



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

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

Dated 21 March 2019

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

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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. Sections 1 to 15, and anything in this instrument not elsewhere covered by this table	31 March 2019.	31 March 2019
2. Section 16	31 March 2021.	31 March 2021
3. Sections 17 to 20	31 March 2019.	31 March 2019
4. Part 3	31 March 2021.	31 March 2021
5. Schedules 1 and 2	31 March 2019.	31 March 2019
6. Schedule 3	31 March 2021.	31 March 2021
7. 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Note: This table relates only to the provisions of this instrument as originally made.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 Interpretation

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;

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- (f) listed goods;
 - (g) medicine;
 - (h) registered goods;
 - (i) standard;
 - (j) United States Pharmacopoeia-National Formulary.

(1) 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 pharmaceutical preparation in the European Pharmacopoeia; or
- (c) an official product in the United States Pharmacopoeia-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 8.

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.

homoeopathic preparation has the same meaning as in the Regulations.

ICH Q3D Guideline means ICH Harmonised Guideline: *Guideline for Elemental Impurities Q3D*, Current *Step 4* version, dated 16 December 2014.

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

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;

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- (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.

- (2) Where the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia-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.

5 Standard

This instrument constitutes a standard for tablets, capsules and pills.

6 Application

- (1) Subject to subsection (2), this instrument applies to therapeutic goods that are intended for oral administration, and manufactured in the following dosage forms:
 - (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 2021 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.

7 Repeals

Each instrument that is specified in Schedule 4 to this instrument is repealed as set out in the applicable items in that Schedule.

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*) together with the requirements relevant to the tablet or capsule that are specified in one of the following:
 - (i) the general monographs in the European Pharmacopoeia;
 - (ii) the general monographs in the British Pharmacopoeia;
 - (iii) the general chapters of the United States Pharmacopoeia-National Formulary.
- (2) The requirements in relation to a tablet or capsule for which there is no applicable monograph are:
 - (a) the Australian specific requirements; and
 - (b) the requirements relevant to the tablet or capsule that are specified in one of the following:
 - (i) the general monographs in the European Pharmacopoeia;
 - (ii) the general monographs in the British Pharmacopoeia;
 - (iii) the general chapters of the United States Pharmacopoeia-National Formulary.

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:

- (a) that are registered goods or listed goods; and
- (b) for which there is an applicable monograph.

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 Dissolution

If:

- (a) a tablet or capsule is a registered good that:
 - (i) does not contain folic acid; or
 - (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 for the relevant dosage form;

then the dissolution test specified for the tablet or capsule is:

- (d) the dissolution test specified in the default standard mentioned in paragraph (1)(c); or
- (e) another dissolution test that is suitable for the tablet or capsule..

Note 1: A dissolution test is specified for tablets and capsules that are registered goods or listed goods, containing folic acid: see section 10.

Note 2: A dissolution test will always be specified in an applicable monograph for modified-release tablets and modified-release capsules.

12 Uniformity relating to dosage units and weight

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

13 Application of Division

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

14 Assay of each active ingredient

- (1) Subject to this section, the assay limits for the stated content of each active ingredient of a tablet or a capsule are specified in item 1 of the table in Schedule 1.
- (2) If the tablet or capsule contains an active ingredient that is mentioned in an item in the table in Schedule 2, then the assay limits for that active ingredient are specified in columns 3 and 4 of that item.
- (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) For the purposes of this section, the assay must be calculated using a pooled sample of not fewer than 20 tablets or capsules.
- (5) 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 each component.
- (6) If the tablet or capsule is a homoeopathic preparation then there are no assay requirements specified in relation to that tablet or capsule.
- (7) If:
 - (a) the tablet or capsule contains an active ingredient that is a multi-component ingredient; and
 - (b) 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 active ingredient.

15 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.

16 Elemental impurities and residual solvents

- (1) The requirements for elemental impurities are those specified in either one of the following:
 - (a) chapter <2232> *Elemental Contaminants in Dietary Supplements* of the United States Pharmacopeia-National Formulary; or
 - (b) the ICH Q3D Guideline.
- (2) The limits for residual solvents are those specified in European Pharmacopoeia (5.4) for solvent impurities.

17 Dissolution

- (1) If:
 - (a) a tablet or capsule is a registered good that:
 - (i) does not contain folic acid; or
 - (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 for the relevant dosage form;then the dissolution test specified for the tablet or capsule is:
 - (c) the dissolution test specified in the default standard mentioned in paragraph (1)(b); or
 - (d) another dissolution test that is suitable for the tablet or capsule.

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- (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 15.

18 Disintegration

- (1) Subject to subsection (2), the test for disintegration specified in item 2 of the table in Schedule 1 applies in relation to tablets or capsules that are not chewable tablets.
- (2) If a test for dissolution of active ingredients is performed in relation to the tablet or capsule in accordance with section 15 or 17, then the tablet or capsule is not required to comply with the test for disintegration specified in item 2 of the table in Schedule 1.

19 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.

20 Uniformity relating to dosage units and weight

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

- (a) for registered goods— specified in item 3 of the table in Schedule 1; and
(b) for listed goods— specified in item 4 of the table in Schedule 1.

Part 3—Pills

21 Application of Part

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

22 General requirements

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

23 Appearance

Pills must be:

- (a) uniform in appearance and colour; and
- (b) without adhesion.

24 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.

25 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.

26 Disintegration

- (1) The following requirements are specified in relation to the pills mentioned in the table in Part 4 of Schedule 3 (the **relevant pills**):
 - (a) a test for disintegration (the **test**) must be performed, subject to the remainder of this section, in accordance with the methods specified in either one of the following:

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- (i) European Pharmacopoeia (2.9.1); or
 - (ii) chapter <701> *Disintegration* of the United States Pharmacopoeia-National Formulary;
- (b) subject to paragraphs (c) and (d), the test must be performed using six pills, a disc, and a sieve with the relevant pore diameter specified in the table in Part 5 of Schedule 3;
 - (c) the test may be performed, in relation to dripping pills, without a disc;
 - (d) if, in the course of the test, one or more pills, or parts of the pills, adhere to the disc, the test must be repeated without the disc, using another six pills;
 - (e) the entirety of the pills used in the test must pass through the sieve within the relevant time, if any, specified in the table in Part 4 of Schedule 3.
- (2) The relevant pills are taken to comply with this section if the only residue remaining in the test comprises softened masses without a hard core.
- Note: No disintegration test is specified in relation to big-honeyed pills, pills for grinding or chewing or pills to be taken after being dispersed with hot water or yellow rice wine.

27 Assay of each active ingredient

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

28 Elemental impurities

- (1) The maximum concentration limits in relation to the following elements:
 - (a) arsenic;
 - (b) cadmium;
 - (c) lead; and
 - (d) mercury;are specified in the table in Part 6 of Schedule 3.
- (2) The total mass of each of the elements referred to in subsection (1) in the pill must be within the permitted daily exposure limit specified for that element in:
 - (a) chapter <2232> *Elemental Contaminants in Dietary Supplements* of the United States Pharmacopoeia-National Formulary; or
 - (b) the ICH Q3D Guideline.

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

Note: See Part 2.

Column 1 Item	Column 2 Property	Column 3 Requirements
1	assay for each active ingredient	(a) for active ingredients in registered goods—90.0 to 110.0% (b) for active ingredients in listed goods—90.0 to 120.0%
2	disintegration	European Pharmacopoeia (2.9.1) or United States Pharmacopoeia-National Formulary, chapter <701>
3	uniformity of dosage units	European Pharmacopoeia (2.9.40) or United States Pharmacopoeia-National Formulary, chapter <905>
4	uniformity of weight (mass)	European Pharmacopoeia (2.9.5) or United States Pharmacopoeia-National Formulary, chapter <711>

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

Note: See section 14.

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, disintegration and elemental impurities

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	Column 2 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

Part 5—Sieve pore diameter

Column 1 Item	Column 2 Pill diameter	Column 3 Sieve pore diameter
1	less than 2.5 mm	0.42 mm
2	2.5 – 3.5 mm	1.0 mm
3	more than 3.5 mm	2.0 mm

Part 6—Elemental impurities

Column 1 Item	Column 2 Element	Column 3 Requirement
1	arsenic	a maximum concentration of 2 parts per million;
2	cadmium	a maximum concentration of 1 part per million;
3	lead	a maximum concentration of 5 parts per million
4	mercury	a maximum concentration of 0.2 parts per million

Schedule 4—Repeals

Note: See section 7.

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

1 The whole of the instrument

Repeal the instrument.