

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)	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
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	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: _____	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
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

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)	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
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)	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: _____	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.
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

以下内容要求指明产品包装所使用的容器以及容器的制作材料
This section pertains to the product's containers and their packaging materials

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)

要求填入产品最内层即接触到产品的包装的相关信息 Information on the innermost packaging that comes in contact with the product

<p>Type of container: 容器类型</p> <p>(Please refer to Page 4 for pictorial description 请参阅第四页图示)</p>	<p>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*</p>		
<p>Container material: 容器材料</p> <p>指产品的最内层包装是否有折封标志, 即是否可以看出产品曾被开封过。 Please indicate if the packaging has a feature for detection that the product has been opened.</p>	<p>Plastic / Glass / Aluminum / Aluminum PVC / Others* 塑料/玻璃/铝箔/铝塑/其它*</p> <p>If others, please state: _____ 如为其它,请注明: _____</p> <p>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</p>		
<p>Tamper-evident: 拆封标志</p>	<p>Yes / No* 有/没有</p>		
<p>Protection from moisture: 是否加入防潮剂</p> <p>指产品的内层包装中, 是否加有防潮剂 Please indicate if the inner packaging provides protection from moisture (e.g. addition of dessicant)</p>	<p>Yes / No* 有/没有</p>	<p>Protection from light: 避光</p> <p>指产品所使用的内层包装, 是否能避光。(如为透明材料, 则不避光) Please indicate if the inner packaging provides protection from light (e.g. amber bottle).</p>	

CONTAINER CLOSURE (FOR BOTTLES)
瓶盖

<p>Type of closure system: 瓶盖类型</p> <p>(Please refer to the end of this document for pictorial description 请参阅后页图示)</p>	<p>Screw cap / Flip-top cap / Pull-off cap / Others* 旋转/翻转</p> <p>If others, please state: _____ 如为其它,请注明: _____</p>		
<p>Closure system material: 瓶盖材料</p> <p>指产品的内层包装中, 是否加有防潮剂 Please indicate if the inner packaging provides protection from moisture (e.g. addition of dessicant)</p>	<p>Plastic / Glass / Aluminium / Others* 塑料/玻璃/铝箔/其它*</p> <p>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</p> <p>If others, please state: _____ 如为其它,请注明: _____</p>		

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

以下内容要求指明产品除内层包装外, 是否还有外层包装。如果没有, 则不需要填写此项内容。(如果有超过一个外层包装, 请另附一页填写此内容) This section pertains to the product's outer packaging. If not, this section can be left blank. If there is more than 1 outer packaging, please fill up another copy of this section.

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	Bottle / Box / Bag / Re-sealable bag / Others *瓶子/盒子/袋子/可开合密封袋 / 其它
(Please refer to Page 4 for pictorial description 请参阅第四页图示)	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

在此选择适合的选项, 指明产品外层包装所使用的容器种类。Please select the type of container for the product.

在此选择适合的选项, 指明产品外层包装所使用的容器的制作材料。Please select the appropriate material used for the container.

指产品的外层包装是否有折封标志。Please indicate if the packaging has a feature for easy detection of that the product has been opened.

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): _____

Name of company (公司名称): _____

Tel (电话): _____ Fax (传真): _____

Date (日期): _____

Signature (签名): _____

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。