UPDATED-FEBRUARY 2005

THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

PART I : ADMINISTRATIVE DATA AND PRODUCT INFORMATION

Section A: Introduction

This section contains the Administrative Data and Product Information which is the Part I of the ASEAN Common Technical Document (ACTD) for application to the Drug Regulatory Authority

Section B:
Table of Contents

THE ASEAN COMMON TECHNICAL DOSSIER (ACTD) FOR THE REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

PART I : ADMINISTRATIVE DATA AND PRODUCT INFORMATION

Section C: Guidance on the Administrative Data and Product Information

1. Application Form
   (Model of Application Form - Appendix I)
   English and/or official native language shall be used.

2. Letter of Authorisation **(where applicable)**
   (Model of Letter of Authorisation - Appendix II)

3. Certifications:
   - For contract manufacturing:
     a. Licence of pharmaceutical industries and contract manufacturer
     b. Contract manufacturing agreement
     c. GMP certificate of contract manufacturer
   - For manufacturing "under-licence" (country specific) :
     a. Licence of pharmaceutical industries
     b. GMP certificate of the manufacturer
     c. Copy of ''under-licence'' agreement.
   - For locally manufactured products (excluding the above):
     a. Licence of pharmaceutical industries
     b. GMP certificate (country specific)
   - For imported products:
     a. Licence of pharmaceutical industries/importer/wholesaler (country specific)
     b. Certificate of Pharmaceutical Product issued by the competent authority in the country of origin according to the current WHO format (Appendix III)
     c. Site master file of manufacturer (unless previously submitted within the last 2 years) (country specific)

4. Labelling
   (Appendix IV)
   English and/or official native language shall be used.

5. Product Information

5.1 Package Insert (Appendix V)
English and/or official native language shall be used.
Package Insert is required for generic products

5.2 Summary of Product Characteristics (Product Data Sheet) (Appendix VI)
English and/or official native language shall be used.
Summary of Product Characteristics is required for NCE and Biotechnology products.

5.3.Patient Information Leaflet (PIL) (Appendix VII)
English and/or official native language shall be used.
PIL is required for Over-the-Counter Products

NOTE:

Language of dossier:
English and/or official native language shall be used
For generic product either SPC or package insert is acceptable

APPENDIX I

MODEL OF APPLICATION FORM

A. DETAILS OF APPLICANT AND MANUFACTURER

1. Applicant's (Marketing Authorisation Holder) Name
2. Applicant's (Marketing Authorisation Holder) Address
3. Manufacturer's* Name
4. Manufacturer's Address

* = *Manufacturer responsible for final batch release*.

Other manufacturers

Name & address	**Role****

** = e.g. "prepares semi-finished product", "packaging", "granulation", "manufactures bulk finished dosage form", "contract research organization", etc.

B. DETAILS OF PRODUCT

1. Product Name, Dosage Form and Strength
2. Product Description
3. Generic Name and Quantity of active ingredients and excipients

C. TECHNICAL DOCUMENTS

1. Part II : ACTD-Quality
2. Part III : ACTD-Safety
3. Part IV : ACTD- Efficacy (Clinical Data)

Note : The documents (Part II or/and III or/and IV) required for submission are determined by the product category/classification

D. PATENT/TRADEMARK EVIDENCE, WHERE APPLICABLE

E. REFERENCE PRODUCT, WHERE APPLICABLE

F. APPLICANT DECLARATION (country specific)

APPENDIX II

MODEL OF LETTER OF AUTHORISATION

Company's Letterhead

LETTER OF AUTHORISATION

We, _____
Product Owner's Name and Address

Hereby appoint _____
Applicant's Name and Address

To apply for registration of our pharmaceutical product

Product Name,
Dosage Form and Strength

With the Drug Regulatory Authority in (state country) on our behalf . They will be the marketing authorisation holder of the registration certificate and be responsible for all matters pertaining to the regulation of this product.

Signature : _____

Date :

APPENDIX III

MODEL CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the WHO (general instructions and explanatory notes attached)

Certificate No :_____

Exporting (Certifying) country:_____

Importing (Requesting) country:_____

1. Name and dosage form of product:

_____

1.1 Active ingredient(s)[2] and amount(s)[3] per unit dose:

_____

_____

_____

For complete qualitative composition including excipients, see attached[4].

1.2 Is this product licensed to be placed on the market for use in the exporting country?[5]

☐ Yes ☐ No

1.3 Is the product actually on the market in the exporting country?

☐ Yes ☐ No ☐ Unknown

If the answer to 1.2 is yes, continue with section 2A and omit section 2B.

If the answer to 1.2 is no, omit section 2A and continue with section 2B[6].

2A.1 Number of product licence[7] and date of issue:

_____

2A.2 Product licence holder (name and address):

Name :_____

Address :_____

2A.3 Status of product-licence holder:[8]

☐ a ☐ b ☐ c

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are:[9]

Name :_____

Address :_____

2A.4 Is Summary Basis of Approval appended?[10]

☐ Yes ☐ No

2A.5 Is the attached, officially approved product information complete and consonant with the licence?[11]

☐ Yes ☐ No ☐ Not provided

2A.6 Applicant for the certificate (name and address):[12]

Name :_____

Address :_____

2B.1 Applicant for certificate (name and address):

Name :_____

Address :_____

2B.2 Status of applicant:[8]

☐ a ☐ b ☐ c

2B.2.1 For categories b and c, the name and address of the manufacturer producing the dosage form is:[9]

Name :_____

Address :_____

2B.3 Why is marketing authorization lacking?

☐ not required ☐ under consideration
☐ not requested ☐ refused

2B.4 Remarks:[13]

_____

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[14]

☐ Yes ☐ No ☐ N/A

If no or not applicable proceed to question 4.

3.1 Periodicity of routine inspection (years):_____

3.2 Has the manufacture of this type of dosage form been inspected?

☐ Yes ☐ No

3.3 Does the facilities and operations conform to GMP as recommended by the WHO?[15]

☐ Yes ☐ No ☐ N/A

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

If no explain: _____

Address of the certifying authority:

_____

Telephone number:_____

Fax number:_____

Name of authorized person:

_____

Signature of authorized person:

_____

Stamp and date:

_____

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Use whenever possible, international Non-proprietary Names (INNs) or national non-proprietary names.

3. The formula (complete composition) of dosage form should be given on the certificate or be appended.

4. Details of quantitative composition are preferred, but their provision is subject to the agreement of the product licence holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

6. Sections 2A and 2B are mutually exclusive.

7. Indicate when applicable, if the licence is provisional, or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in non of the above

9. This information can be provided only with the consent of the product licence holder or, in the case of non registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.
   It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence must be updated or it will cease to be valid.

10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to the product information approved by the competent national regulatory authority, such as a Summary of Product Characteristics (SmPC).

12. In this circumstance, permission for issuing the certificate is required from the product licence holder. This permission must be provided to the authority by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:
   (a) the product has been developed exclusively for the treatment of conditions – particularly tropical diseases – not endemic in the country of export;
   (b) the product has been reformulated with a view to improving its stability under tropical conditions;
   (c) the product has been reformulated to exclude excipients not approved for used in pharmaceutical products in the country of import;
   (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
   (e) any reason, please specify.

14. Not applicable means that the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series No. 823, 1992 Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992 Annex 1)

16. This section is to be completed when the product licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

APPENDIX IV

LABELLING

A Labelling Parameters required for **UNIT CARTON**

1. Product Name
2. Dosage Form
3. Name of Active Ingredient(s)
4. Strength of Active Ingredient(s)
5. Batch Number
6. Manufacturing Date
7. Expiration Date
8. Route of Administration
9. Storage Condition
10. Registration Number
11. Name and Address of Marketing Authorisation Holder and / or Product Owner
12. Name and Address of Manufacturer
13. **Special Labelling (if applicable) eg. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, porcine)**
14. Recommended Daily Allowance (For Vitamins and Minerals)
15. Warning (if applicable)
16. Pack sizes (Unit/Volume)

B Labelling Parameters required for **INNER LABEL**

1. Product Name
2. Dosage Form*
3. Name of Active Ingredient(s)
4. Strength of Active Ingredient(s)
5. Batch Number
6. Manufacturing Date*
7. Expiration Date
8. Route of Administration
9. Storage Condition*
10. Country's Registration Number*
11. Name and Address of Marketing Authorisation Holder*
12. Name and Address of Manufacturer*
13. Special Labelling (if applicable) eg. Sterile, External Use, Cytotoxic, Alcohol Content, Animal Origin (Bovine, porcine)*
14. Recommended Daily Allowance (For Vitamins and Minerals)*
15. Warning (if applicable)*
16. Pack sizes (unit/Volume)

Note: * (exempted for small label such as =j5 ml size ampoule and vial)

C Labelling Parameters required for **BLISTER/STRIPS**

1. Product Name
2. Name of Active Ingredient(s)#
3. Strength of Active Ingredient(s)#
4. Batch Number
5. Expiration Date
6. Name/Logo of Manufacturer/Product Owner/Marketing Authorisation Holder (country specific)
7. Country's registration number (country specific)

Note: # (exempted for multi-ingredients product with more than 3 ingredients. For example multivitamins and multiminerals it is suggested to label as multivitamins and multiminerals.)

APPENDIX V

PACKAGE INSERT

1. Product Name
2. Name and Strength of Active Ingredient (s)
3. Product Description
4. Pharmacodynamics / Pharmacokinetics
5. Indication
6. Recommended Dose
7. Mode of Administration
8. Contraindication
9. Warnings and Precautions
10. Interactions With Other Medicaments
11. Pregnancy and Lactation
12. Undesirable Effects
13. Overdose and treatment
14. Storage Condition
15. Dosage Forms and packaging available
16. Name and Address of Manufacturer/Marketing Authorization Holder
17. Date of Revision of Package Insert

APPENDIX VI

SUMMARY OF PRODUCT CHARACTERISTICS (PRODUCT DATA SHEET)

1. Name of the Medicinal Product
   - 1.1 Product Name
   - 1.2 Strength
   - 1.3 Pharmaceutical Dosage Form

2. Quality and Quantitative Composition
   - 2.1 Qualitative Declaration
     The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant
   - 2.2 Quantitative Declaration
     The quantity of the active substance must be expressed per dosage unit (for metered dose inhalation products, per puff) per unit volume or per unit of weight).

3. Pharmaceutical Form
   Visual description of the appearance of the product (colour, markings, etc) e.g.:
   "Tablet White, circular flat beveled edge tablets marked '100' on one side

4. Clinical Particulars
   - 4.1 Therapeutic indications
   - 4.2 Posology and method of administration
   - 4.3 Contraindications
   - 4.4 Special warning and precautions for use
   - 4.5 Interaction with other medicinal products and other forms of interactions
   - 4.6 Pregnancy and lactation
   - 4.7 Effects on ability to drive and use machine
   - 4.8 Undesirable effects
   - 4.9 Overdose

5. Pharmacological Properties
   - 5.1 Pharmacodynamic Properties
   - 5.2 Pharmacokinetic Properties
   - 5.3 Preclinical safety Data

6. Pharmaceutical Particulars
   - 6.1 List of excipients
   - 6.2 Incompatibilities
   - 6.3 Shelf life
     Shelf life of the medicinal product as packages for sale. Shelf life after dilution or reconstitution according to directions. Shelf-life after first opening the container
   - 6.4 Special precautions for storage
   - 6.5 Nature and contents of container

7. Marketing Authorization Holder

8. Marketing Authorization Numbers

9. Date of first authorization/renewal of the authorization

10. Date of revision of the text

APPENDIX VII

PATIENT INFORMATION LEAFLET (PIL)

1 Name of Product

2 Description of Product

3 What is in the medicine?

4 Strength of the medicine

5 What is this medicine used for?

6 How much and how often should you use this medicine?

7 When should you not take this medicine?

8 Undesirable effects

9 What other medicine or food should be avoided whilst taking this medicine?

10 What should you do if you miss a dose?

11 How should you keep this medicine?

12 Signs & Symptoms of over dosage

13 What to do when you have taken more than the recommended dosage?

14 Name/logo of manufacturer/importer/Marketing Authorisation Holder

15 Care that should be taken when taking this medicine?

16 When should you consult your doctor?

17. Date of Revision of PIL