Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018

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

Dated 30 November 2018

(*signed by*)

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Department of Health

Contents

1 Name

(1) This instrument is the *Therapeutic Goods (Microbiological Standards for Medicines) (TGO 100) Order 2018*;

(2) This instrument may also be cited as Therapeutic Goods Order 100, or TGO 100.

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	The day after registration.	

Note: This table relates only to the provisions of this instrument as originally made.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 the Act, including the following:
(a) British Pharmacopoeia;
(b) default standard;
(c) European Pharmacopoeia;
(d) export only medicine;
(e) medicine;
(f) standard;
(g) United States Pharmacopeia-National Formulary.

In this instrument:

acceptance criteria, in relation to microbiological quality, are interpreted as:
(a) 10^1 CFU: maximum acceptable count is 20;
(b) 10^2 CFU: maximum acceptable count is 200;
(c) 10^3 CFU: maximum acceptable count is 2000, and so forth.

Act means the *Therapeutic Goods Act 1989*.

antimicrobial preservation means the presence of an ingredient(s) in a medicine that inhibits the growth of microorganisms in the medicine.

CFU means colony forming units.

complementary medicine has the same meaning as in the Regulations.

herbal substance has the same meaning as in the Regulations.

monograph means the requirements of an individual or general monograph in a default standard read in conjunction with the General Notices contained in the same edition that are applicable to that monograph.

Regulations means the *Therapeutic Goods Regulations 1990*.

5 Incorporation by reference

Where a default standard 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.

6 Application

(1) The requirements set out in this instrument apply to all therapeutic goods that are medicines.

(2) However, the requirements set out in this instrument do not apply to a medicine that is exempt under section 7 of this instrument.

7 General exemptions

The requirements of this instrument do not apply to a medicine that:

(a) is an export only medicine; or

(b) is imported into Australia for use in the treatment of the importer or the importer's immediate family, in accordance with item 1 of Schedule 5 to the Regulations; or

(c) is a starting material used in the manufacture of medicines, except when:

(i) pre-packaged for supply for other therapeutic purposes; or

(ii) formulated as a dosage form; or

(d) the starting material has not reached its final stage of manufacture.

8 Repeals

The instruments specified in Schedule 3 are repealed.

9 Sterility and Bacterial Endotoxin testing

Where:

(a) a medicine is required to be sterile or to comply with a bacterial endotoxin test by an individual or general monograph of a default standard; or

(b) a medicine through its labelling or packaging states or implies that the medicine is sterile,

the medicine must comply with the Test for Sterility and, if applicable, the Bacterial Endotoxin Test, of a default standard.

10 Efficacy of antimicrobial preservation of a multidose medicine

A medicine that is an aqueous multidose medicine must comply with the British Pharmacopoeia, Appendix XVI C. Efficacy of Antimicrobial Preservation or the European Pharmacopoeia, Efficacy of Antimicrobial Preservation (5.1.3), except that an aqueous multidose medicine that is a liquid oral antacid medicine may comply with the relevant test in the United States Pharmacopeia – National Formulary, chapter <51> Antimicrobial Effectiveness Test including its acceptance criteria.

11 Microbiological attributes of a non-sterile medicine

(1) A non-sterile medicine, other than a complementary medicine oral dosage form containing raw material of natural (animal, vegetal or mineral) origin, must comply with the relevant acceptance criteria for microbiological quality of one of the following:

(a) the British Pharmacopoeia, Appendix XVI. D Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use; when tested by the methods of:

(i) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 2. Microbial Enumeration Tests; and

(ii) the British Pharmacopoeia, Appendix XVI B. Microbiological Examination of Non-Sterile Products: 1. Test for Specified Micro-organisms; or

(b) the European Pharmacopoeia, Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use (5.1.4); when tested by the methods of:

(i) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests (2.6.12); and

(ii) the European Pharmacopoeia, Microbiological Examination of Non-Sterile Products: Test for Specified Micro-organisms (2.6.13); or

(c) the United States Pharmacopeia – National Formulary, chapter <1111> , MICROBIOLOGICAL EXAMINATION OF NONSTERILE

PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE, when tested by the methods of:

(i) the United States Pharmacopeia – National Formulary, chapter <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS; and

(ii) the United States Pharmacopeia – National Formulary, chapter <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS.

(2) A complementary medicine oral dosage form containing raw material of natural (animal, vegetal or mineral) origin must comply with the acceptance criteria for microbiological quality specified in Schedule 1 when tested by a method stated in subsection 11(1), other than a herbal medicine consisting solely of one or more herbal substances (whole, reduced or powdered) to which boiling water is added before use, which must comply with the acceptance criteria specified in Schedule 2 when tested with a method mentioned in subsection 11(1).

Schedule 1— Microbial attributes for a complementary medicine oral dosage form containing raw material of natural (animal, vegetal or mineral) origin

(subsection 11(2))

1 Table of acceptance criteria

Microbiological Quality	Acceptance Criteria
Total aerobic microbial count	Less than or equal to 10^4 CFU per g or per mL
Total yeast and mould count	Less than or equal to 10^2 CFU per g or per mL
Bile-tolerant Gram negative bacteria	Less than or equal to 10^2 CFU per g or per mL
Salmonella	absent in 10 g or 10 mL
Escherichia coli	absent in 1 g or 1 mL
Staphylococcus aureus	absent in 1 g or 1 mL

Schedule 2— Microbial attributes for a complementary medicine oral dosage form containing raw material of natural (vegetal) origin that is a herbal medicinal product consisting solely of one or more herbal substances (whole, reduced or powdered) to which boiling water is added before use

(subsection 11(2))

1 Table of acceptance criteria

Microbiological Quality	Acceptance Criteria
Total aerobic microbial count	Less than or equal to 10^7 CFU per g
Total yeast and mould count	Less than or equal to 10^5 CFU per g
Bile-tolerant Gram negative bacteria	Less than or equal to10^2 CFU per g
Escherichia coli	absent in 1 g
Salmonella	absent in 10 g

Schedule 3— Repeals

(section 8)

Therapeutic Goods Order No.98 – Microbiological Standards for Medicines 2018

1 The whole of the instrument

Repeal the instrument