HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

JULY 2024

GUIDELINES ON CHINESE PROPRIETARY MEDICINES PRODUCT LISTING

HSA Health Sciences Authority

Contents

Submission of Application

In additional to dealer's licences, CPM importers, manufacturers and assemblers are also required to obtain product listing approvals for the CPM products dealt by them.
The following items must be submitted during applications for CPM product listing approvals:

Item	For imported product	For locally manufactured product
Labels of product to be sold/supplied in Singapore which meet labelling requirements, including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	✓	✓
Photograph of the product's contents (e.g. capsules, tablets) Physical sample of product to be sold/supplied in Singapore, only upon request	✓	✓
Labels of product sold/supplied in country of manufacture, including: a) Inner label b) Outer label / carton (if any) c) Package insert (if any)	✓	
Manufacturer's Licence or certificate	✓	
Good Manufacturing Practice (GMP) certificate (if any)	✓	
Product registration certificate (if applicable) [#]	✓	
Free sale certificate or equivalent from country of manufacture	✓	

Test results of toxic heavy metals and microbial contamination	✓	✓
Storage condition/containers*	✓	✓
Quality parameters for CPM products	✓	✓
Endorsement of product formula (including all active and inactive ingredients) by overseas manufacturer and undertaking by overseas manufacturer that product does not contain any Western drugs or active synthetic substances	✓	
Information on legal classifications of product in countries of sales*	✓	
Website undertaking* – *for products with website stated on label(s)*	✓	✓
TSE undertaking* – *for products containing materials (including those used for making capsule shells) derived from ruminants (e.g. cattle, buffalo, sheep, goat, deer, antelope)*	✓	✓
Info for Fermented Substance* – *for products containing fermented substance(s) (e.g. Cordyceps, Red Yeast Rice)*	✓	✓

* Forms are available at Annexes 1-7

If product registration certificate is not available, a FSC, CPP or similar documents would be required.

In addition to the above items, dealers may be required to furnish any other information as requested by the Licensing Authority.

Before you submit your application, please ensure that your product does not contain:

- Any synthetic drugs;
- Any other substances listed in the Poisons Act, except for the list of allowable naturally occurring substances within limits (see section under "Requirements of Test Reports);

If the CPM contains substances listed under the Endangered Species (Import & Export) Act, dealers should contact the Wildlife Management Group of the NParks to obtain the necessary Convention on the International Trade in Endangered Species of Wild Fauna and Flora (CITES) import and export permits.

Apply online

Photograph of Product's Content

Examples of Pictures Showing Product Contents
产品样本的图片范例

Sample of Granules & Powders 颗粒剂和散剂的样本

Sample of Capsules胶囊的样本

Sample of see-through teabags 茶袋的样本

Sample of Tablets片剂的样本

Sample of Pills丸剂的样本

POINTS TO NOTE注意事项:

a) All samples are to be taken against a **contrasting** background.
所有的样本图片必须摄于可产生对比的背景

b) For capsules and sachets, the contents must be poured out to show the details.
对于胶囊和袋装品，应将其内含物倒出，以显示细节。

c) Tablets are to be cut into halves to display cross-sections.
片剂应切割成大小相似的两半，显示其横切面的细部

Guideline on Signatory of Forms and Undertaking for CPM

This document is meant to provide general guidance on the acceptable signatory for the forms* and undertakings submitted during the application of Chinese Proprietary Medicines (CPM) through PRISM:

1. For CPM Manufactured for Local Sale / Manufactured for Local Assembly

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF6.4_Website undertaking	Manufacturer
2	CPMF8.3_Advertisement Undertaking	Manufacturer
3	CPMF9.6_TSE undertaking	Manufacturer
4	CPMF11.5_Info for Fermented Substance	CMM Supplier and Manufacturer
5	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Manufacturer
6	Undertaking to test products at accredited labs	Manufacturer

2. For CPM Imported for Local Sale / Imported for Local Assembly

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Importer or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Importer
3	CPMF8.3_Advertisement Undertaking	Importer
4	CPMF9.6_TSE undertaking	Importer
5	CPMF10.3_Undertaking form for Amended formula	Overseas Manufacturer
6	CPMF11.5_Info for Fermented Substance	CMM Manufacturer and Importer
7	CPMF13.4a_Storage Condition of CPM - Imported Products	Importer
8	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
9	Undertaking to test products at accredited labs	Importer

3. For CPM Assembled for Local Sale (Primary Assembly)

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Primary Assembler or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Primary Assembler
3	CPMF8.3_Advertisement Undertaking	Primary Assembler
4	CPMF9.6_TSE undertaking	Primary Assembler
5	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Primary Assembler
6	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
7	Undertaking to test products at accredited labs	Primary Assembler

4. For CPM Assembled for Local Sale (Secondary Assembly)

	Name of Form / Undertaking	Acceptable Signatory
1	CPMF5.3_Forensic classification	Secondary Assembler or Overseas Manufacturer or Product Owner
2	CPMF6.4_Website undertaking	Secondary Assembler
3	CPMF8.3_Advertisement Undertaking	Secondary Assembler
4	CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products	Secondary Assembler
5	Undertaking that product does not contain western drugs or chemical substances	Overseas Manufacturer
6	Undertaking to test products at accredited labs	Secondary Assembler

* Forms are available at Annexes 1-7

Labelling Requirements and Prohibited Claims

Full labelling in English is required for all CPM. Chinese or other languages, if any, may be used in addition to English. The information in languages other than Chinese and English, if applicable, should be the same as the English version of the approved labels. The details required are as follows:

Inner label must state:

- Trade / brand name
- Product name
- Batch number
- Expiry date
- Names and quantities of ingredients *

* *If inner label is too small, the information may be stated on the outer label.*

Outer label must state:

- Trade / Brand name
- Product name
- Batch number
- Expiry date
- Importer's or wholesaler's name and address **
- Manufacturer's name and address **
- Assembler's name and address (if any) **
- "Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority. Consumer discretion is advised. 根据向当局提呈的资料允许作为中成药销售。谨慎选用。" ** (Please see next page for more details)

** *If there is no outer label, the information must be stated in the inner label.*

Additional label:

"Allowed for sale as a Chinese Proprietary Medicine based on information submitted to the Authority. Consumer discretion is advised. 根据向当局提呈的资料允许作为中成药销售。谨慎选用。"

- The words must be clearly legible and printed in an indelible manner.
- The English words should not be less than 1.5 mm in height and the Chinese characters not less than 2 mm in height.
- It is the responsibility of the applicant/company to measure the height of the words and characters before printing/submission of labels.
- The words must be enclosed in a boxed area which is clearly visible. Nothing else should appear in the boxed area other than the words of the label.
- The label must appear conspicuously in a prominent position.

Package insert must state:

- Trade / Brand Name
- Product Name
- Manufacturer's name and address
- Names & quantities of ingredients
- Dosage ***
- Indication ***
- Contraindication ***
- Side effects ***
- The frequency and method of administration ***

*** *If there is no package insert, the information must be stated on either the inner or outer label.*

Guidelines on Electronic Labelling (E-labelling)

E-labelling refers to product information which is distributed via electronic means, such as through a machine-readable code (e.g. QR code) or URL on the product packaging, linking to product information in digital format. Presently, e-labelling for CPM is applicable to the product leaflet only.

Dealers who are interested to use e-labelling for their CPM have to inform HSA. For more details, please refer to this guideline.

Prohibition of Stipulation of Certain Diseases / Conditions

The labels, packaging and package inserts of CPM shall not make references to any of the 19 diseases/conditions specified in the First Schedule to the Medicines Act:

1. Blindness	11. Leprosy
2. Cancer	12. Menstrual disorders
3. Cataract	13. Paralysis
4. Drug addiction	14. Tuberculosis
5. Deafness	15. Sexual function
6. Diabetes	16. Infertility
7. Epilepsy or fits	17. Impotency
8. Hypertension	18. Frigidity
9. Insanity	19. Conception and pregnancy
10. Kidney diseases	

Requirements of Test Reports

Parameters to be Tested and Their Limits
Toxic heavy metal limits for CPM products are as follows:

Heavy metal	Permissible limits
Arsenic	5 ppm
Cadmium	0.3 ppm
Lead	10 ppm
Mercury	0.5 ppm

Dealers may wish to take note of the following suggestions in controlling the heavy metal contents of their products:

- Identify starting materials (e.g. certain herbs, minerals) that may contribute to higher heavy metal content in their product;
- Source for starting materials which have been tested to contain heavy metals below stipulated limits;
- Ensure that herbal materials are free from soil particles before use (e.g. by washing thoroughly, if applicable); and
- Incorporate relevant extraction processes in the manufacturing workflow to remove heavy metals in the product, if necessary.

Microbial limits for CPM products are as follows:

For oral CPM	Microbial limits
Total aerobic microbial count	Not more than 10^5 per g or ml
Yeast and mould count	Not more than 5 X 10^2 per g or ml
Escherichia coli Salmonellae Staphyloccocus aureus	Absent in 1g or ml
For topical CPM	**Microbial limits**
Total aerobic microbial count	Not more than 10^4 per g or ml
Yeast and mould count	Not more than 5 X 10^2 per g or ml
Pseudomonas aeruginosa Staphyloccocus aureus	Absent in 1g or ml

Toxic heavy metals and microbial contamination tests should be conducted using methods that are in accordance with the latest edition of one of the following pharmacopoeias: British Pharmacopeia, Chinese Pharmacopeia, European Pharmacopeia, United States Pharmacopeia, etc.

Limits and conditions for specific naturally occurring substances in CPM are as follows:

Substances	Acceptable limit
Ephedra alkaloids	< 1%
Lovastatin	< 1%
Boric acid, sodium borate	Not more than 5% boric acid or 5% sodium borate or 5% of a combination of both
Lobelia alkaloids	< 0.1%
Aconite alkaloids	Dosing of ≤ 60 mcg/day
Tetrahydropalmatine	Dosing of ≤ 19 mg/day

Test reports for CPM containing herbs with specific naturally occurring substances have to be tested at laboratories with accredited testing methods, and the test results must be quantified in the test reports to be within the stipulated limits.

Requirements on Test Reports

a. The tests must be conducted on finished products. Tests done on intermediate products or raw materials would not be acceptable.

b. The product's batch number must be stated on the test report, and it must be in accordance with the batch numbering system declared in the online application form. A written explanation should be submitted for any deviation from the declared batch numbering system. The same batch number should be tested and reflected on both test reports if the tests on toxic heavy metals and microbial limits were done separately.

c. The product's full product name must be stated on the test report:

Type of CPM	Acceptable product name on test report
Imported products	Either the product name in the country of origin or the one intended for local sale
Locally manufactured products	Product name stated in online application form
Locally assembled Products (Primary assembly)	Product name of CPM after assembly
Locally assembled Products (Secondary assembly)	Either the product name of CPM before or after assembly

d. The date of analysis stated on the test report must be within 2 years from the date of evaluation of the CPM product listing.

e. If the test result is "not detected/ND", the limit of detection must be stated on the test report.

f. The test result cannot be stated as "less than legal limit" (e.g. "Arsenic < 5 ppm"). A product with a test result that is too close to the legal limit is likely to fail re-testing conducted by different laboratories or using equipment.

g. Every batch of CPM containing herbs with specific naturally occurring substances, as well as those considered as high-risk (e.g. those with slimming claims) has to be tested at laboratories with accredited testing methods for the contents of toxic heavy metals and microbial contamination.

Sample of Test Report

Reference number: 0001001 Page 1 of 1

Date: 15 February 2012

Company: XYZ Pte Ltd

Date Analysed: 09 February 2012

Date Completed: 15 February 2012 → Within 2 years of application

Sample description: One sample of CPM product was collected on 09 February 2012
With references:

Product Name: COLD & FLU REMEDY PILLS → Product name should be consistent with application

Dosage form: pills

Batch Number: 20120105C → Batch number must be stated

Expiry Date: 04 Jan 2015

Results: On analysis, the following results were obtained:

→ The limits required by HSA

Microbiological Analysis (USP 34(2011), Microbial Limit Tests)	Permissible limits	Results
Total aerobic microbial count, 需氧微生物的总数	<1 X 10^5 /g	e.g. 20 CFU/g
Yeast and mould count , 酵母及霉菌	<5 X 10^2 /g	e.g. 10 CFU/g
Escherichia coli, per 10g 大肠埃希氏杆菌	Absent /g	Absent
Salmonellae, per 10g 沙门氏菌族	Absent /g	Absent
Staphyloccocus aureus , per 10g 金黄色葡萄球菌	Absent /g	Absent
Chemical Analysis		
Mercury as Hg, ppm 汞	<0.5ppm	Not detected
Arsenic as As, ppm 砷	<5ppm	e.g. 0.21
Copper as Cu, ppm 铜	<150ppm	e.g. 6.80
Lead as Pb, ppm 铅	<20ppm	e.g.1.90

Note: CFU, Colony forming Unit
Detection Limit of Hg is 0.01ppm. → If "not detected" is printed in test report, the detection Limit must be provided.

XXXXXXXXXX

Name & Signature of Analyst

Accredited Laboratories

The requirement for testing of CPM to be conducted at laboratories with accredited testing methods has commenced in stages and CPM dealers are encouraged to send their products for testing at such laboratories.

Dealers with specific products that require testing at the laboratories accredited for testing of CPM have been informed by HSA accordingly. For new CPM product applications, the applicant will be informed prior to product approval whether the CPM requires testing at such laboratories.

HSA has compiled a list of laboratories accredited for testing of CPM in Singapore as well as a list of overseas laboratories for dealers' easy reference. Test reports from overseas laboratories accredited for testing of CPM would be acceptable for the following tests:

a) Toxic heavy metals
b) Microbial contamination
c) Other substances as may be required by HSA

For the list of laboratories accredited for testing of CPM in Singapore, please refer to the following website:
https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chinese-proprietary-medicines/list_of_local_lab_for_cpm_testing.pdf

For the list of overseas laboratories accredited for testing of CPM in Singapore, please refer to the following website:
https://www.hsa.gov.sg/docs/default-source/hprg-tmhs/chinese-proprietary-medicines/list_of_overseas_lab_for_cpm_testing.pdf

Please be reminded that the lists serve as a reference and may not necessarily be valid. In view that the types of tests and test methods that the laboratories are accredited to conduct may vary from time to time, dealers are advised to verify the accreditation status of the laboratories' test methods when intending to engage their services. The onus of responsibility remains with the dealers to ensure that the laboratory they have engaged holds the necessary valid accreditation for the relevant test methods.

For the detailed description of the laboratories' scope of accreditation, please visit the websites stated in the User Guide which HSA has prepared to help dealers navigate the websites.

User Guide for Local and Overseas Laboratory Accreditation Websites

Accredited laboratories in China
For latest updates and a more detailed description of the laboratories' scopes of accreditation, please visit the website at:
http://www.cnas.org.cn/english/index.shtml

Please follow the steps below in order to navigate through the web pages of the official website for China National Accreditation Service for Conformity Assessment:

i. Select "Find an accredited body".

ii. Under "Laboratory", select "Testing & Calibration Laboratories".

iii. Under "Organization Name", key in the name of the laboratory and click "Search".

iv. Click on the link to the laboratory, the details of the laboratory will be shown.

v. Under "Certificate Appendix (Accredited Scope):", click "Structured Scope Officially Released".

vi. Under "ACCREDITED TESTING SCOPE", and then "Test Object", look for "Drug", or "Chinese medicine", or "medicine/Traditional Chinese Medicine".

vii. The test required should be covered under "Item/Parameter".

viii. For the test required (e.g. lead, mercury, arsenic and cadmium), the "Standard or Method" should include details of the reference e.g. Chinese Pharmacopoeia 2020.

ix. Also verify that the accreditation is still valid by checking the date stated under "Term of Validity" section.

Accredited laboratories in Hong Kong
For latest updates and a more detailed description of the laboratories' scopes of accreditation, please visit the website at:
https://www.itc.gov.hk/en/quality/hkas/conformity_assessment_bodies/hoklas.html

Please follow the steps below in order to navigate through the web pages of the official website for Innovation and Technology Commission, Hong Kong:

i. Under the "Name of Organisation", key in the name of the laboratory and click "GO".

ii. The accredited laboratory's registration number and name will be shown.

iii. Click "Download" under "Scope of Accreditation", and the details of the selected laboratory will be shown.

iv. Verify that the "Item tested or Measured" includes "Proprietary Chinese Medicines" and the type of test required is included under "Specific tests or properties measured".

Accredited laboratories in Malaysia
For latest updates and a more detailed description of the laboratories' scopes of accreditation, please visit the website at: https://cab.jsm.gov.my/cab-directories/resultSamm

Please follow the steps below in order to navigate through the web pages of the official website for Department of Standards Malaysia:

i. In "Search Conformity Assessment Body", key in the name of the laboratory and click "Search!".

ii. The accredited laboratory's information will be shown.

iii. Under "Status SAMM No" of the laboratory, click the SAMM No.

iv. The certificate of the laboratory will be shown.

v. Verify that the "Scope of Testing" covers "Traditional medicine" for material/product tested and the type of tests include the required test.

vi. Also verify that the accreditation is still valid by checking the date stated under "Valid until" section.

Accredited laboratories in Singapore
For latest updates and a more detailed description of the laboratories' scopes of accreditation, please visit the SAC website at:
http://www.sac-accreditation.gov.sg

Please follow the steps below in order to navigate through the web pages of the official website for Singapore Accreditation Council:

i. Select "SEARCH SAC Accredited Organisations".

ii. Click on "Advanced Search".

iii. Under "Company name", key in the name of the laboratory and click "Search".

iv. The accredited laboratory will be shown.

v. Click on the name of the selected laboratory.

vi. Under “Terms of Accreditation”, click “Download Schedule”.

vii. Verify that the “Field of Testing” covers “Complementary Health Products”, “Chinese Proprietary Medicines” or “Traditional Medicine” under “Materials/Products Tested” and the "Tests/Properties” include the required test.

viii. Also verify that the accreditation is still valid by checking the date stated under “Expiry Date of Accreditation” section.

Accredited laboratories in Taiwan

For latest updates and a more detailed description of the laboratories’ scopes of accreditation, please visit the website at: https://www.taftw.org.tw/en/find-facility/scheme/testLab/list/

Please follow the steps below in order to navigate through the web pages of the official website for Taiwan Accreditation Foundation:

i. Under “View Accredited Organizations”, click on “Drugs, Chinese Herbal Preparations and Pharmaceuticals”.

ii. A list of tests will be shown.

iii. Under “Chinese herbal materials and Chinese Herbal Preparations”, click on the “Accreditation Number” to view laboratory information and scope of accreditation.

iv. Also verify that the accreditation is still valid by looking at the date stated under “Effective Period” section.

Quality Parameters

General Quality Parameters
It is mandatory for CPM applications to include the following information:

a. storage condition for imported products; or
b. storage condition and container(s) for locally manufactured/assembled products;
c. physical characteristics of the product such as colour, taste, smell, shape, size of capsule; and
d. physical specifications of the product (see Annex 8).

Requirements (a) and (b) should be submitted using the relevant forms while requirements (c) and (d) could be included in the product's COA or as separate document. The form is available during the submission of application.

The shelf-life of a product is determined by the product formulation, packaging and storage conditions and the proposed shelf-life should be supported by evidence. CPM dealers must ensure the product remains stable and safe for use during the period of proposed shelf-life.

Requirements of Storage Condition/Containers

In the process of CPM listing application, the applicant is required to submit the form on Storage Condition of Chinese Proprietary Medicines (CPM), which can be downloaded from the HSA website.

The applicant will use either of the two forms, depending on the listing type of the product selected:

1) Imported products (CPMF13.4a); and
2) Locally manufactured/assembled products (CPMF13.3b).

Please refer to the following detailed description for more information on how to fill up the forms.

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

进口产品使用此表格
For imported products

STORAGE CONDITION OF CHINESE PROPRIETARY MEDICINES (CPM) – IMPORTED PRODUCTS 中成药产品的贮存条件 – 适用于进口的中成药产品

Product name 产品名称 (English / Chinese) (英文/中文)	
Brand name 商标	
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others* 胶囊 / 颗粒 / 合剂 / 软膏剂 / 丸剂 / 散剂 / 片剂 / 茶剂 /其它* If others, please state:
Pack size 包装规格	

产品名称及商标名称应与 PRISM 申请中的一致
Product and brand names should be consistent with those stated in the application

指进口时的产品的包装规格，如 60 粒/瓶；12 片/板，3 板/盒等。如果此产品同时有多种包装规格，请全部填入此格。此项填入的信息，应与 PRISM 申请中的一致。This refers to the format of the product to be sold in Singapore (e.g. 60 capsules/bottle, 12 tablets/blister, 3 blister strips per box). Please list all the different pack sizes where applicable, and the information should be consistent

STORAGE CONDITION 贮存条件

Storage temperature (°C) 贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C / 低于 30 °C / 其它* If others, please state: _____ 如为其它,请注明: _____
Relative humidity (%) 相对湿度	Not more than 75% / Others* 不超过 75% / 其它* If others, please state: _____ 如为其它,请注明: _____

在此选择适合的选项，指明产品贮存所要求的温度及相对湿度。Please select the appropriate temperature and relative humidity at which the product should be

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名): _____ Designation (职务): _____

Name of company (公司名称): _____

Tel (电话): _____ Fax (传真): _____ Date 日期: _____

Signature (签名): _____

* Please select the appropriate 请选择适合的选项
CPMF 13.4a

要求填入申请人及公司的相关信息
Please fill up the relevant applicant and company details

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

本地生产或一级分装的产品使用此表格
For locally manufactured/ primary assembled products

STORAGE CONDITION AND CONTAINER(S) OF CHINESE PROPRIETARY MEDICINES (CPM) – LOCALLY MANUFACTURED / PRIMARY ASSEMBLED PRODUCTS
中成药产品的贮存条件和贮存容器 - 适用于本地生产的/一级分装的中成药产品

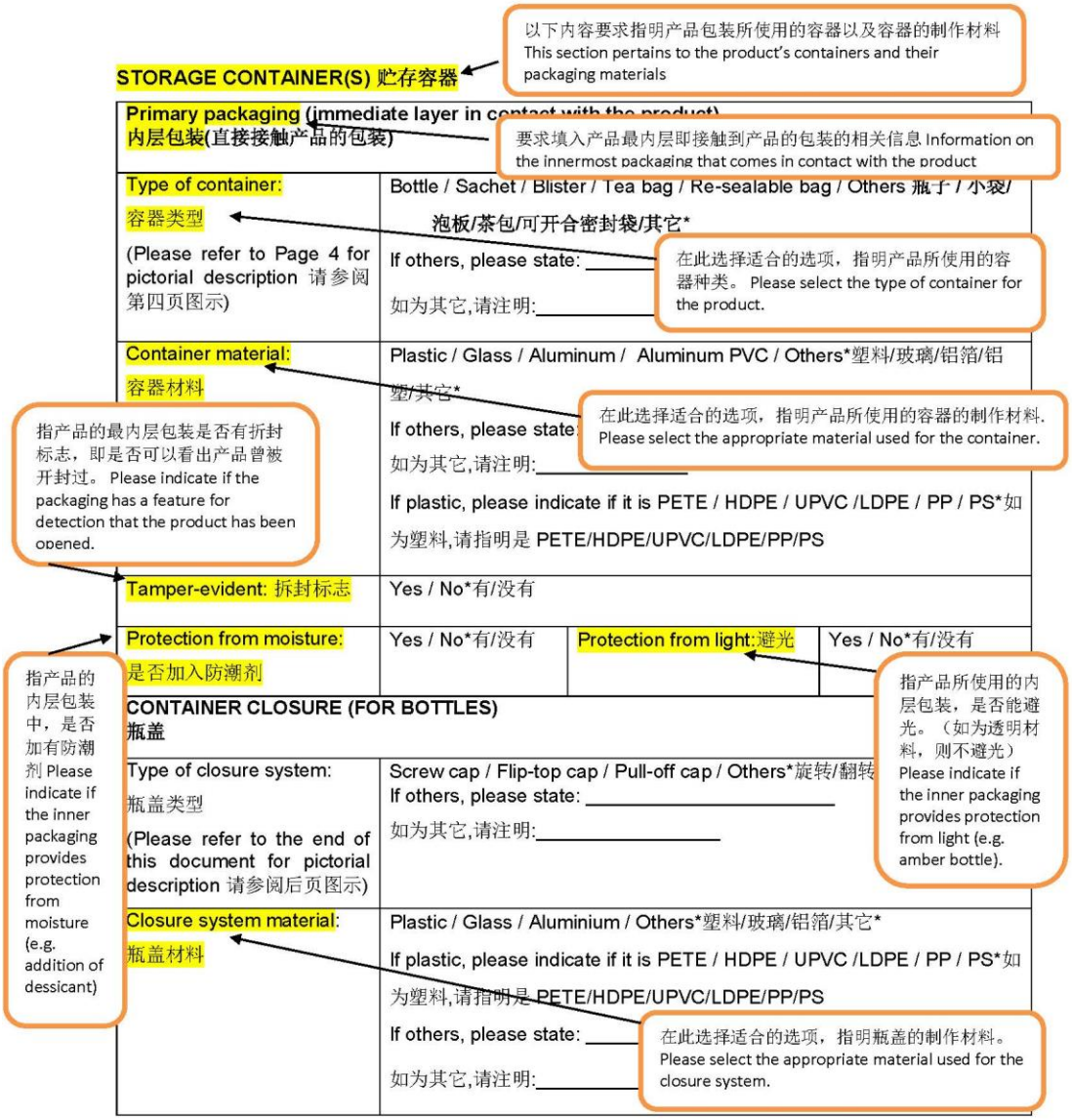
Product name 产品名称 (English / Chinese)(英文/中文) Brand name 商标	产品名称及商标名称应与所申请的产品名一致 Product and brand names should be consistent with those stated in the application
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others*胶囊/颗粒/合剂/软膏剂/丸剂/散剂/片剂/茶剂/其它* If others, please state:_____ 如为其它,请注明:_____
Pack size(If different material, please submit separate form) 包装规格(如产品有多种包装规格，且使用不同的包装材料,请填写多份表格)	指所销售的产品的包装规格，如 60 粒/瓶；12 片/板，3 板/盒等。如果此产品同时有多种包装规格，并且使用的包装材料不同，则需要使用多份表格分别填写。此项填入的信息，应与 PRISM 申请中的一致。This refers to the format of the product to be sold in Singapore (e.g. 60 capsules/bottle, 12 tablets/blister, 3 blister strips per box). Please list all the different pack sizes, and if different materials are used, please fill up using separate forms. All information should be consistent with that stated in PRISM.

STORAGE CONDITION 贮存条件

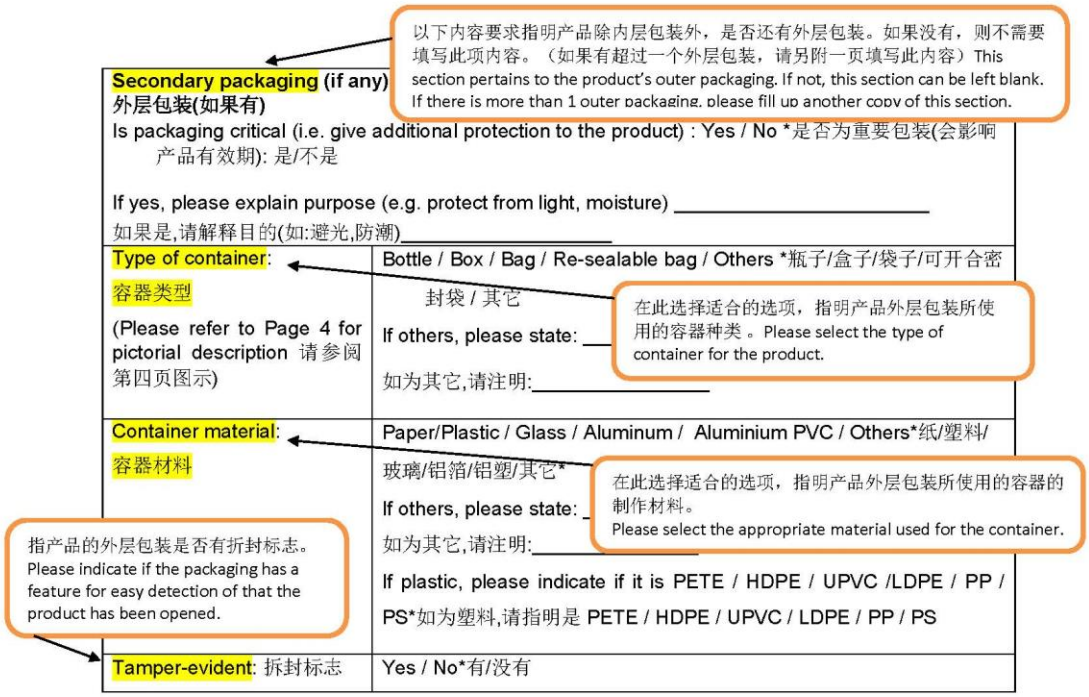
Storage temperature (°C):贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C/低于 30 °C/其它* If others, please state:_____ 如为其它,请注明:_____
Relative humidity (%):相对湿度	Not more than 75% / Others* 不超过 75%/其它* If others, please state:_____ 如为其它,请注明:_____

在此选择适合的选项，指明产品贮存所要求的温度及相对湿度。
Please select the appropriate temperature and relative humidity at which the product should be stored.

* Please select the appropriate 请选择适合的选项
CPMF 13.3b



* Please select the appropriate 请选择适合的选项
CPMF 13.3b



I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名)
(Dr/Mr/Mdm/Ms*):_____

Designation (职务):_____ Signature (签名):_____

Name of company (公司名称):_____

Tel (电话):_____ Fax (传真): _____

Date (日期):_____

要求填入申请人及公司的相关信息 Please fill up the relevant applicant and company details

Please note that the detail submitted on this form is for Authority's information only.
请注意,以上信息仅供当局备案.

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Turn-around-time

The turn-around-time for new product listing applications is 60 working days, excluding the time taken by you to respond to our request for clarification or additional information (applicant's stop-clock).

Listing Process

Process	Description
Step 1: **Verification**	A CPM listing application is submitted to us and the Verification Officer (VO) screens the application form and attachments for completeness and basic irregularities. If irregularities are found, the VO would raise Input Requests to seek your clarification. If the application is found to be generally complete at this initial stage, the VO would submit it for evaluation.
Step 2: **Evaluation**	The Evaluation Officer (EO) reviews the technical aspects of the application, including test reports, substantiation of label claims and manufacturing process. Input Requests may also be raised by the EO, until the final recommendation for approval or rejection of the application is made.
Step 3: **Regulatory decision**	The Approving Officer (AO) assesses the recommendation by the EO against the information submitted in the application and formally issues the approval or rejection notification to you. The AO could also request for further clarification by sending the application back to the EO, who would then raise an Input Request to you accordingly. When you resubmit the application, the process from Steps 2 to 3 is repeated, until the AO issues the final regulatory outcome.

Note: We strive to meet the turn-around-time for all submitted applications. You should ensure that the applications and replies to Input Requests are complete before submission, to prevent unnecessary delays to the processing due to incomplete information and untimely responses.

Responsibilities of Applicant

Product Safety

The applicant for the CPM product listing is responsible for the safety and quality of the CPM in the market. The applicant should ensure that the product meets all the legal requirements, conforms to the standards and specifications of the product that have been submitted and approved by the HSA and the product remains stable and safe for use during the period of proposed shelf-life. The shelf-life of a product is determined by the product formulation, packaging and storage conditions and the proposed shelf-life should be supported by evidence. In addition, the applicant should ensure that the levels of pesticides and/or other environmental contaminants that could be present in the product have been scientifically assessed not to pose any dangers to the intended users.

Adulteration

The applicant shall take full responsibility should the CPM product be found adulterated with substances listed under the Poisons Act and/or active synthetic substances.

Report of Changes in Particulars

After a company has been licensed, any subsequent change(s) in the particulars relating to the CPM or company will render the licence invalid unless prior approval of such change(s) has been obtained from the Health Sciences Authority. This includes any changes to the legal status of the product in the country of origin e.g. registration status, free sale status, classification.
Licence holders shall seek prior approval of the Health Sciences Authority to import / manufacture / assemble any new product.

Make CPM licence/product amendments online

Report of Adverse Drug Reaction

Licence holders shall report to the Vigilance and Compliance Branch, Health Products Regulation Group, Health Sciences Authority, 11 Biopolis Way #11-01 Helios Singapore 138667, as soon as possible (within 7 days) upon receipt of any information of adverse drug reactions arising from the CPM which they are dealing.
The Adverse Drug Reaction Report Form and more details can be found in the Safety Information and Recalls section.

Record Keeping

All licence holders must keep records of their transaction for a period of 2 years from the date of last entry.

Product Recall

It is the responsibility of the licence holders to recall any product manufactured / assembled / imported / distributed by them when directed by the Health Sciences Authority for reasons of safety or poor quality.

Advertisement of CPM

The advertisement and sales promotion of CPM require a permit from the Health Sciences Authority under the Medicines (Medical Advertisements) Regulations. Please note that the product listing approval of a CPM does not imply that the product name and/or its claims will be allowed for advertising purposes.

It is the responsibility of the applicant to refrain from using the CPM product listing approval as a marketing tool to advertise or promote the product.

Please refer to the advertisements and promotions guidelines section for more details.

Suspension, Revocation and Variation of Licence

The Health Sciences Authority may suspend, revoke or amend the details in any licence or certificate. The Licensing Authority shall serve on the licence or certificate holder a notice giving particulars and reasons for such suspensions, revocation or variation. Any person who is aggrieved by such a decision may appeal to the Minister for Health whose decision shall be final.

Penalty

Any person who contravenes any provision of the legislation on CPM is liable, to a fine of not more than $5000 or to an imprisonment of not more than 2 years or both.

Submission of Documents for Every Consignment at Point of Import

All CPM import licence holders are reminded that the following documents are required to be submitted to the Complementary Health Products Branch (CHPB) for the import of every consignment of the CPM:

(a) Supplier's invoice with the following (either in print or legible handwriting):
   i. the CPM import licence number (at the top right hand corner of the invoice) and
   ii. the CPM product reference number and batch number for each product (next to the corresponding product name)
(b) A declaration on the absence of any poisons as defined in the Poisons Act (Cap. 234) and any active synthetic substance in the CPM
(c) Test results of toxic heavy metals
(d) Test results of microbial contamination
(e) Other documents and test results as may be required by the licensing authority
(f) Notification of CPM Import and Test Report Submission

The required documents (a) to (f) are to be submitted within 2 months of import to the CHPB by email: HSA_CPM@hsa.gov.sg. You shall receive an acknowledgement from the CHPB within 1 month from the date of submission of the required documents if they are in order. It is advisable for you to retain the acknowledgement from CHPB till the expiry of the CPM. Please note that there should be no sale / supply of the imported CPM unless and until the required test reports with satisfactory results are submitted.

Please be reminded that non-submission or late submission (exceeding 2 months of import) of the required documents is an offence under the Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 2007.

Application of Certificate for Exporter of CPM (Free Sale Certificate)

Some importing countries may require a certificate to show that a CPM is approved for sale and distribution in Singapore.

To assist in such scenarios, companies may apply for a Certificate for Exporter of CPM, also known as a Free Sale Certificate.

Each certificate is specific to one product and allow the inclusion of up to five importing countries.

Apply online

Annex 1: CPMF5.3_Forensic Classification

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

FORENSIC CLASSIFICATION IN COUNTRIES OF SALES

The forensic classification of the product in the various countries where it is being sold are as follows (please tick where applicable):

Country of sale *	Forensic classification					
	Chinese medicine	Traditional medicine	Complementary medicine (Australia)	Health / dietary supplement	Food	Others (please specify)
China						
Taiwan						
Malaysia						
Australia						
South Korea						
Japan						
USA						

** If product is sold in other countries in addition to those listed above, please also include them in the table above with the appropriate forensic classification in these countries. If the rows in the table are insufficient, please attach the additional information on a separate sheet.*

Name: _____ Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 5.3

Annex 2: CPMF6.3_Website Undertaking

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Website address stated on packaging materials: _____

CHINESE PROPRIETARY MEDICINE (CPM) UNDERTAKING FORM: WEBSITE ADDRESS ON PACKAGING MATERIALS

I _____ (full name) being a person authorised by my company to make this application hereby undertake to:

- Ensure that the product claims on the website would not exceed those which are stated on the final packaging materials for the above product.
- Comply with the Medicines (Medical Advertisements) Regulations 1977, including the need if any, to apply for the relevant advertisement permits for the advertisement and sales promotion of the product on the website. I understand that approval for sale of the above product, where appropriate, does not imply that the product name and/or its claims will be allowed for advertising purposes.
- Refrain from using the CPM product approval as a marketing tool to advertise or promote the above product on the website.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 6.3

Annex 3: CPMF8.3_Advertisement Undertaking

To: Complementary Health Products Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Manufacturer: _____

CHINESE PROPRIETARY MEDICINES (CPM) UNDERTAKING FORM FOR ADVERTISEMENTS

I _____ (full name) being a person authorised by my company to make this application hereby make the following undertaking:

- I understand that the above product, with its product name and claims, is not appropriate for the purpose of advertising and I undertake that that no form of advertisement will be conducted if the product is approved for listing.

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 8.3

Annex 4: CPMF9.5_TSE Undertaking

To: **Complementary Health Products Branch**
Health Products Regulation Group, Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name (English / Chinese): _____

Brand name: _____ Dosage form: _____

Manufacturer: _____

UNDERTAKING FORM: EVIDENCE FOR TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE) STATUS OF ANIMAL-DERIVED MATERIALS**

I _____ (full name) being a person authorised by my company to make this application hereby undertake that the above product complies with the Complementary Health Products Branch (CHPB) TSE Guidelines* of the Health Sciences Authority (HSA) if it contains animal-derived materials**, and I hold evidence to demonstrate that the product is prepared:

i) From animal-derived materials** without any risk of exposure to TSE, and the health authorities in the country of origin has endorsed that they are sourced from TSE-free herds.

ii) By a manufacturing process with adequate measures taken to prevent cross-contamination between different tissues from different categories of infectivity.

iii) By a manufacturing process that has shown experimentally to minimise the TSE transmissible agent, if the above product contains tallow and/or gelatin derived from animal-derived materials** (including those for making capsule shells).

Should the above product be listed by HSA, I shall retain all the necessary evidence at all times while the above product remains listed, and would supply the evidence to HSA if required to do so. I shall report any changes in the TSE status of the animal-derived materials** of the above product to the Complementary Health Products Branch as soon as possible.

I hereby declare that the information on this form is current and correct.

Signature: _____ Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

** The TSE Guidelines for minimising the risk of contamination in CPM is available at the following HSA webpage: http://www.hsa.gov.sg/content/dam/HSA/HPRG/Complementary_Health_Products/CHPB_TSE_guidelines.pdf*

*** From species known to be affected by TSE e.g. ruminants like cattle, buffalo, sheep, goat, deer, antelope etc.*

CPMF 9.5

Annex 5: CPMF10.3_Undertaking Form for Amended Formula

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name of amended formula (English / Chinese): _____

_____

Brand name: _____ Dosage form: _____

Original product name in the country of origin: _____

CHINESE PROPRIETARY MEDICINE (CPM) UNDERTAKING FORM FOR AMENDED FORMULA (修改方)

I _____ (full name) being a person authorized by my company to make this application hereby:

- Confirm the changes to the following ingredients in the original formula for the product to be marketed in Singapore:

S/N	Latin Name	Chinese Name	Remarks*

*To specify the change(s) e.g. deletion, substitution with another ingredient, quantity adjustment to certain % etc.

- Certify that I hold evidence to support the indications and claims on the label and package insert (if any) of the above amended formula.

- Undertake that should the above product (amended formula) be listed by the Health Sciences Authority, I shall retain the evidence at all times while the above product remains listed, and would supply the evidence to the Health Sciences Authority if required to do so.

I hereby declare that the information on this form is current and correct.

Signature: _____

Designation: _____

Name of company: _____

Tel: _____ Fax: _____

Date: _____

CPMF 10.3

Annex 6: CPMF11.4_Info for Fermented Substance

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

Product name 所申请的中成药产品名称：_____

(English / Chinese)（英文/中文）：_____

Brand name 商标名：_____ Dosage form 剂型：_____

Manufacturer 所申请的中成药成品的生产商：_____

INFORMATION REQUIRED FOR FERMENTED SUBSTANCE(S) IN CPM
中成药中所含的发酵成份的信息资料

A. Please fill up the following 请填写以下信息（信息需由生产发酵成份的厂商提供）：

I. Fermented Substance(s) (e.g. Cordyceps, Red Yeast Rice)发酵成份（如虫草菌丝体，红曲）：
1. Species (Please include strain identification report, except for *Monascus pupureus*) 发酵成份所使用的菌种的名称（请附上菌种的鉴定报告，红曲霉菌种不需要提交）
2. Source(s), including the name(s) and address(es) of the manufacturer(s) 发酵成份的来源，请指明其生产商的名称和地址

B. Please fill up and attach the following 请填写以下信息:

I. Fermented Substance(s):发酵成份的外观描述及化学特性	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the specifications and Certificate of Analysis (COA) of the fermented substance(s), including description of physical characteristics such as colour, texture and quantity of active constituents (e.g. adenosine ≥XX%) 请呈交发酵物的规格及检验报告，需注明其物理性状，如颜色和质地等，及其有效化学组分的含量要求（如腺苷≥XX%）	
II. Details of Manufacturing Process of Fermented Substance(s):发酵的详细工艺过程	Name of Document(s) Attached 请呈交文件，并在此注明所附文件名
Please submit the manufacturing process in the form of flowchart(s), and indicate the type of fermentation (e.g. liquid/solid) and conditions used (e.g. temperature, pressure, humidity) 请呈交发酵的工艺流程图，并指明发酵的类型（如固体/液体），以及发酵的条件（如温度、压力、湿度）	
2. Manufacturer's licence and GMP Certificate, where applicable 生产发酵物的厂商的生产许可证及 GMP 证书，如有	

CPMF 11.4 1

C. Please confirm the following and attach the required details where applicable
请确认并根据要求附加详细资料：

I. Details of Manufacturing Process of Fermented Substances: 发酵的详细生产工艺	Yes/No 有/没有	If yes, details to be submitted 如有，请提交相关资料
1. Animal-derived materials used, if any (e.g. animal lipids in culture media) 是否使用来源于动物的成份（如以动物油脂作为培养基），如有		1. List of animal-derived materials 列出使用的来源于动物的成份 2. If ruminant-derived material is used, please attach CPMF9.4* 如含反刍动物成份，需填表格 CPMF9.4*
2. Impurities / By-products produced during manufacturing, if any 杂质/发酵过程的副产品，如有		Allowable impurities / by-products limits / specifications 允许的杂质/发酵过程的副产品的限量/规格
3. Solvents / chemicals used for purification, if any 是否使用溶剂/化学品进行提纯，如有		List of solvents / chemicals 列明所用的溶剂/化学品名
4. Solvents / chemicals used for extraction, if any 是否使用溶剂/化学品进行提取		List of solvents / chemicals 列明所用的溶剂/化学品名
5. Hazardous additives, e.g. bleaching agents used during manufacturing 是否使用了有害的添加剂，如发酵过程中使用漂白剂		List of hazardous additives and the allowable residual limits 列明该添加剂及允许的限量
6. Residues, if any 残留物，如有		Allowable residues limits / specifications 允许的残留物的限量/规格

*CPMF9.4_TSE undertaking form, to be filled up by the local applicant, can be downloaded from the HSA website. 表格 CPMF9.4 可由卫生科学局网站下载，并需由本地的产品申请人填写。

D. Additional Information 其它附加资料：

Details 详细资料	Yes/No 有/没有	If yes, Name of Document(s) Attached 如有，请呈交文件，并在此注明所附文件名
1. Information on system for quality control (e.g. SOPs or workflows to avoid strain mutation, degeneration and contamination in the fermented substance) 质量控制的相关资料（如：避免菌种变异、衰退及污染的标准作业程序或流程）		
2. COA of the fermented substance showing testing of other by-products or toxic substances, 发酵物中可能产生的副产品或有毒物质的检验报告		
3. Composition of culture media used in manufacturing process 生产过程中所使用的培养基的组成成分		

E. Manufacturer of Fermented Substances 生产发酵物厂商的详细资料：

I hereby declare that the above information on this form is current and correct. 我声明以上所提供的信息是完全真实并正确的。

Name 姓名：_____ Designation 职务：_____

Name and address of company 生产发酵物的厂商名称及地址：_____

_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 签名：_____

F. Local Applicant 本地申请者的详细资料:

Should the above CPM product be listed by HSA, I shall report any changes to the above details to the Complementary Health Products Branch as soon as possible. 以上产品若经卫生科学局登记后有任何变更，我会尽快通知辅助医疗保健产品组.

Name 本地申请人的姓名：_____ Designation 职位：_____

Name of company: 本地申请公司的名称：_____

Tel 电话：_____ Fax 传真：_____ Date 日期：_____

Signature 申请人签名：_____

Annex 7a: CPMF13.4a_Storage Condition of CPM - Imported Products

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

STORAGE CONDITION OF CHINESE PROPRIETARY MEDICINES (CPM) – IMPORTED PRODUCTS 中成药产品的贮存条件 – 适用于进口的中成药产品

Product name 产品名称 (English / Chinese) (英文/中文)	
Brand name 商标	
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others* 胶囊 / 颗粒 / 合剂 / 软膏剂 / 丸剂 / 散剂 / 片剂 / 茶剂 /其它* If others, please state: _____ 如为其它,请注明: _____
Pack size 包装规格	

STORAGE CONDITION 贮存条件

Storage temperature (°C) 贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C / 低于 30 °C / 其它* If others, please state: _____ 如为其它,请注明: _____
Relative humidity (%) 相对湿度	Not more than 75% / Others* 不超过 75% / 其它* If others, please state: _____ 如为其它,请注明: _____

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名): _____ Designation (职务): _____

Name of company (公司名称): _____

Tel (电话): _____ Fax (传真): _____ Date 日期: _____

Signature (签名): _____

* Please select the appropriate 请选择适合的选项
CPMF 13.4a

Annex 7b: CPMF13.3b_Storage Condition and Container(s) of CPM - Locally Manufactured or Assembled Products

To: **Complementary Health Products Branch**
Health Products Regulation Group
Health Sciences Authority (HSA)
11 Biopolis Way #11-01 Helios Singapore 138667

STORAGE CONDITION AND CONTAINER(S) OF CHINESE PROPRIETARY MEDICINES (CPM) – LOCALLY MANUFACTURED / PRIMARY ASSEMBLED PRODUCTS
中成药产品的贮存条件和贮存容器 - 适用于本地生产的 / 一级分装的中成药产品

Product name 产品名称 (English / Chinese) (英文/中文)	
Brand name 商标	
Dosage form 剂型	Capsule / Granules / Liquid / Ointment / Pill / Powder / Tablet / Tea / Others* 胶囊 / 颗粒 / 合剂 / 软膏剂 / 丸剂 / 散剂 / 片剂 / 茶剂 /其它* If others, please state: _____ 如为其它,请注明: _____
Pack size(If different material, please submit separate form) 包装规格(如产品有多种包装规格，且使用不同的包装材料,请填写多份表格)	

STORAGE CONDITION 贮存条件

Storage temperature (°C) 贮存温度	Below 25 °C / Below 30 °C / Others* 低于 25 °C / 低于 30 °C / 其它* If others, please state: _____ 如为其它,请注明: _____
Relative humidity (%) 相对湿度	Not more than 75% / Others* 不超过 75%/其它* If others, please state: _____ 如为其它,请注明: _____

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

STORAGE CONTAINER(S) 贮存容器

Primary packaging (immediate layer in contact with the product) **内层包装(直接接触产品的包装)**			
Type of container 容器类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Bottle / Sachet / Blister / Tea bag / Re-sealable bag / Others* **瓶子 / 小袋 / 泡板 / 茶包 / 可开合密封袋 / 其它*** If others, please state: _____ 如为其它,请注明: _____		
Container material 容器材料	Plastic / Glass / Aluminum / Aluminum PVC / Others* 塑料 / 玻璃 / 铝箔 / 铝塑 / 其它* If others, please state: _____ 如为其它,请注明: _____ If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS*		
Tamper-evident 拆封标志	Yes / No* 有 / 没有*		
Protection from moisture 是否加入防潮剂	Yes / No* 有 / 没有*	Protection from light 避光	Yes / No* 有 / 没有*
CONTAINER CLOSURE （FOR BOTTLES) **瓶盖**			
Type of closure system 瓶盖类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Screw cap / Flip-top cap / Pull-off cap / Others* 旋转 / 翻转 / 拉启式 / 其它* If others, please state: _____ 如为其它,请注明: _____		
Closure system material 瓶盖材料	Plastic / Glass / Aluminium / Others* 塑料 / 玻璃 / 铝箔 / 其它* If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS* If others, please state: _____ 如为其它,请注明: _____		

2

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Secondary packaging (if any) **外层包装(如果有)** Is packaging critical (i.e. give additional protection to the product) : Yes / No* 是否为重要包装(会影响产品有效期): 是 / 不是* If yes, please explain purpose (e.g. protect from light, moisture): _____ 如果是,请解释目的(如:避光,防潮): _____	
Type of container 容器类型 (Please refer to Page 4 for pictorial description) (请参阅第四页图示)	Bottle / Box / Bag / Re-sealable bag / Others* 瓶子 / 盒子 / 袋子 / 可开合密封袋 / 其它* If others, please state: _____ 如为其它,请注明: _____
Container material 容器材料	Paper / Plastic / Glass / Aluminum / Aluminium PVC / Others* 纸 / 塑料 / 玻璃 / 铝箔 / 铝塑 / 其它* If others, please state: _____ 如为其它,请注明: _____ If plastic, please indicate if it is PETE / HDPE / UPVC / LDPE / PP / PS* 如为塑料,请指明是 PETE / HDPE / UPVC / LDPE / PP / PS*
Tamper-evident 拆封标志	Yes / No* 有 / 没有*

I hereby declare that the information on this form is current and correct, and undertake to inform the Complementary Health Products Branch if there are any amendments to the above.
我保证所提供的上述信息是正确的,并保证如果有任何修改将会通知辅助医疗保健产品组.

Name (姓名) (Dr/Mr/Mdm/Ms*): _____

Designation (职务): _____ Signature (签名): _____

Name of company (公司名称): _____

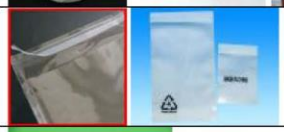
Tel (电话): _____ Fax (传真): _____

Date (日期): _____

Please note that the detail submitted on this form is for Authority's information only.
请注意, 以上信息仅供当局备案.

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Type of storage container 贮存容器的类型

Bottle 瓶子	
Re-sealable bag 可开合密封袋	
Sachet 小袋	
Blister 泡板	
Tea bag 茶包	

Type of closure system 瓶盖类型

Screw cap 旋转	
Flip-top cap 翻转	
Pull-off cap 拉启	
Tamper-evident seals 内包装的拆封标志	

* Please select the appropriate 请选择适合的选项
CPMF 13.3b

Annex 8: Physical Specifications of the Product

Physical specifications required for different dosage forms:

Dosage Form	**Physical Specifications Required**
Capsule	Filling variation
	Water content
	Disintegration
Granules	Filling/filling variation (for single dose packing)
	Water content
	Granules size variation
	Dispersibility
Liquid (Mixture)	Filling/filling variation (for single dose packing)
	pH
	Relative density
	Sucrose content (where applicable)
	Preservatives (where applicable)
Liquid (Syrup)	Filling/filling variation (for single dose packing)
	pH
	Relative density
	Sucrose content (where applicable)
	Preservatives (where applicable)
Liquid (Tincture)	Filling/filling variation (for single dose packing)
	Determination of ethanol
	Determination of methanol

Pills	Filling/filling variation (for single dose packing)
	Weight variation
	Water content
	Disintegration
Powder	Filling/filling variation (for single dose packing)
	Water content
	Uniformity
	Particle size variation
Suppository	Weight variation
	Disintegration
Tablet	Weight variation
	Disintegration
Tea	Filling/filling variation (for single dose packing)
	Water content
	Weight variation (for tea lumps only)
	Dispersibility (for sugar containing tea lumps only)

Please note that for all dosage forms, in addition to the above, the following must be specified:

i. unit weight
ii. minimum fill (for multiple dose product)

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Complementary Health Products Branch
Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-01 Helios
Singapore 138667
www.hsa.gov.sg
T: 6866 1111

HSA
Health Sciences Authority