

## Therapeutic Goods Act 1989

**Therapeutic Goods Order No. 56**

**General standard for tablets, pills and capsules**

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**Therapeutic Goods Act 1989 Therapeutic Goods Order No. 56**

# General standard for tablets, pills and capsules

I, JOHN CABLE, delegate of the Minister for Health and Family Services for the purposes of the exercise of the Minister’s powers under section 10 of the *Therapeutic Goods Act 1989*, and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the said Act, by this Order:

1. DETERMINE that:
	1. tablets, pills and capsules to which this Order applies and that are the subject of an application lodged under section 23 of the Act on or after 1 January 1997 must comply with the requirements specified in this Order instead of Therapeutic Goods Order No. 35 (General Standard for Tablets and Pills) or Therapeutic Goods Order No. 36 (General Standard for Capsules);
	2. during the period from 1 January 1997 to 31 December 1998 (both dates inclusive), tablets, pills and capsules (other than tablets, pills and capsules that are the subject of an application under section 23 of the Act on or after 1 January 1997) to which this Order and Therapeutic Goods Order No. 35 (General Standard for Tablets and Pills) or Therapeutic Goods Order No. 36 (General Standard for Capsules), both of which were made on 12 July 1990 and published in the Gazette No. GN 36 dated 12 September 1990, apply, must comply either with the requirements of this Order or with the requirements of Therapeutic Goods Order No. 35 or Therapeutic Goods Order No. 36, as appropriate; and
	3. tablets, pills and capsules to which this Order applies and which are manufactured on or after 1 January 1999 must comply with the requirements of this Order; and
2. REVOKE Therapeutic Goods Order No. 35 and Therapeutic Goods Order No. 36 with effect from 1 January 1999.

## Application

1. This Order applies to all therapeutic goods, other than radiopharmaceuticals, which are in the form of tablets, pills or capsules intended for oral administration and are for human use.

## Interpretation

1. In this Order -

unless otherwise expressly indicated, the word “tablet” is to be read as including a reference to a “pill”.

“active ingredient” means a therapeutically active substance included in a tablet or capsule;

“British Pharmacopoeia” has the same meaning as in subsection 3(1) of the

*Therapeutic Goods Act 1989*;

“capsules” means solid preparations with hard or soft shells, of various shapes and capacities, usually containing a single dose of active ingredient and intended for oral administration;

“capsules which are not intended to be swallowed whole” means capsules, the labelling of which includes a direction to ingest the contents of the capsules by a means other than swallowing the capsules whole;

“coated tablets” means tablets, where the coating materials constitute greater than ten (10) per cent of the mass of the tablets and consist of one or more layers of mixtures of various substances such as natural or synthetic resins, polymers, gums, inactive and insoluble fillers, sugars, plasticisers, polyols, waxes, colouring agents and sometimes flavouring substances and active ingredients;

“chewable”, in relation to tablets or capsules, means tablets or capsules which have been formulated to be chewed rather than swallowed whole and for which the label includes a direction to chew the tablet or capsule;

“colouring agent” means a substance included in a tablet or capsule for the sole purpose of imparting colour;

“dispersible tablets” means uncoated tablets that produce a uniform dispersion in water;

“enteric capsules” means hard or soft shelled capsules prepared in such a manner that the capsule shell and/or the contents of the capsule resist the action of the gastric fluid but are attacked by the intestinal fluid to release the contents of the capsule or the active ingredients from the contents of the capsules;

“enteric coated tablets” means tablets where the coating materials consist of one or more layers of coating intended to resist the gastric fluid but permit

disintegration in the intestinal fluid;

“film-coated tablets” means tablets with a thin coating that constitutes less than or equal to ten (10) per cent of the mass of the tablets;

“for use in the mouth”, in relation to tablets or capsules, means tablets or capsules that are formulated to produce a slow release or local action of the active ingredient under the tongue or in other parts of the mouth;

“general requirements for precision”, in relation to the microbiological assay of antibiotics, means that the precision of the assay is such that the fiducial limits of error (P=0.95) are not less than 95 per cent and not more than 105 per cent of

the estimated potency;

“modified release”, in relation to tablets, means tablets, with or without a coating, that:

* 1. contain special auxilairy substances; or
	2. are prepared by special procedures;

that are designed to modify the rate or place at which the active ingredient is released;

“modified release”, in relation to capsules, means capsules that:

1. may contain special auxiliary substances within the capsule shell or within the contents of the capsule; or
2. are prepared by special procedures;

that are designed to modify the rate or place at which the active ingredient is released;

“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;

“Poisons Standard” has the same meaning as in regulation 2 of the Therapeutic Goods Regulations;

“soluble tablets” means uncoated tablets that dissolve in water. The solution may be slightly opalescent due to added substances used in the manufacture of the

tablets;

“stated content”, in relation to tablets or capsules, means the quantity of the active ingredient that is stated on the label to be present in the tablets or capsules;

“tablets” means solid preparations intended for oral administration each containing a single dose of one or more active ingredients and obtained by compressing uniform volumes of particles;

“uncoated”, in relation to tablets, means tablets including single layer dosage forms resulting from a single compression of particles and multi-layer dosage forms consisting of concentric or parallel layers obtained by successive compression of particles of different composition, where the substances used are not specifically intended to modify the release of the active ingredient in the digestive fluids; and

“United States Pharmacopoeia” means the current edition of the book of that name, published by authority of the United States Pharmacopoeial Convention Incorporated, or, if that edition has been added to or amended by one or more Supplements, that edition as affected by such Supplements published as at the date of commencement of this Order.

## Colouring agents

1. If tablets or capsules contain a colouring agent, it shall be a colouring included in the list of Colorings for Use in Pharmaceuticals for Ingestion recommended and adopted by the National Health and Medical Research Council in November 1986.

## Content of active ingredient

1. (1) Where therapeutic goods in the form of tablets or capsules are the subject of a specific monograph of the British Pharmacopoeia, the tablets, or capsules shall be deemed to comply with the standard for content of active ingredient, if the estimated content of active ingredient in each tablet or capsule is within the limits specified in the monograph.
2. Where therapeutic goods in the form of tablets or capsules are not the subject of a specific monograph of the British Pharmacopoeia, the tablets or capsules shall be deemed to comply with the standard for content of active ingredient, when determined in accordance with the test for content of active ingredient in each tablet or capsule specified in clause 10, where -
	1. the estimated content of active ingredient in each tablet or capsule is not less than 92.5 per cent and not more than 107.5 per cent of the stated content; or
	2. if the active ingredient is an antibiotic and 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; or

* 1. if the active ingredient is an antibiotic and a microbiological assay is not used, the estimated content of active ingredient in each tablet or capsule is not less than 92.5 per cent and not more than 110.0 per cent of the stated content; or
	2. if the active ingredient is included in the [First Schedule](#_bookmark13) to this Order and the tablets or capsules contain one or more other active ingredient in the [First Schedule,](#_bookmark13) the estimated content of each active ingredient in the tablets or capsules is not less than the percentage of the stated content specified in the second column of the [First](#_bookmark13) [Schedule](#_bookmark13) and not more than the percentage specified in the third column of the [First Schedule](#_bookmark13) in relation to that active ingredient.
1. Where the tablets or capsules contain homoeopathic preparation or herbal ingredients, the standard for content of active ingredient does not apply to these preparations or ingredients.

## Uniformity or weight

1. All tablets and capsules shall be deemed to comply with the standard for uniformity of weight, if they comply with the requirements for uniformity of weight specified in the general monograph for Tablets or in the general monograph for Capsules, respectively, of the British Pharmacopoeia.

## Uniformity of content

1. Except in the circumstances described in paragraphs (a) to (c) inclusive in this clause, tablets and capsules shall be deemed to comply with the standard for uniformity of content, if they comply with the requirements for uniformity of content specified in the general monograph for Tablets or in the general monograph for Capsules, respectively, of the British Pharmacopoeia.

Where:

* 1. the active ingredient is present in a homoeopathic dose; or
	2. the active ingredient is a herbal substance not included in a Schedule of the Poisons Standard; or
	3. the active ingredient is included in a multivitamin tablet or capsule or in a multivitamin and mineral tablet or capsule;

then the standard for uniformity of content does not apply.

## Disintegration

1. Tablets and capsules shall be deemed to comply with the standard for disintegration if, subject to paragraphs (a) to (e) inclusive in this clause, they comply with the relevant requirements for maximum disintegration time specified in the general monograph for Tablets or in the general monograph for Capsules, respectively, of the British Pharmacopoeia.

Where:

* 1. the tablets or capsules are the subject of a specific monograph of the British Pharmacopoeia, which specifies a different maximum disintegration time then that requirement shall apply; or
	2. the tablets or capsules are the subject of a specific monograph of the British Pharmacopoeia, which specifies that the requirement for Disintegration does not apply to these tablets or capsules, then no requirement for disintegration shall apply; or
	3. tablets contain one or more herbal active ingredients or contain one or more herbal active ingredients and one or more active ingredients which are nutritional supplements, then the maximum disintegration time for the tablets, using the Disintegration Test for Tablets and Capsules of the British Pharmacopoeia, shall be:
		1. for uncoated tablets - 30 minutes
		2. for film-coated tablets - 30 minutes;
		3. for coated tablets - 60 minutes;
	4. the tablets are soluble tablets that are not the subject of a specific monograph of the British Pharmacopoeia or are dispersible tablets that are not the subject of a specific monograph of the British Pharmacopoeia, then the maximum disintegration time shall be three minutes when tested by the Disintegration Test for Tablets and Capsules of the British Pharmacopoeia, using water at 19°C to 21°C without discs in the baskets; or
	5. the tablets or capsules are required to comply with the standard for dissolution or they are chewable, or for use in the mouth or are for modified release, then the test for disintegration can be omitted.

## Uniformity of dispersion

1. Where tablets are dispersible tablets that are not the subject of a specific monograph of the British Pharmacopoeia, the tablets shall be deemed to comply with the standard for uniformity of dispersion, if, when two tablets are placed in 100 mL of water and stirred completely dispersed, a smooth dispersion is

produced, which passes through a sieve with a normal mesh aperture of 710 micrometres.

## Dissolution

1. When tested as specified in clause 14 of this Order, tablets or capsules that contain an active ingredient included in the [Second Schedule](#_bookmark14) to this Order shall comply with the relevant dissolution requirements of the United States Pharmacopoeia, except where the active ingredient is included in tablets or capsules which are the subject of a dissolution requirement of the British Pharmacopoeia, in which case the tablets or capsules shall comply with the relevant dissolution requirement of the British Pharmacopoeia.

## Test for content of active ingredient

1. (1) Unless the tablets or capsules are the subject of a specific monograph of the British Pharmacopoeia, or unless the active ingredient is an antibiotic with a prescribed microbiological method or assay, the test for content of active ingredient shall be carried out by -
	1. for tablets, determining the weight, W, of 20 tablets, or, for capsules, pooling the contents of 20 capsules and determining the weight, W, of the pooled contents; and
	2. for tablets, pulverising the 20 tablets and thoroughly mixing the resulting powder, or, for capsules, mixing the pooled contents thoroughly; and
	3. determining the quantity, Q, of the active ingredient in a suitable portion of weight, w, of the mixed powder or pooled contents, using a method of assay acceptable to the Secretary; and
	4. calculating the determined quantity, E, of the active ingredient in each tablet or capsule, where -

E= QW/20w

and

* 1. calculating the determined percentage, P, of the stated content, L, of the active ingredient in the tablets or capsules, where -

P=100E/L

1. Where the active ingredient is an antibiotic with a prescribed microbiological method of assay and the tablet or capsule is not the subject of a specific monograph of the British Pharmacopoeia, the test for content of active ingredient shall be carried out in the sequence as specified in paragraphs (1)(a) and (1)(b) and then by -
	1. determining the quantity, Q, of active ingredient in a suitable portion of the pulverised tablets or of the pooled contents of the capsules, of weigh, w, using the potency estimate from only those statistically valid assay results which also meet the general requirements for precision of antibiotic assays; and
	2. repeating the calculation to obtain, respectively, the values QU and QL corresponding to the upper and lower fiducial limits of error of the estimated quantity, Q; and
	3. using, in turn, the values Q, QU and QL, calculating the corresponding determined quantities, E, EU and EL, of the active ingredient per average tablet or capsule and then expressing the result as a percentage, P, PU and PL, of the stated content, L, as follows -

E = QW/20w

and

P = 100E/L

where E is expressed in micrograms per milligram or Units per milligram and L is expressed in milligrams or Units; and similarly

EU,L = QU,L W/20w

and

PU,L = 100EU,L/L

and

* 1. determining whether the estimates, PU and PL, meet the requirements specified in paragraph 4(2)(b).

## Test for uniformity of weight

1. The test for uniformity of weight for tablets and capsules shall be carried out as specified in the British Pharmacopoeia.

## Test for uniformity of content

1. Where required, the test for uniformity of content for tablets and capsules shall be carried out as specified in the British Pharmacopoeia.

## Test for disintegration

1. The test for disintegration for tablets and capsules shall be carried out as specified in the British Pharmacopoeia.

## Test for dissolution

1. The test for dissolution for tablets and capsules shall be carried out -
	1. where the tablets or capsules are the subject of a dissolution requirement in the British Pharmacopoeia, by using the apparatus and test method described in the British Pharmacopoeia; or
	2. in any other case, where the tablets or capsules contain an active ingredient included in the [Second Schedule](#_bookmark14) to this Order, by following the recommendations contained in “D5. Guidelines for Dissolution Testing” in Appendix D “Guidelines for Laboratory Instrumentation” (dated November 1991) of the “Australian Code of Good Manufacturing Practice for Therapeutic Goods - Medicinal Products”, published by the Therapeutic Goods Administration.

## Packaging requirements

1. Tablets and capsules shall be packaged in a manner which affords protection of the tablets or capsules against breakage or crushing, access of moisture, contamination and deterioration due to air and light.

Dated this nineteenth day of September 1996

JOHN CABLE

Director

Conformity Assessment Branch Therapeutic Goods Administration

(Delegate of the Minister for Health and Family Services)

## FIRST SCHEDULE

**Content limits for vitamins in multivitamin or multivitamin and mineral tablets and capsules**

**Vitamin Not Less Than Not More Than**

|  |  |  |
| --- | --- | --- |
|  | **(per cent)** | **(per cent)** |
| Thiamine hydrochloride | 85 | 150 |
| Thiamine nitrate | 85 | 150 |
| Riboflavine | 85 | 150 |
| Riboflavine sodium phosphate | 85 | 150 |
| Nicotinamide | 85 | 150 |
| Nicotinamide ascorbate | 85 | 150 |
| Nicotinic acid | 85 | 150 |
| Pyridoxine hydrochloride | 85 | 150 |
| Ascorbic acid | 85 | 150 |
| Sodium ascorbate | 85 | 150 |
| Calcium ascorbate | 85 | 150 |
| Magnesium ascorbate | 85 | 150 |
| d-alpha-Tocopherol | 85 | 150 |
| dl-alpha-Tocopherol | 85 | 150 |
| d-alpha-Tocopheryl acetate | 85 | 150 |
| dl-alpha-Tocopheryl acetate | 85 | 150 |
| d-alpha-Tocopheryl acid succinate | 85 | 150 |
| dl-alpha-Tocopheryl acid succinate | 85 | 150 |
| Phytomenadione | 85 | 150 |
| Menadione | 85 | 150 |
| Acetomenaphthone | 85 | 150 |
| Cyanocobalamin | 85 | 150 |
| Biotin | 85 | 150 |
| Panthenol | 85 | 150 |

Ergocalciferol

25 micrograms (1000 I.U.) or less per dosage unit

Ergocalciferol

More than 25 micrograms (1000 I.U.) per dosage unit

Cholecalciferol

25 micrograms (1000 I.U.) or less per dosage unit

85 150

85 115

85 150

|  |  |  |
| --- | --- | --- |
| Cholecalciferol | 85 | 115 |
| More than 25 micrograms (1000 I.U.) per dosage unitVitamine A (synthetic or derived from natural sources) | 85 | 165 |

5000 I.U. or less per dosage unit

Vitamine A (synthetic or derived from natural sources) More than 5000 I.U. per dosage unit

Retinyl acetate

5000 I.U. or less per dosage unit

Retinyl acetate

More than 5000 I.U. per dosage unit

Retinyl palmitate

5000 I.U. or less per dosage unit

Retinyl palmitate

More than 5000 I.U. per dosage unit

Folic Acid

500 micrograms or less per dosage unit

Folic Acid

More than 500 micrograms per dosage unit

85 115

85 165

85 115

85 165

85 115

85 125

85 115

|  |  |  |
| --- | --- | --- |
| Betacarotene | 85 | 180 |
| Pantothenic Acid | 85 | 175 |
| Sodium Pantothenate | 85 | 175 |
| Calcium Pantothenate | 85 | 175 |

## SECOND SCHEDULE

Acetazolamide

* Acetohexamide Allopurinol Aminophylline Aminosalicylic Acid Amoxycillin Trihydrate Ampicillin Amylobarbitone Azathioprine Bendrofluazide

Betamethasone Biperiden Hydrochloride Bromocriptine Mesylate Carbamazepine Carbarsone

Carbidopa

* Chloramphenicol Chlordiazepoxide Chlordiazepoxide Hydrochloride
* Chloroquine Phosphate
* Chloroquine Sulphate Chlorothiazide Chlorpromazine Hydrochloride
* Chlorpropamide Chlorprothixene
* Chlortetracycline Hydrochloride Chlorthalidone

Chlorzoxazone Clomiphene Citrate Clonazepam

Clonidine Hydrochloride Cortisone Acetate Cyclopenthiazide Cyproheptadine Hydrochloride Danazol

* Dapsone Dexamethasone

Dextropropoxyphene Hydrochloride Dextropropoxyphene Napsylate Diazepam

Dichlorphenamide Dicoumarol Diethylcarbamazine Citrate Diflunisal

Digitoxin

* Digoxin Dipyridamole

Dydrogesterone

* Ergotamine Tartrate Erythromycin

Erythromycin Ethylsuccinate Erythromycin Stearate Ethacrynic Acid

Ethambutol Hydrochloride Ethinamate

Ethopropazine Hydrochloride Ethosuximide

Fenoprofen Calcium Flucytosine Fludrocortisone Acetate Fluoxymesterone

Fluphenazine Hydrochloride Frusemide

Glutethimide

Griseofulvin - Ultramicrosize Guanethidine Monosulphate Haloperidol

Hetacillin

Hetacillin Potassium Hexobarbitone Hydrochlorothiazide Hydroxyzine Hydrochloride Hydroxyzine Embonate Ibuprofen

Imipramine Hydrochloride Indomethacin Isocarboxazid

* Isoniazid Isosorbide Dinitrate

Isoxsuprine Hydrochloride Levodopa Levpropoxyphene Napsylate Lithium Carbonate Meclozine Hydrochloride

Medroxyprogesterone Acetate Megestrol Acetate

* Metformin Hydrochloride Methaqualone Hydrochloride Metharbitone

Methotrexate Methsuximide Methylclothiazide

* Methylprednisolone Methyltestosterone
* Methysergide Maleate Minoxidil

Nalidixic Acid Naproxen

Nitrofurantoin Norethisterone Acetate Oxazepam

Oxycodon Hydrochloride Oxyphenbutazone

* Oxytetracycline Hydrochloride Pargyline Hydrochloride Penicillamine

Perphenazine Phenacemide Phenindione Phenobarbitone

* Phenoxymethylpenicillin Potassium Phenprocoumon

Phensuximide

* Phenylbutazone Phenytoin Sodium Polythiazide
* Prednisolone
* Prednisone Primidone Probenecid

Procainamide Hydrochloride Procarbazine Hydrochloride Pyomethazine Hydrochloride Pyrimethamine

* Quinidine Bisulphate
* Quinine Sulphate Reserpine Secbutobarbitone Sodium Spironolactone Stanozolol

Sulfamerazine Sulindac Sulphadiazine Sulphamethoxazole Sulphapyridine Sulphasalazine Sulphinpyrazone Tamoxifen Citrate

* Tetracycline Hydrochloride Theophylline Thiabendazole Thioguanine

Thiothixene Timolol Maleate Tolazamide

* Tolbutamide Tranylcypromine Sulphate Triamcinolone Trichlormethiazide

Triflupromazine Hyrdochloride Trimeprazine Tartrate Trimethoprim

Trioxysalen Trisulfapyrimidines

* Warfarin Sodium

*\* Active ingredients marked with an asterisk are the subject of a dissolution requirement of the British Pharmacopoeia.*

## Supplementary notes to the general standard for tablets, pills and capsules

1. This standard applies to all therapeutic goods that are tablets, pills or capsules intended for ingestion by humans, other than radiopharmaceuticals. Homoeopathic or herbal tablets, pills or capsules are only required to comply with the requirements for uniformity of weight and disintegration.
2. The main purpose of the standard is to provide a set of specifications with which the product must comply throughout its claimed shelf life. To ensure compliance with the standard, a prudent manufacturer will apply release specifications that are more exacting than those included in the standard.
3. The standard also specifies the testing procedures that will be used by an official testing laboratory to assess the quality of any sample from any batch of a product.
4. The requirement to carry out the tests and methodology as specified in this standard is only obligatory where a manufacturer may wish to contest the test results of the official testing laboratory. Manufacturers should be aware that products of acceptable quality can be produced by following in-house, in-process controls and ensuring compliance with the Code of Good Manufacturing Practice.
5. Under section 14 of the *Therapeutic Goods Act 1989,* therapeutic goods imported into Australia, supplied in Australia or exported from Australia are required to comply with a standard applicable to the goods. However, a mechanism exists under this section of the Act for the Secretary of the Department to give his/her consent to an exemption from a standard or a particular aspect of a standard, if the manufacturer can provide adequate justification for the exemption.
6. In the absence of an official pharmacopoeial method, assay methods acceptable to the Secretary of the Department are those which have been approved by the Department as being of adequate selectivity to assure product quality for the parameter being assessed.
7. Dissolution testing of tablets and capsules provides a means of monitoring possible changes in drug release rate between samples of the same batch and also between batches which may in turn give rise to varying bioavailability of the drug. Causes of changes in drug release rate can include variations in the formulation or in the manufacturing process.

The criteria adopted in deciding which active ingredients should be included in the Second Schedule to the Order were -

* + where there is a dissolution requirement in a specific monograph of the British Pharmacopoeia;
	+ where the active ingredient has a solubility of less than 1 per cent in water at 25°C;
	+ where there is a documented low therapeutic index;
	+ where there are documented or potential bioavailability problems; or
	+ where the product is a modified release tablet or capsule (refer Supplementary Note No.9 below).
1. Some manufacturers may prefer to specify a dissolution requirement rather than a disintegration requirement for a product. This is permissible if the dissolution test has been authorised during the product registration process.
2. "Modified release" is an expression used to describe those tablets and capsules the labelling of which includes the words "prolonged release", "sustained release", "extended release", "delayed release", "time release" or any other words that indicate that the release of the active ingredient is intended to be delayed,

intermittent or prolonged.

The reasons for including a dissolution requirement for modified release tablets or capsules are to assure batch to batch uniformity, dose to dose repeatability and absence of "dose dumping" over the extended time claimed on the label and to confirm that the product demonstrates modified release of the active ingredient from the tablet or capsule matrix.

Dissolution specifications for modified release tablets are not intended to be used to distinguish between products or to categorise expected performance.

New modified release formulations of existing drug products are regarded by the Department as new drugs requiring evidence of safety and efficacy.