Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019

I, , as delegate for the Minister for Health, make the following order.

Dated

Department of Health

Contents

Part 1—Preliminary

1 Name

(1) This instrument is the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019.*

(2) This instrument may also be cited as TGO 101.

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. Parts 1 and 2 and anything in this instrument not elsewhere covered by this table	31 March 2019.	31 March 2019
2. Part 3	31 March 2020.	31 March 2020
3.Schedules 1 and 2	31 March 2019.	31 March 2019
4. Schedule 3	31 March 2020.	31 March 2020
5. Schedule 4	31 March 2019.	31 March 2019

Note: This table relates only to the provisions of this instrument as originally made.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 Repeals

Each instrument that is specified in Schedule4 to this instrument is repealed as set out in that Schedule.

5 Definitions

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

(a) British Pharmacopoeia;
(b) default standard;
(c) European Pharmacopoeia;
(d) export only medicine;
(e) label;
(f) listed goods;
(g) medicine;
(h) registered goods;
(i) standard;
(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.

applicable monograph, in relation to therapeutic goods, means a default standard specified with reference to:

(a) a formulated preparation in the British Pharmacopoeia;
(b) a preparation in the European Pharmacopoeia; or
(c) an official product in the United States Pharmacopeia-National Formulary;

whether or not those goods are labelled as conforming to that standard, and comprises:

(d) a specific monograph;
(e) one or more applicable general monographs; and
(f) one or more applicable general chapters;

interpreted in accordance with the General Notices section of the relevant pharmacopoeia.

Note 1: Subsection 3(1) of the Act provides that the default standard must be interpreted in accordance with the General Notices section of the relevant pharmacopoeia.

Note 2: Subsection 13(7) of the Act specifies how to work out whether therapeutic goods conform with a default standard at a particular time.

Australian specific requirements has the meaning given by section 7.

capsule means a solid preparation with a hard or soft shell of various shapes and capacities, containing one or more active ingredients.

chewable, in relation to a tablet, means a tablet which has been formulated to be chewed rather than swallowed whole and for which the label includes a direction to chew the tablet.

dispersible, in relation to a tablet, means an uncoated or film-coated tablet intended to be dispersed in water before administration, giving a homogeneous dispersion.

effervescent, in relation to a tablet, means an uncoated tablet generally containing acid substances and carbonates or hydrogen carbonates which react

rapidly in the presence of water to release carbon dioxide, and that is intended to be dissolved or dispersed in water before administration.

enzyme means a protein that acts as a catalyst for biochemical reactions.

herbal material means a plant or part of a plant (defined by its botanical scientific name according to the binominal nomenclature system, including author, and the plant part), whether fresh or dried, that is whole, fragmented, cut or ground.

herbal preparation means an ingredient that is the result of the processing of a herbal material.

homoeopathic preparation has the same meaning as in the Regulations.

mineral means an inorganic material of defined composition.

mineral compound means a salt or other compound of one or more elements that has a Recommended Dietary Intake for that element in the publication *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes* endorsed by the National Health and Medical Research Council on 13 July 2017.

modified-release means:

(a) in relation to a tablet, a coated or uncoated tablet which contains special excipients or which is prepared by special procedures, or both, designed to modify the rate, the place or the time at which the active ingredient is, or active ingredients are, released; or

(b) in relation to a capsule, a hard or soft capsule in which the contents or shell, or both, contain special excipients or are prepared by special procedures designed to modify the rate, the place or the time at which the active ingredient is, or active ingredients are, released.

pill means a solid preparation in a spherical or ovoid shape, with or without a coating, which is formed from a pliable mass that retains its shape during storage, containing one or more active ingredients, and is one of the following:

(a) a honeyed pill;

(b) a water-honeyed pill;

(c) a watered pill;

(d) a pasted pill;

(e) a waxed pill;

(f) a concentrated pill;

(g) a dripping pill; or

(h) a sugar pill.

probiotic means viable, defined micro-organisms in sufficient numbers to alter the microflora (by implantation or colonisation) in a compartment of the host.

provitamin means a chemical precursor to a vitamin.

Regulations mean the *Therapeutic Goods Regulations 1990*.

stated content, in relation to tablets, capsules and pills, means the quantity of the active ingredient that is stated on the label to be present in each tablet, capsule or pill.

tablet means a solid preparation containing one or more active ingredients and obtained by compressing uniform volumes of particles or by another suitable manufacturing technique, such as extrusion, moulding or freeze-drying (lyophilisation).

vitamin means a naturally occurring organic substance or a synthetic equivalent, or a salt or other compound, comprising one of the following:

(a) vitamin A;
(b) vitamin B1;
(c) vitamin B2;
(d) vitamin B3;
(e) vitamin B5;
(f) vitamin B6;
(g) vitamin B12;
(h) vitamin C;
(i) vitamin D;
(j) vitamin E;
(k) vitamin K;
(l) biotin;
(m) choline; or
(n) folic acid.

6 Incorporation by reference

Where the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia-National Formulary adopts a different name or number for a test or method that is referenced in this instrument, this instrument incorporates that renamed or renumbered test or method.

7 Application

(1) Subject to subsection (2), this instrument applies to therapeutic goods that are manufactured in the following dosage forms and that are intended for oral administration:

(a) tablet;
(b) capsule; and
(c) pill.

Note: Part 3 and Schedule 3 of this instrument, which sets out requirements in relation to pills, commences on 31 March 2020 in accordance with section 2.

(2) This instrument does not apply to therapeutic goods that are:

(a) a radiopharmaceutical;
(b) an export only medicine;
(c) exempt under section 18 or 18A of the Act;

(d) the subject of an approval or authority under section 19 of the Act; or
(e) the subject of an approval under section 19A of the Act.

Part 2—Tablets and capsules

Division 1—Requirements for tablets and capsules

8 General requirements

(1) The requirements in relation to a tablet or capsule for which there is an applicable monograph are:

(a) those requirements specified in that monograph, subject to the matters specified in Division 2; or

(b) those requirements specified in Division 3 (the ***Australian specific requirements***).

(2) The requirements in relation to a tablet or capsule for which there is no applicable monograph are the Australian specific requirements.

Division 2—Requirements for tablets and capsules for which there is an applicable monograph

9 Application of Division

This Division applies to tablets and capsules that are registered goods or listed goods.

10 Tablets or capsules containing folic acid

(1) If a tablet:

(a) has a stated content of 100 micrograms or more of folic acid; and

(b) is not a chewable, effervescent, dispersible or modified-release tablet;

then the following requirements are specified:

(c) if folic acid is the single active ingredient— the dissolution requirements of the Folic Acid Tablets monograph in the United States Pharmacopeia-National Formulary; or

(d) if there are multiple active ingredients— the dissolution requirements for folic acid in chapter <2040> *Disintegration and Dissolution of Dietary Supplements* of the United States Pharmacopeia-National Formulary.

(2) If a capsule:

(a) has a stated content of 100 micrograms or more of folic acid; and

(b) is not a soft capsule or a modified-release capsule;

then the following requirements are specified:

(c) the dissolution requirements for folic acid in chapter <2040> *Disintegration and Dissolution of Dietary Supplements* of the United States Pharmacopeia-National Formulary.

11 Impurities

The following requirements are specified for tablets and capsules:

(a) if the specific monograph applied to a tablet or capsule specifies concentration limits in relation to arsenic, cadmium, lead or mercury— the concentration limits for the tablet or capsule are those specified in that monograph; or

(b) if:

(i) the specific monograph applied to a tablet or capsule does not specify concentration limits in relation to arsenic, cadmium, lead or mercury; and

(ii) a separate specific monograph for that tablet or capsule in another pharmacopoeia specifies concentration limits in relation to arsenic, cadmium, lead or mercury;

then the concentration limits for the tablet or capsule are those specified in the separate specific monograph; or

(c) if there are no concentration limits specified in any specific monograph for a tablet or capsule in relation to arsenic, cadmium, lead or mercury— the concentration limits for the tablet or capsule are those specified in the applicable general monographs or applicable general chapters.

12 Dissolution

If:

(a) a tablet or capsule is a registered good that:

(i) does not contain folic acid; and

(ii) is not a modified release tablet, chewable tablet, effervescent tablet, dispersible tablet or modified release capsule; and

(b) the applicable monograph that is applied to the tablet or capsule does not specify a test for dissolution; and

(c) a default standard in relation to any active ingredient contained in that tablet or capsule specifies a dissolution test;

then that dissolution test is specified for the tablet or capsule.

Note: A dissolution test is specified for tablets and capsules that are registered goods or listed goods, containing folic acid: see section 10.

13 Uniformity

If:

(a) the tablet or capsule is a listed good; and

(b) the applicable monograph specifies a test for uniformity of dosage units;

then that test may be substituted with the test for uniformity of weight (mass) specified in Schedule 1.

Division 3—Australian specific requirements

14 Application of Division

This Division applies to tablets and capsules that are registered goods or listed goods.

15 Assays for each active ingredient

(1) Subject to this section, the assay limit for each active ingredient of a tablet or a capsule is specified in item 1 of the table in Schedule 1.

(2) If the tablet or capsule contains an active ingredient that is mentioned in Schedule 2, then the assay limit for each active ingredient of that tablet or capsule is specified in the table in Schedule 2.

(3) If:

(a) a tablet or a capsule contains an active ingredient that is an antibiotic; and

(b) a microbiological method is used in relation to the assay of that active ingredient;

then:

(c) the upper fiducial limit of error of the estimated content of active ingredient in each tablet or capsule (P = 0.95) must not be less than 97.0 per cent of the stated content of active ingredient; and

(d) the lower fiducial limit of error of the estimated content of active ingredient in each tablet or capsule (P = 0.95) must not be more than 115.0 per cent of the stated content of active ingredient.

(4) If:

(a) the tablet or capsule contains an active ingredient that comprises two or more components that are each quantified on the label of the medicine; and

(b) the proportions of these components vary independently of each other;

then the estimated average content of each component in a pooled sample of not fewer than 20 tablets or capsules must be not less than 90.0 per cent of the stated content of the active ingredient.

(5) If the tablet or capsule:

(a) is a homoeopathic preparation; or

(b) contains an active ingredient that is a multi-component ingredient and no quantitative claim is made on the label of the goods for any component;

then there are no assay requirements specified in relation to that tablet or capsule.

(6) For the purposes of this section, the assay must be calculated using a pooled sample of not fewer than 20 tablets or capsules.

16 Tablet or capsule containing folic acid

(1) If a tablet:

(a) has a stated content of 100 micrograms or more of folic acid; and

(b) is not a chewable, effervescent, dispersible or modified-release tablet;

then the following requirements are specified:

(c) if folic acid is the single active ingredient— the dissolution requirements of the Folic Acid Tablets monograph of the United States Pharmacopeia-National Formulary; or

(d) if there are multiple active ingredients— the dissolution requirements for folic acid in chapter <2040> *Disintegration and Dissolution of Dietary Supplements* of the United States Pharmacopeia-National Formulary.

(2) If a capsule:

(a) has a stated content of 100 micrograms or more of folic acid; and

(b) is not a soft capsule or a modified-release capsule;

then the following requirements are specified:

(c) the dissolution requirements for folic acid in chapter <2040> *Disintegration and Dissolution of Dietary Supplements* of the United States Pharmacopeia-National Formulary.

17 Impurities

The following requirements are specified for tablets and capsules:

(a) if a specific monograph specifies concentration limits in relation to arsenic, cadmium, lead or mercury— the concentration limits for the tablet or capsule are those specified in that monograph; or

(b) subject to paragraph (c), if:

(i) there is no specific monograph; or

(ii) there is a specific monograph but the specific monograph does not specify concentration limits in relation to arsenic, cadmium, lead or mercury;

then the concentration limits for the tablet or capsule are specified in item 2 of the table in Schedule 1; or

(c) if the tablet or capsule contains one or more active ingredients, each of which are herbal materials or herbal preparations—the concentration limits for the tablet or capsule are specified in item 3 of the table in Schedule 1.

18 Dissolution

(1) If:

(a) a tablet or capsule is a registered good that:

(i) does not contain folic acid; and

(ii) is not a modified release tablet, chewable tablet, effervescent tablet, dispersible tablet or modified release capsule; and

(b) a default standard in relation to any active ingredient contained in that tablet or capsule specifies a dissolution test ;

then that dissolution test is specified for the tablet or capsule.

(2) If the tablet or capsule is a modified-release tablet or capsule, then a test for dissolution that demonstrates the appropriate release of each active ingredient must be performed.

Note: A dissolution test is specified for tablets and capsules that are registered goods or listed goods, containing folic acid: see section 16.

19 Disintegration

(1) Subject to subsection (2), the test for disintegration specified in item 4 of the table in Schedule 1 applies in relation to tablets or capsules.

(2) If a test for dissolution of active ingredients is performed in relation to the tablet or capsule in accordance with section 18, then the tablet or capsule is not required to comply with the test for disintegration specified in item 4 of the table in Schedule 1.

20 Fineness of dispersion

If the tablet is a dispersible tablet, then the test for fineness of dispersion of the British Pharmacopoeia, specified in the general monograph entitled 'Tablets' applies in relation to that tablet.

21 Uniformity

The tests for uniformity of dosage units in relation to tablets and capsules are:

(a) for registered goods— specified in item 5 of the table in Schedule 1; and

(b) for listed goods— specified in item 6 of the table in Schedule 1.

Part 3—Pills

22 Application of Part

This Part applies to pills that are registered goods or listed goods.

23 General requirements

The requirements of this Part are specified in relation to pills.

24 Appearance etc

Pills must be:

(a) uniform in appearance and colour; and

(b) without adhesion.

25 Water content

The following requirements are specified in relation to water content:

(a) honeyed pills and concentrated honeyed pills must not contain more than 15.0% water;

(b) water-honeyed pills and concentrated water-honeyed pills must not contain more than 12.0% water; and

(c) watered pills, pasted pills and concentrated watered pills must not contain more than 9.0% water.

Note: No determination of water content is required for waxed pills.

26 Weight variation

(1) The weight variation in relation to a dripping pill is specified in the table in Part 1 of Schedule 3.

(2) The weight variation in relation to a sugar pill is specified in the table in Part 2 of Schedule 3.

(3) The weight variation for other pills, which are not dripping pills or sugar pills, is specified in the table in Part 3 of Schedule 3.

(4) The core weight variation of sugar-coated pills, which are not dripping pills or sugar pills, must be examined before coating.

Note: Weight variation testing after coating is not required for sugar-coated pills, but must be undertaken for all other-coated pills.

27 Disintegration

The tests for disintegration are specified in the table in Part 4 of Schedule 3.

Note: No disintegration test is required for big-honeyed pills, pills for grinding or chewing or pills to be taken after being dispersed with hot water or yellow rice wine.

28 Assay

(1) Subject to subsection (2), the assay limits for each active ingredient of a pill are those specified in item 1 of the table in Schedule 1.

(2) If:

(a) a pill contains an active ingredient that is a multi-component ingredient; and

(b) no quantitative claim is made on the label of the pill for any individual component;

then there are no assay requirements specified in relation to that pill.

(3) For the purposes of this section, the assay must be calculated using a pooled sample of not fewer than 20 pills.

29 Impurities

(1) Subject to subsection (2), the concentration limits in relation to each of the following elements:

(a) arsenic;
(b) cadmium;
(c) lead; and
(d) mercury;

are specified in item 2 of the table in Schedule 1.

(2) If the pill contains one or more active ingredients, each of which are herbal materials or herbal preparations, then the concentration limits for the pill are specified in item 3 of the table in Schedule 1.

Schedule 1—Tablets and capsules: assay, impurities, disintegration and uniformity

Note: See Part 2 and section 29.

Column 1 Item	Column 2 Property	Column 3 Requirements
1	assay for each active ingredient	(a) for active ingredients in registered goods—90 to110% (b) for active ingredients in listed goods—90 to 120%
2	impurities	(a) for arsenic— a maximum concentration of 1.5 parts per million; (b) for cadmium— a maximum concentration of 0.5 parts per million; (c) for lead— a maximum concentration of 0.5 parts per million; (d) for mercury— a maximum concentration of 3 parts per million; (e) for residual solvents— the limits specified in European Pharmacopoeia (5.4);
3	impurities for goods containing herbal materials or herbal preparations	**OPTION 1 for consultation:** (a) for arsenic— a maximum concentration of 2 part per million; (b) for cadmium— a maximum concentration of 1parts per million; (c) for lead— a maximum concentration of 5 parts per million; (d) for mercury— a maximum concentration of 0.1 parts per million; (e) for residual solvents— the limits specified in European Pharmacopoeia (5.4); **OR** **OPTION 2 for consultation** (a) for arsenic— a maximum concentration of 1.5 parts per million; (b) for cadmium— a maximum

Column 1 Item	Column 2 Property	Column 3 Requirements
		concentration of 0.5 parts per million; (c) for lead— a maximum concentration of 0.5 parts per million; (d) for mercury (total)— a maximum concentration of 1.5 parts per million; (e) for methyl mercury (as Hg)— a maximum concentration of 0.2 parts per million; (f) for residual solvents— the limits specified in European Pharmacopoeia (5.4);
4	disintegration	European Pharmacopoeia (2.9.1) or United States Pharmacopoeia-National Formulary, chapter <701>
5	uniformity of dosage units	European Pharmacopoeia (2.9.40) or United States Pharmacopoeia-National Formulary, chapter <905>
6	uniformity of weight (mass)	European Pharmacopoeia (2.9.5) or United States Pharmacopoeia-National Formulary, chapter <711>

Schedule 2—Tablet and capsules: assay limits for content of active ingredient or component in a tablet or capsule

Note: See section 15.

Column 1 Item	Column 2 Active ingredient	Column 3 Not less than (percent)	Column 4 Not more than (percent)
1	vitamin or provitamin:		
	(a) water soluble;	90.0	150.0
	(b) oil soluble;	90.0	165.0
	(c) betacarotene, panthenol, pantothenic acid or salt of pantothenic acid	90.0	175.0
2	mineral or mineral compound:		
	(a) generally;	90.0	125.0
	(b) when used as a source of boron, chromium, fluorine, iodine, molybdenum or selenium	90.0	160.0
3	enzyme	90.0	200.0
4	probiotic	not less than stated content	

Schedule 3—Pills: weight variation and disintegration

Note: See Part 3.

Part 1—Weight variation: dripping pills

Column 1 Item	Column 2 Labelled or average weight	Column 3 Variation (percent)
1	0.03 grams or less	15
2	more than 0.03 grams to 0.1 grams	12
3	more than 0.1 grams to 0.3 grams	10
4	more than 0.3 grams	7.5

Part 2—Weight variation: sugar pills

Column 1 Item	Column 2 Labelled or average weight	Column 3 Variation (percent)
1	0.03grams or less	15
2	more than 0.03 grams to 0.3 grams	10
3	more than 0.3 grams	7.5

Part 3—Weight variation: other pills

Column 1 Item	Column2 Labelled or average weight	Column 3 Variation (percent)
1	0.05 grams or less	12
2	more than 0.05 grams to 0.1 grams	11
3	more than 0.1 grams to 0.3 grams	10
4	more than 0.3 grams to 1.5 grams	9
5	more than 1.5 grams to 3 grams	8
6	more than 3 grams to 6 grams	7
7	more than 6 grams to 9 grams	6
8	more than 9 grams	5

Part 4—Disintegration

Column 1 Item	Column 2 Pill type	Column 3 Requirement
1	small honey pills, water-honeyed pills and watered pills	the pill must completely disintegrate within 1 hour
2	concentrated pills and pasted pills	the pill must completely disintegrate within 2 hours
3	dripping pills (excluding coated dripping pills)	the pill must completely disintegrate within 30 minutes
4	coated dripping pills	the pill must completely disintegrate within 1 hour
5	waxed pills	the pill must comply with a suitable disintegration test

Schedule 4—Repeals

Note: See section 4.

Therapeutic Goods Order No.78 *Standard for Tablets and Capsules*

1 The whole of the instrument

Repeal the instrument.