity of psilocin	Ph Eur 2.2.29	not less than 80.0% and not more than 120.0%, calculated on a dried basis
5	test for purity of psilocybine	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0%, calculated on a dried basis
6	test for purity of any tryptamines	Ph Eur 2.2.29	not less than 80.0% and not more than 120.0%, calculated on a dried basis
7	test for residual solvents	Ph Eur 2.4.24	not more than the limits specified in Ph Eur 5.4

Part 2—Psilocybine isolate

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for heavy metals	Ph Eur 2.4.27	not more than the limits specified in the ICH Q3D guideline document
2	test for impurities	Ph Eur 2.2.29	all of the following: (a) for psilocin—not more than 2.0%; (b) for any other single impurity—not more than 0.5%; (c) not more than 2.0% total impurities

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
3	test for purity of psilocybine	Ph Eur 2.2.29	not less than 98.0% and not more than 102.0%, calculated on a dried basis
4	test for residual solvents	Ph Eur 2.4.24	not more than the limits specified in Ph Eur 5.4

Schedule 2—Specified tests for plant derived psilocybine products

Note: See section 14.

Part 1—Psilocybine extract product

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for average content of psilocin	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0% of the stated content in a pooled sample of not less than 20 capsules
2	test for average content of psilocybine	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0% of the stated content in a pooled sample of not less than 20 capsules
3	test for average content of nominated tryptamines	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0% of the stated content in a pooled sample of not less than 20 capsules
4	test for disintegration	either: (a) Ph Eur 2.9.1; or (b) USP Chapter 701	complete disintegration of the capsule must occur in a period of not more than 30 minutes
5	test for related substances	Ph Eur 2.2.29	not more than the limits specified in Ph Eur 5.10
6	test for uniformity of dosage units	either: (a) mass variation; or (b) content uniformity; as specified in Ph Eur 2.9.40	not more than the limits specified in Ph Eur 2.9.40

Part 2—Psilocybine isolate product

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for average content of psilocybine isolate	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0% of the stated content in a pooled sample of not less than 20 capsules

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
2	test for disintegration	either: (a) Ph Eur 2.9.1; or (b) USP Chapter 701	complete disintegration of the capsule must occur in a period of not more than 30 minutes
3	test for related substances	Ph Eur 2.2.29	not more than the limits specified in Ph Eur 5.10
4	test for uniformity of dosage units	either: (a) mass variation; or (b) content uniformity; as specified in Ph Eur 2.9.40	not more than the limits specified in Ph Eur 2.9.40

Schedule 3—Specified tests for synthetic psilocybine

Note: See section 17.

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for heavy metals	Ph Eur 2.4.20	not more than the limits specified in the ICH Q3D guideline document
2	test for impurities	Ph Eur 2.2.29	all of the following: (a) for psilocin—not more than 2.0%; (b) for any other single impurity—not more than 0.5%; (c) not more than 2.0% total impurities
3	test for purity of psilocybine	Ph Eur 2.2.29	not less than 98.0% and not more than 102.0%, calculated on a dried basis
4	test for residual solvents	Ph Eur 2.4.24	not more than the limits specified in Ph Eur 5.4

Schedule 4—Specified tests for synthetic psilocybine products

Note: See section 22.

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for average content of synthetic psilocybine	Ph Eur 2.2.29	not less than 90.0% and not more than 110.0% of the stated content in a pooled sample of not less than 20 capsules
2	test for disintegration	either: (a) Ph Eur 2.9.1; or (b) USP Chapter 701	complete disintegration of the capsule must occur in a period of not more than 30 minutes
3	test for related substances	Ph Eur 2.2.29	not more than the limits specified in Ph Eur 5.10
4	test for residual solvents	Ph Eur 2.4.24	not more than the limits specified in Ph Eur 5.4
5	test for uniformity of dosage units	either: (a) mass variation; or (b) content uniformity; as specified in Ph Eur 2.9.40	not more than the limits specified in Ph Eur 2.9.40