Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Order No. 78
Standard for Tablets and Capsules

I, ROHAN HAMMETT, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* ('the Act') and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the Act, HEREBY:

(1) REVOKE, on and from 1 November 2010, Therapeutic Goods Order No. 56 entitled "General standard for tablets, pills and capsules" made on 19th September 1996; and

(2) DETERMINE that matters specified in this Order constitute a standard for the therapeutic goods identified in this Order.

Dated this 29th day of October 2008

ROHAN HAMMETT

Delegate of the Minister for Health and Ageing

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1 Name of Order

This Order may be cited as the **Therapeutic Goods Order No. 78** ***Standard for Tablets and Capsules***.

2 Commencement

This Order commences on the day after the day it is registered on the Federal Register of Legislative Instruments.

3 Transition Arrangements

(1) On or before 31 October 2010 each medicine to which this Order applies must comply with either:

(i) the requirements specified in this Order, or

(ii) the requirements specified in Therapeutic Goods Order No 56 *General standard for tablets, pills and capsules.*

(2) On and from 1 November 2010 each medicine to which this Order applies must comply with the requirements specified in this Order.

4 Introduction

The objective of this Order is to specify the general minimum quality requirements for tablets and capsules that apply throughout the shelf-life of the medicine.

5 Interpretation

In this Order:

the Act means the *Therapeutic Goods Act 1989,* as amended from time to time.

active ingredient has the same meaning as "active ingredient" in section 52F of the Act.

British Pharmacopoeia has the same meaning as "British Pharmacopoeia" in subsection 3(1) of the Act, as amended from time to time.

capsule means a solid preparation with a hard or soft shell of various shapes and capacities, usually containing a single dose of one or more active ingredients, and includes the types of capsules identified in the British Pharmacopoeia monographs for “Capsules” and “Oromucosal Preparations” with the relevant definitions.

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

effervescent 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 are intended to be dissolved or dispersed in water before administration.

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

export only medicine has the same meaning as "export only medicine" in subsection 3(1) of the Act.

homoeopathic preparation has the same meaning as "homoeopathic preparation" in regulation 2 of the Regulations.

label has the same meaning as "label" in subsection 3(1) of the Act.

listable goods has the same meaning as "listable goods" in subsection 3(1) of the Act.

listed goods has the same meaning as "listed goods" in subsection 3(1) of the Act.

medicine has the same meaning as "medicine" in subsection 3(1) of the Act.

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 9 September 2005.

modified-release, in relation to tablets, means coated or uncoated tablets which contain special excipients or which are prepared by special procedures, or both, designed to modify the rate, the place or the time at which the active ingredient or ingredients are released.

modified-release, in relation to capsules, means hard or soft capsules 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 or ingredients are released.

monograph means the requirements of, and definitions within, an individual or general monograph of the British Pharmacopoeia or the United States Pharmacopeia-National Formulary, read in conjunction with the General Notices contained in the same edition that are applicable to that monograph.

pill means a spherical or ovoid preparation with or without a coating which is intended for ingestion and is formed from a pliable mass of such consistency that it retains its shape on storage.

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

provitamin means a chemical precursor to a vitamin.

registered goods has the same meaning as "registered goods" in subsection 3(1) of the Act.

Regulations mean the Therapeutic Goods Regulations 1990, as amended from time to time.

Secretary has the same meaning as "Secretary" in subsection 3(1) of the Act.

standard has the same meaning as "standard" in subsection 3(1) of the Act.

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

tablet means a solid preparation containing a single dose of 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), and includes the types of tablets identified in the British Pharmacopoeia monographs for “Tablets” and “Oromucosal Preparations” with relevant definitions, but does not include pills.

United States Pharmacopeia-National Formulary has the same meaning as “United States Pharmacopeia-National Formulary” in subsection 3(1) of the Act, as amended from time to time, or if no such meaning is included in the Act, means the 31st edition of the United States Pharmacopeia – 26th edition of the National Formulary in the English language published by The United States Pharmacopeial Convention.

vitamin means a naturally occurring organic substance, or a synthetic equivalent, or a salt or other compound of: vitamin A, vitamin B1, vitamin B2, vitamin B3, vitamin B5, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K, biotin, choline or folic acid.

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

6 Application

(1) The requirements set out in this Order apply to each medicine that is a tablet or capsule intended for oral administration and for human use and that comes within the operation of the Act.

(2) However, the requirements set out in this Order do not apply to a medicine:

(a) that is exempt under section 7 of this Order; or

(b) in relation to which an exemption from compliance with this Order has been granted by the Secretary in writing for the supply, importation or export of a medicine to occur although the medicine does not conform to this Order or parts of this Order in accordance with sections 14 or 14A of the Act.

7 General Exemptions

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

(a) an export only medicine; or

(b) a personal import as described under Item 1 of Schedule 5 of the Regulations; or

(c) a radiopharmaceutical.

8 Tablet or capsule with an individual British Pharmacopoeia monograph

A tablet or capsule must comply with the individual monograph of the British Pharmacopoeia for a tablet or capsule of that type, with the following changes:

(a) for a tablet or capsule that is a listed good:

(i) a requirement for compliance with a test for Uniformity of Dosage Units in a monograph is replaced with compliance with the requirements of Uniformity of Weight (Mass), Appendix XII C of the British Pharmacopoeia; and

(ii) for the active ingredient folic acid, section 9 of this Order also applies; or

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

(i) if the British Pharmacopoeia monograph does not include a test for dissolution, and an individual monograph of the United States Pharmacopeia-National Formulary for a tablet or capsule containing that active ingredient does require a test for dissolution, then the tablet or capsule must also comply with a suitable test for dissolution, except that the test is not required for:

(a) a chewable, effervescent or dispersible tablet; or

(b) the active ingredient folic acid, unless section 9 of this Order is relevant.

9 Tablet or capsule containing folic acid

(1) A tablet with a stated content of 100 micrograms or more of folic acid, that is not a chewable, effervescent, dispersible or modified-release tablet, must:

(a) where folic acid is the single active ingredient, comply with the dissolution requirements of the Folic Acid Tablets monograph of the United States Pharmacopeia-National Formulary; or

(b) where there are multiple active ingredients, comply with the dissolution requirements for folic acid of the United States Pharmacopeia-National Formulary, chapter <2040> "Disintegration and Dissolution of Dietary Supplements".

(2) A capsule with a stated content of 100 micrograms or more of folic acid, that is not a soft capsule or a modified-release capsule, must comply with the dissolution requirements for folic acid of the United States Pharmacopeia-National Formulary, chapter <2040> "Disintegration and Dissolution of Dietary Supplements".

10 Listed tablet or capsule without an individual British Pharmacopoeia monograph

A listed good in the form of a tablet or capsule that is not the subject of an individual monograph of the British Pharmacopoeia must comply with the following:

(a) the requirements of Uniformity of Weight (Mass), Appendix XII C of the British Pharmacopoeia; and

(b) the estimated average content of each active ingredient or component in an active ingredient that is quantified on the label, in a pooled sample of not fewer than 20 tablets or capsules, must be not less than 90.0 per cent and not more than 120.0 per cent of the stated content of that active ingredient or component, except:

(i) where an active ingredient or a component in an active ingredient that is quantified on the label is included in a group included in Schedule 1 of this Order, the estimated average content in a pooled sample of not fewer than 20 tablets or capsules must comply with the limits specified in Schedule 1 for that group; or

(ii) other than where (i) applies, where a tablet or capsule contains an active ingredient of natural origin that comprises two or more components that are each quantified on the label, and the proportions of these components vary independently of each other, 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 amount; or

(iii) where the active ingredient is a multi-component ingredient and no quantitative claim is made on the label for any component; or

(iv) where an active ingredient is a homoeopathic preparation; and

(c) a suitable test for dissolution that demonstrates the appropriate release of each active ingredient in a modified-release tablet or capsule; and

(d) unless (c) applies, the requirements of the relevant test for disintegration (if any) of the British Pharmacopoeia, in the general monographs "Tablets" or "Capsules", respectively; and

(e) for a dispersible tablet, the test for fineness of dispersion of the British Pharmacopoeia, in the general monograph “Tablets”; and

(f) for a tablet or capsule containing folic acid, section 9 of this Order if relevant.

11 Registered tablet or capsule without an individual British Pharmacopoeia monograph

A registered good in the form of a tablet or capsule that is not the subject of an individual monograph of the British Pharmacopoeia must comply with the following:

(a) the test for Uniformity of Dosage Units of the British Pharmacopoeia, in the general monographs “Tablets” or “Capsules”, respectively; and

(b) the estimated average content of each active ingredient in a pooled sample of not fewer than 20 tablets or capsules must be not less than 92.5 per cent and not more than 107.5 per cent of the stated content of that active ingredient, except that:
  (i) for an active ingredient that is an antibiotic and where a microbiological method of assay is used in the test, the upper fiducial limit of error of the estimated content of active ingredient in each tablet or capsule (P = 0.95) is not less than 97.0 per cent of the stated content and the lower fiducial limit of error of the estimated content of active ingredient in each tablet or capsule (P = 0.95) is not more than 115.0 per cent of the stated content; and

(c) a suitable test for dissolution that demonstrates the appropriate release of each active ingredient, for each active ingredient for which the British Pharmacopoeia or the United States Pharmacopeia-National Formulary includes an individual monograph for a tablet or capsule and requires a test for dissolution, except that this test is not required for:
  (i) a chewable, effervescent or dispersible tablet; and
  (ii) the active ingredient folic acid, unless section 9 of this Order applies; and

(d) a tablet or capsule that is not required to comply with a dissolution requirement under paragraph (c) or section 9 of this Order must comply with the requirements of the relevant test for disintegration (if any) of the British Pharmacopoeia, in the general monographs “Tablets” or “Capsules”; and

(e) for a dispersible tablet, the test for fineness of dispersion of the British Pharmacopoeia, in the general monograph “Tablets”; and

(f) for a tablet or capsule containing folic acid, section 9 of this Order if relevant.

Schedule 1 Limits for content of each active ingredient or component in a listed good that is a tablet or capsule

Group	Not Less Than (per cent)	Not More Than (per cent)
Vitamin or provitamin:		
water soluble	90.0	150.0
oil soluble	90.0	165.0
betacarotene, panthenol, pantothenic acid, salt of pantothenic acid	90.0	175.0
Mineral or mineral compound:		
generally	90.0	125.0
when used as a source of chromium, fluorine, iodine, molybdenum or selenium	90.0	160.0
Enzyme	90.0	200.0
Probiotic	stated content	-