Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024

I, Tracey Duffy, as delegate of the Minister 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 MDMA) (TGO 112) Order 2024*.

(2) This instrument may also be cited as TGO 112.

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Note: This table relates only to the provisions of this instrument as originally made.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 MDMA hydrochloride or a MDMA hydrochloride 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.

MDMA hydrochloride means the substance 3,4-methylenedioxy-N-methylamphetamine hydrochloride with the chemical formula $C_{11}H_{15}NO_2$, HCl.

MDMA hydrochloride product means a therapeutic good that:

(a) contains MDMA hydrochloride as the active ingredient; and

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

Ph Eur means the European Pharmacopoeia.

quantity of the MDMA hydrochloride product means the stated number of units in the container.

Regulations means the *Therapeutic Goods Regulations 1990.*

stated content means the quantity of each substance that is stated on the label to be present in a MDMA hydrochloride product.

USP means the United States Pharmacopeia-National Formulary.

5 Standard

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

(a) MDMA hydrochloride; and

(b) MDMA hydrochloride products.

6 Application

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

(a) MDMA hydrochloride; and

(b) MDMA hydrochloride 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 MDMA hydrochloride

7 Application of this Part

This Part applies to MDMA hydrochloride.

8 Assay limits

The following assay limits apply in relation to MDMA hydrochloride:

(a) the purity of MDMA hydrochloride must be not less than 98.0% and not more than 102.0%, calculated on an anhydrous basis;

(b) the purity of chloride present in MDMA hydrochloride must be not less than 15.3% and not more than 15.9%.

9 Tests

For each item in the table in Schedule 1, MDMA hydrochloride 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 MDMA hydrochloride products

10 Application of this Part

This Part applies to MDMA hydrochloride products.

11 General

A MDMA hydrochloride product must:

(a) contain MDMA hydrochloride as the only active ingredient; and

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

12 Assay limits

The average content of MDMA hydrochloride 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 MDMA hydrochloride.

13 Tests

(1) Subject to subsection (2), for each item in the table in Schedule 2, a MDMA hydrochloride 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 MDMA hydrochloride product where:

(a) the MDMA hydrochloride used in the manufacture of that product was tested in accordance with the requirements specified in section 9 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.

14 Information to be included on the label

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

(a) the name of the MDMA hydrochloride 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 MDMA hydrochloride 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 MDMA hydrochloride product.

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

(a) in English; and

(b) legible, clearly visible and not obscured; and

(c) durable.

Schedule 1—Specified tests for MDMA hydrochloride

Note: See section 9.

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 purity of chloride	Ph Eur 2.2.29	not less than 15.3% and not more than 15.9%
3	test for purity MDMA hydrochloride	Ph Eur 2.2.29	not less than 98.0% and not more than 102.0%, calculated on an anhydrous basis
4	test for related substances	Ph Eur 2.2.29	not more than the limits specified in Ph Eur 5.10
5	test for residual solvents	Ph Eur 2.4.24	not more than the limits specified in Ph Eur 5.4
6	test for water content	Ph Eur 2.5.12	not more than 2.0%

Schedule 2—Specified tests for MDMA hydrochloride products

Note: See section 13.

Specified tests			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Test**	**Test method**	**Requirement**
1	test for average content of MDMA hydrochloride	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