Guidance on
Therapeutic Goods Order No. 78

General Requirements for Tablets and Capsules

DRAFT

January 2008
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This guidance document is intended to provide a plain English explanation of various requirements of Therapeutic Goods Order (TGO) No. 78 General Requirements for Tablets and Capsules (TGO 78) and their application, thereby assisting sponsors to achieve compliance. This document does not form part of the Order.

General

The requirements of the Order apply to a medicine that comes within the operation of Part 3-1 of the Therapeutic Goods Act 1989 (“the Act”), which provides for the application of standards to therapeutic goods.

Such standards may relate to any matter relevant to the quality, safety or efficacy of a medicine and, generally, a medicine must not be imported, exported or supplied if it does not conform to an applicable standard.

Paragraph (b) of subsection 10(2) of the Act states that an Order establishing a standard for therapeutic goods may require that a matter relating to the standard be determined in accordance with a particular test.

Responsibility for compliance with the requirements of the Order rests with the sponsor of the medicine to which the Order applies.

Explanation of sections

Section 1 Name of Order

This section states the legal title of the Order.

Section 2 Commencement

This section states when the Order will commence to have effect.

This is on the day following the day on which the Order is registered on the Federal Register of Legislative Instruments (FRLI - http://www.frli.gov.au), which is the official repository of Commonwealth legislative instruments.

Following commencement of the Order, a transition period for products to achieve compliance will be allowed. Transition arrangements are given in the following section.
Section 3  Transition arrangements

This section provides the date by which medicines must comply with TGO 78. This date is 1 July 2010.

Until 1 July 2010, sponsors have the choice of complying with either TGO 78, or its predecessor – Therapeutic Goods Order No. 56 – General requirements for tablets, pills and capsules (TGO 56).

The same transition timeframe applies to both existing products and new products.

Sponsors should consult the guidelines for prescription medicines, over-the-counter (OTC) medicines, registered complementary medicines and listed complementary medicines for information about making quality changes that are consequent upon requirements of a new Therapeutic Goods Order.

Stock that is under the control of the sponsor on and after 1 July 2010 will be subject to this Order. Stock that has been supplied to warehouses, retailers and consumers prior to 1 July 2010 in accordance with TGO 56 will not be subject to this Order.

Section 4  Introduction

This section states the purpose of the Order.

Standards, including this Order, apply throughout the shelf life of the medicine.

To ensure compliance with this standard, a prudent manufacturer will apply release specifications that are more exacting than those included in the Order.

Section 5  Interpretation

This section provides definitions of terms used in the Order and, where relevant, directs the reader to meanings given in the Act or Regulations. Readers should check the current compilation of the Act or Regulations.

The British Pharmacopoeia (BP) is defined in the Act, as is the process for the adoption of new editions, additions or amendments. When the definition of the British Pharmacopoeia is amended under subsection 3(1) of the Act the new definition will apply in this Order.

The definition of the United States Pharmacopoeia-National Formulary (USP) will be updated periodically.

Section 6  Application

This section describes which medicines are subject to the Order. The Order applies to tablets and capsules intended for oral administration for human use that come within the operation of the Act.

The Order applies to listed medicines, registered medicines, and medicines that are not required to be listed or registered, unless exempt from the Order.
There are two mechanisms for a medicine to be exempt from the Order:

1. if the medicine is mentioned in Section 7 (see below); or
2. if the sponsor seeks an exemption from the Secretary of the Department of Health and Ageing or her delegate. The Secretary may grant permission for the supply, import or export of a medicine to occur although that medicine does not conform to this Order or parts of this Order in accordance with sections 14 and 14A of the Act. Where an exemption is granted it may be in respect of one batch or all batches of the medicine. A request for an exemption should explain why the standard cannot be met and detail what alternative quality control measure is proposed and why.

**Section 7  General exemptions**

This section describes the medicines that are not subject to the Order.

The standard that applies to an export-only medicine is currently specified in Therapeutic Goods Order No. 70B – *Standard for export only medicine*.

**Section 8  Tablet or capsule with an individual British Pharmacopoeia monograph**

This section specifies that a tablet or capsule that is the subject of an individual monograph in the British Pharmacopoeia (BP) must comply with that monograph.

There are some departures from strict and exclusive compliance with the BP monograph:

- For a listed tablet or capsule, compliance with the Uniformity of Dosage Units requirements in an individual BP monograph is replaced with compliance with the BP’s requirements for uniformity of weight.
- For a registered tablet or capsule, when an individual BP monograph does not include a dissolution test, but a United States Pharmacopoeia (31st edition) monograph for the same active ingredient in a tablet or capsule does require a dissolution test, then the tablet or capsule must meet a dissolution requirement.
- A tablet or capsule containing folic acid must comply with Section 9.

**Section 9  Tablet or capsule containing folic acid**

This section requires tablets (other than chewable, effervescent, dispersible and modified release tablets) and capsules (other than soft gelatine or modified release capsules) that contain 100 micrograms or more of folic acid to demonstrate dissolution of folic acid.

### Section 10  Listed tablet or capsules without an individual British Pharmacopoeia monograph

This section specifies the requirements for a listed tablet or capsule that is not the subject of an individual British Pharmacopoeia (BP) monograph.

Paragraph (a) requires that the tablet or capsule complies with the BP’s requirements for uniformity of weight.

Paragraph (b) sets out the requirements regarding the content of each active ingredient. The requirement is that the estimated average content is in the range 90.0 – 120.0% of the stated content (label claim) for each active ingredient. However, there are exceptions from this requirement:

- Subparagraph (i) applies to an active ingredient (eg, betacarotene) or a component in an active ingredient (eg, iodine in *Fucus vesiculosus*) included in a group mentioned in Schedule 1. Instead of the 90-120% limits, the limits in Schedule 1 apply.
- Subparagraph (ii) applies to the components in a multicomponent active ingredient of natural origin when the proportions of these components vary independently of each other. There must be a minimum of 90% of the stated content (label claim) of each component. If some components are included in Schedule 1, then the Schedule 1 limits apply to those components. For example, a natural fish oil capsule would be required to contain a minimum of 90% of the label claim of each of Eicosapentaenoic acid and Docosahexaenoic acid and 90-165% of the label claims of Vitamin A and Cholecalciferol.
- Subparagraph (iii) applies to multicomponent ingredient for which no quantitative claim is made for any component. For such an active ingredient (eg, a non-standardised herbal extract) there are no quantitative limits for the content of any component of the active ingredient. Sponsors should refer to the TGA document *Guidance on the use of the term ‘Quantified By Input’ for Complementary Medicines* for further information.
- Subparagraph (iv) applies no quantitative limits for the content of a homoeopathic active ingredient.

Paragraph (c) requires that a modified release tablet or capsule complies with a suitable dissolution test.

Paragraph (d) requires that, when a dissolution test is not required, the tablet or capsule complies with the BP’s requirements for disintegration.

Paragraph (e) requires that a dispersible tablet complies with the BP’s requirement for fineness of dispersion.

Paragraph (f) requires that a tablet or capsule containing folic acid may need to comply with section 9.

### Section 11  Registered tablet or capsule without an individual British Pharmacopoeia monograph

This section specifies the requirements for a registered tablet or capsule that is not the subject of an individual British Pharmacopoeia (BP) monograph.
Paragraph (a) requires that the tablet or capsule complies with the BP’s requirements for uniformity of dosage units.

Paragraph (b) sets out the requirements regarding the content of each active ingredient. The requirement is that the estimated average content is in the range 92.5 – 107.5% of the stated content for each active ingredient. However, there is an exception from this:

Subparagraph (i) applies different limits for an antibiotic active ingredient that is assayed by a microbiological method. Supplementary Chapter I L. Microbiological Assay of Antibiotics in the BP provides relevant details.

Paragraph (c) specifies which tablet or capsule must comply with a dissolution test. A tablet or capsule for which there is an individual monograph for a tablet or capsule containing that active ingredient in either the BP or the USP that includes a dissolution test must show compliance with a dissolution test. However, a chewable, effervescent or dispersible tablet is not required to demonstrate compliance with a dissolution test.

Paragraph (d) requires that, when a dissolution test is not required, the tablet or capsule complies with the BP’s requirements for disintegration.

Paragraph (e) requires that a dispersible tablet complies with the BP’s requirement for fineness of dispersion.

Paragraph (f) requires that a tablet or capsule containing folic acid may need to comply with section 9.

**Schedule 1  Limits for content of active component(s) or ingredient(s) in a listed good that is a tablet or capsule**

This Schedule specifies the limits to the content that apply to a listed tablet or capsule when there is no individual BP monograph. The limits apply to components and active ingredients, in single ingredient and multi-ingredient tablets or capsules.


Examples of provitamins are betacarotene, choline bitartrate and palm tocotrienols complex.

Examples of enzymes are bromelains and papain.

**Questions and answers relating to general requirements for tablets and capsules**

1. **Why is this Order necessary now?**

Therapeutic Goods Order No. 78 – General Requirements for Tablets and Capsules (TGO 78) will replace Therapeutic Goods Order No. 56 General standard for tablets, pills and capsules (TGO 56). TGO56 came into effect in 1996. Industry experience and progress on pharmacopoeial harmonisation have contributed to the changes introduced in TGO 78. This Order also applies different requirements regarding dissolution, disintegration and uniformity.
to listed (lower risk) and registered (higher risk) medicines. This reflects the risk-based regulatory model of the TGA.

The draft Order has been proposed following the advice of the Therapeutic Goods Committee, which includes representatives of the manufacturers of prescription medicines, non-prescription medicines and complementary medicines, and consumers.

2. **If this new Order will replace TGO 56, why is there no mention of “pills”?**

Pills are generally used in traditional Chinese medicines and in homoeopathic medicines. The application of the Order to these types of medicines is inappropriate.

3. **If this new Order will replace TGO 56, where do I now find information on controls on colouring agents?**

A guideline on colourings permitted in medicines for oral use was published by the TGA in 2004; see *Colourings permitted in medicines for oral use*.

4. **Is compliance with this Order all I have to demonstrate to gain product approval?**

No. This Order defines the general requirements for tablets and capsules. It does not anticipate every quality attribute for every medicine. For example, the shelf-life for a tablet may be controlled by the level of degradation products (which is not controlled by this Order) rather than by the loss of content of the active ingredient (a parameter which is controlled by this Order). Another example would be requirements for the uniformity of weight or content for halves of tablets, when subdivision of a tablet is required by the directions for use for a registered medicine.

5. **Export - only tablets and capsules are subject to TGO 56 but not this revised Order. What standard applies to export-only tablets and capsules during the transition period?**

Export-only tablets and capsules will continue to be subject to both *Therapeutic Goods Order No. 70B Standards for export only medicine* (TGO 70B) and *Therapeutic Goods Order No. 56 General standard for tablets, pills and capsules* (TGO 56) until TGO56 is revoked. Following that date, TGO 70B only will apply.

6. **Does a medicine have to comply with the British Pharmacopoeia (BP) statements about labelling, packaging, storage and microbial limits?**

Medicines need to comply with the Therapeutic Goods Orders (TGOs) on labelling, child-resistant packaging and, when approved, microbiological standards.

7. **Manufacture of this tablet will occur in the UK. There is no individual BP monograph for this tablet. Is compliance with the BP general monograph for Tablets sufficient?**

No. If there is no individual monograph in the BP, the tablet must comply with the requirements shown under the section “Listed [or Registered] tablet or capsule without an individual British Pharmacopoeia monograph”.

*Guidance on Therapeutic Goods Order No.78 – General Requirements for Tablets and Capsules*

Consultation Draft – January 2008
8. Can we use our in-house assay method for the active ingredient, as our method is easier to perform than the BP method?

The BP method is only obligatory where a sponsor wishes to contest the test results obtained by the TGA. The Order does not prevent the use of in-house methods for routine quality control purposes. For a registered medicine, the TGA will evaluate the in-house method before the medicine is approved.

9. Why are there special requirements in this Order for tablets and capsules containing folic acid?

Folic acid taken by the prospective mother daily for one month before conception and during early pregnancy may reduce the risk of a baby having spina bifida/neural tube defects. In 2001 the Complementary Medicines Evaluation Committee (CMEC) recommended that there should be a legal requirement for tablets containing 100 micrograms or more of folic acid to comply with a dissolution standard. This recommendation was in response to a public health concern to ensure the effectiveness of folic acid supplements.

The requirement for tablets containing folic acid to comply with a dissolution specification was introduced in late 2003. This requirement is now included in this Order. The Order also extends the requirement to capsules that contain 100 micrograms or more of folic acid.

10. The use of USP Calibrator tablets adds expense to the dissolution testing for folic acid. Is this necessary?

See Q 8.

11. Is dissolution testing required for any listed tablet or capsule?

Compliance with a dissolution specification will be required for:
- A tablet or capsule that is the subject of an individual BP monograph that includes a dissolution test.
- A modified release tablet or capsule.
- A tablet or capsule that contains 100 micrograms or more of folic acid.

All other listed tablets and capsules must comply with a disintegration requirement.

12. The limits in Schedule 1 for the contents of active components or ingredients in listed tablets and capsules are different to those included in TGO 56. Why?

The Order nominates a range of limits for the content of active components or ingredients in listed tablets and capsules, depending on the nature and stability of the active component or ingredient. The Order seeks to harmonise requirements with international standards where possible. The rationales for the proposed lower and upper limits are included in Schedule 1 at the consultation stage. This information will not be included in the final Order.

The limits for vitamins and minerals in Schedule 1 are largely consistent with the limits specified in the United States Pharmacopoeia – National Formulary for dietary supplements. The experience of Australian manufacturers supports the use of the proposed limits for betacarotene, panthenol and pantothenate salts.

There are no general standards in the British Pharmacopoeia, or United States Pharmacopoeia – National Formulary, for the content of probiotics and enzymes as active ingredients.
13. Do the limits in Schedule 1 include overages?

Yes. The limits stated in Schedule 1, and elsewhere in the Order, are designed to accommodate normal analytical and manufacturing variations and to allow for recognised deterioration of active ingredients. No further tolerances are to be applied to the limits given in the Order, including situations where manufacturing overages are employed.

14. Why has the Uniformity of Dosage Units requirement been introduced, and which registered medicines have to comply with this requirement?

The test for Uniformity of Dosage Units has become an international standard. The harmonised test for Uniformity of Dosage Units has been official in the European Pharmacopoeia since July 2005, the British Pharmacopoeia (BP) since December 2005, the Japanese Pharmacopoeia since April 2006, and the United States Pharmacopoeia since January 2007.

The general monographs for Tablets and Capsules in the BP allow for the Uniformity of Content and/or Uniformity of Weight tests to replace the requirements of the Uniformity of Dosage Units test where justified and authorised.

Tablets and capsules registered by the TGA prior to the revocation of TGO 56 will be considered to have justified the continuing use of Uniformity of Content and/or Uniformity of Weight tests. This is consistent with the approach now in place in Europe.

However, sponsors should be aware that the European Pharmacopoeia has recently proposed that all tablets and capsules (including ones already approved for supply) will be required to comply with the Uniformity of Dosage Units requirements after 2013. It may be prudent for sponsors to take this into account when reviewing product specifications.

15. Which registered tablets must comply with a dissolution specification?

If there is a dissolution test in the individual British Pharmacopoeia (BP) monograph, then the tablet must comply with that dissolution test.

If there is no dissolution test in the individual BP monograph, but there is a dissolution test in a United States Pharmacopoeia (USP) monograph for a tablet or capsule containing that active ingredient, then the tablet must comply with a dissolution test.

If there is no individual BP monograph, a tablet must comply with a dissolution test if either the BP or the USP require a dissolution test for a tablet or capsule containing that active ingredient.

16. Which dissolution test is required for a tablet that is not the subject of an individual BP monograph?

In the absence of a specific method and assessment criteria in the BP, methods and criteria acceptable to the Minister for Health and Ageing are those that have been validated to assure product quality for the parameter being assessed. The TGA would need to be satisfied that the test method and limits selected are a suitable quality measure for the performance of the tablet in vivo. Compliance with the agreed test method and limits may be imposed as a Condition of Registration by the TGA.
## Summary of main differences between TGO 56 and draft TGO 78

<table>
<thead>
<tr>
<th>ATTRIBUTE</th>
<th>DRAFT TGO 78</th>
<th>TGO 56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transition arrangements</td>
<td>Approximately two years</td>
<td>Two years</td>
</tr>
<tr>
<td>Introduction</td>
<td>As required</td>
<td>Not included</td>
</tr>
<tr>
<td>Application / Exemptions</td>
<td>All tablets and capsules for oral human use, other than radiopharmaceuticals, export-only products, or personally imported medicine, unless given an exemption</td>
<td>All therapeutic goods, other than radiopharmaceuticals, which are tablets, capsules or pill for oral human use.</td>
</tr>
<tr>
<td>Colouring agents</td>
<td>Not included (Note: see TGA’s “Colourings permitted in medicines for oral use” published in 2004)</td>
<td>According to named NHMRC publication of 1986</td>
</tr>
<tr>
<td>Content of active ingredients</td>
<td>1. Comply with BP individual monograph</td>
<td>1. Comply with BP individual monograph</td>
</tr>
<tr>
<td></td>
<td>2. In absence of BP individual monograph:</td>
<td>2. In absence of BP individual monograph:</td>
</tr>
<tr>
<td></td>
<td>- 90-120% generally for Listed medicines;</td>
<td>- 92.5-107.5% generally for all medicines</td>
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<tr>
<td></td>
<td>- 92.5-107.5% for Registered medicines;</td>
<td>- 97.0 – 115% for antibiotic assayed by microbiological method, or 92.5-110.0 % for antibiotic assayed by non-microbiological method</td>
</tr>
</tbody>
</table>

1 This summary is provided to assist in the consultation process. Please refer to TGO 56 for full details of current Australian requirements.
<table>
<thead>
<tr>
<th>ATTRIBUTE</th>
<th>DRAFT TGO 78</th>
<th>TGO 56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content of active ingredients (cont’d)</td>
<td>- for Listed actives in Schedule 1:</td>
<td>- for vitamins in multivitamin products:</td>
</tr>
<tr>
<td></td>
<td>- 90-125% for certain minerals (for Ca, Cu, Fe, Mg, Mn, P, K, Zn)</td>
<td>- 85-115% for some Registered oil soluble vitamins and Registered folic acid</td>
</tr>
<tr>
<td></td>
<td>- 90-160% for certain minerals (for Cr, F, I, Mo, Se)</td>
<td>- 85-125% for Listed folic acid</td>
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<td></td>
<td>- 90-150% for water soluble vitamins</td>
<td>- 85-150% for water soluble vitamins and some Listed oil soluble vitamins</td>
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<td></td>
<td>- 90-165% for oil soluble vitamins</td>
<td>- 85-165% for Listed Vitamin A and related substances</td>
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<tr>
<td></td>
<td>- 90-175% for betacarotene and pantothenates</td>
<td>- 85-175% for pantothenate salts</td>
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<td></td>
<td>- 90-200% for enzymes</td>
<td>- 85-180% for betacarotene</td>
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<td></td>
<td>- stated content with no upper limit, for probiotics</td>
<td>for herbal ingredients, no limits</td>
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<td></td>
<td>- for Listed multicomponent ingredients with quantitative claims for components and natural variation in quantity of components (eg, fish oils), minimum of 90% of stated content</td>
<td>for homoeopathic preparations, no limits</td>
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<td></td>
<td>- for Listed ingredients with no quantitative claim for components, no limits (Note: this is intended to be consistent with the guidance “Quantified by Input”)</td>
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<td></td>
<td>- for Listed homoeopathic preparations, no limits</td>
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<tr>
<td>ATTRIBUTE</td>
<td>DRAFT TGO 78</td>
<td>TGO 56</td>
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</tr>
<tr>
<td>Uniformity of Weight</td>
<td>Listed medicines comply with BP general monograph</td>
<td>All comply with BP general monograph</td>
</tr>
<tr>
<td>Uniformity of content</td>
<td>(see below)</td>
<td>All comply with BP general monograph, except not required for</td>
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<tr>
<td></td>
<td></td>
<td>- homoeopathic actives</td>
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<td>- herbal substances not in SUSDP</td>
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<td></td>
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<td>- actives in a multivitamin or multivitamin and mineral product</td>
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<tr>
<td>Uniformity of dosage units</td>
<td>Registered medicines comply with BP general monograph, which overrides</td>
<td>Not included</td>
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<td></td>
<td>requirements in BP individual monographs. In practice:</td>
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<tr>
<td></td>
<td>- new medicines to comply with Uniformity of Dosage Units</td>
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<td>- existing medicines to comply with Uniformity of Weight or Content, as</td>
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<td>approved</td>
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<td>Listed medicines, including Listed medicines with a BP individual monograph,</td>
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<td>not required to comply.</td>
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<tr>
<td>ATTRIBUTE</td>
<td>DRAFT TGO 78</td>
<td>TGO 56</td>
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<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------</td>
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<tr>
<td>Disintegration</td>
<td>1. Comply with BP individual monograph</td>
<td>1. Comply with BP individual monograph</td>
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<td></td>
<td>2. In absence of BP individual monograph, all medicines comply with BP general monograph unless required to comply with a dissolution test</td>
<td>2. In absence of BP individual monograph, all medicines comply with BP general monograph (including where test is omitted) except for:</td>
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<td>- when the active is a herbal ingredient, 30 minutes disintegration for uncoated or film-coated tablets, or 60 minutes for coated tablets</td>
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<td></td>
<td></td>
<td>- three minute disintegration for soluble or dispersible tablets</td>
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<tr>
<td>Uniformity of dispersion</td>
<td>Comply with BP general monograph</td>
<td>Comply with specified test</td>
</tr>
<tr>
<td>ATTRIBUTE</td>
<td>DRAFT TGO 78</td>
<td>TGO 56</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Dissolution</td>
<td>1. Comply with BP individual monograph, except that:</td>
<td>If the active ingredient is named in the Second Schedule:</td>
</tr>
<tr>
<td></td>
<td>- Registered medicine must comply with a dissolution test if either the BP or the USP requires a dissolution test for that active ingredient, unless such a test is not necessary for the dosage form, that is, chewable, effervescent or dispersible tablets</td>
<td>- comply with the BP dissolution requirement if such exists, or</td>
</tr>
<tr>
<td></td>
<td>2. In absence of BP individual monograph, Registered medicine must comply with a suitable dissolution test if either the BP or the USP requires a dissolution test for that active ingredient, unless such a test is not necessary for the dosage form, that is, chewable, effervescent or dispersible tablets</td>
<td>- comply with the USP requirement</td>
</tr>
<tr>
<td></td>
<td>All tablets and capsules must comply with USP dissolution test for folic acid, if content is 100 micrograms or more</td>
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<tr>
<td></td>
<td>Modified release Listed medicines must comply with a suitable dissolution test.</td>
<td></td>
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<tr>
<td>Packaging requirements</td>
<td>Not included</td>
<td>Packaged to afford protection, etc.</td>
</tr>
<tr>
<td>Supplementary Notes</td>
<td>Not included. (Note: see separate Guidance notes above).</td>
<td>As required</td>
</tr>
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</table>