



LABELLING REQUIREMENTS

9.1 GENERAL LABELLING REQUIREMENTS

The following information in **Table 1** shall present on the label of a product at outer carton immediate container or blister/ strips:

No.	Parameters	Outer Carton (Unit Carton)	Immediate Labels	Blister/ Strips
1.	Product Name	✓	✓	✓
2.	Dosage Form	✓	✓*	NA
3.	Name of Active Substance(s)	✓	✓	✓**
4.	Strength of Active Substance(s)	✓	✓	✓**
5.	Batch Number	✓	✓	✓
6.	Manufacturing Date	✓	✓*	NA
7.	Expiry Date	✓	✓	✓
8.	Route of Administration	✓	✓	NA
9.	Storage Condition	✓	✓*	NA
10.	Country's Registration Number	✓	✓*	NA
11.	Name & Address of Product Registration Holder (PRH)	✓	✓*	Name/ Logo of Manufacturer/ Product Owner
12.	Name & Address of Manufacturer	✓ At least name of town/ city and country of manufacturer	✓* At least name of town/ city and country of manufacturer	NA
13.	Warnings and/or Specific Labelling (if applicable)	✓	✓*	NA
14.	Pack Sizes (unit/ volume)	✓	✓	NA

No.	Parameters	Outer Carton (Unit Carton)	Immediate Labels	Blister/ Strips
15.	Name & content of preservative(s) where present	✓	✓	NA
16.	Name & content of alcohol, where present	✓	✓	NA
17.	To declare source of ingredients derived from animal origin (active and excipient) including starting materials and gelatine.	✓	✓	NA
18.	To declare the source of capsule shell (if applicable)	✓	✓	NA
19.	Recommended daily allowance (RDA) for vitamins/ multivitamins/ mineral preparations used as dietary supplements (optional)	✓	✓	NA
20.	The words "Keep medicine out of reach of children" or words bearing similar meaning in both <i>Bahasa Malaysia</i> & English	✓	✓*	NA
21.	Other country specific labelling requirements (if applicable)	✓	✓*	NA
22.	The words "Controlled Medicine/ <i>Ubat Terkawal</i> " (For scheduled poison only)	✓	✓*	NA
23.	Security Label (Hologram)	✓ #	-	NA

NA : Not Applicable

* Exempted for small labels (i.e. 5ml and less) used for ampoules/ cartridge, vials, e drops, ear drops, and nose drops.

** For multi-vitamins and minerals preparations it is suggested to label as mu vitamins and minerals.



LABELLING REQUIREMENTS

Additional notes:

- 1) Declaration of nutrition information per serving (for example energy, carbohydrate, protein and fat) is not permitted in a health supplement product label.
- 2) All labels and package inserts must be in Bahasa Malaysia or English. In addition to this, translation to another language will be allowed.
- 3) Official website of the company or website for any purpose of product promotion from the PRH/ product owner/ manufacturer is not allowed to be printed on the product label (applicable to all categories of products inclusive of imported products). However, the email address of the company is permissible on the label.
- 4) Only a single label artwork is permitted for all pack sizes of a registered product.
- 5) No stick-on label is permitted. Any usage of stick-on label shall have prior approval by the Authority.



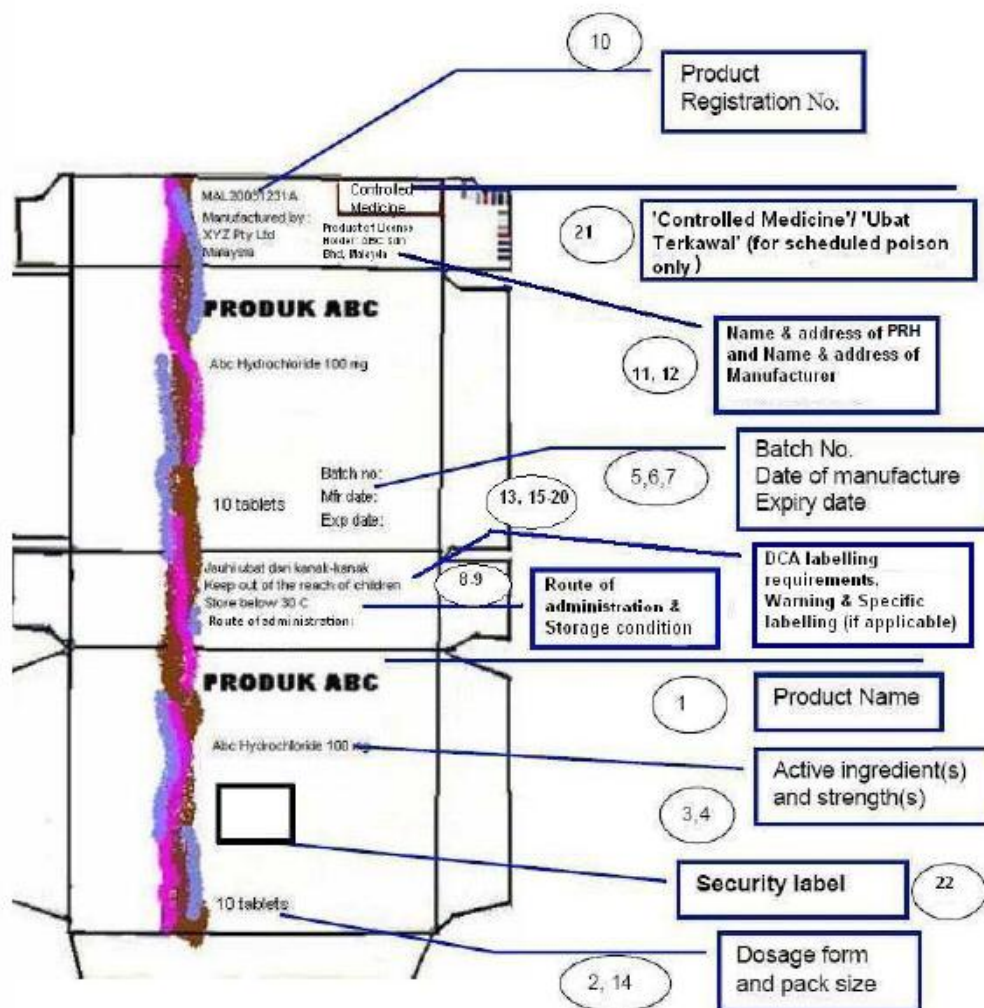
LABELLING REQUIREMENTS:

Additional notes

- 6) Use of QR code is permitted only for the purpose of monitoring inventory of the product, such as batch number, expiry date and manufacturing date, BUT NOT for linkage to any website. The addition of QR code on registered product labels without variation approval from NPRA can be considered only if that is the only proposed change to the currently approved labels.
- 7) Font size of the product name on the label, including alphabets and numbers, should be equal in size.
- 8) For a product containing 2 or more active ingredients, font size of each active ingredient that is highlighted on the inner/ outer carton must be of equal size and equal prominence. Justification for highlighting certain ingredients only on the product name / label must be provided and subject to approval by the Evaluation Committee.



LABELLING REQUIREMENTS: Example





LABELLING REQUIREMENTS: Package insert

The following information is required to be included in the PI:

- a) Brand or Product Name
- b) Name and Strength of Active Substance(s)
- c) Product Description
- d) Pharmacodynamics/
Pharmacokinetics
- e) Indication
- f) Recommended Dosage
- g) Route of Administration
- h) Contraindications
- i) Warnings and Precautions
- j) Interactions with Other Medicaments
- k) Statement on usage during pregnancy and lactation
- l) Adverse Effects/ Undesirable Effects
- m) Overdose and Treatment
- n) Incompatibilities (For injections only)
- o) Storage Conditions (may be omitted if the information is stated on the label or outer carton labels)
- p) Dosage forms and packaging available
- q) Name and address of manufacturer/ product registration holder
- r) Date of revision of PI



PRODUCT INFORMATION: Warnings/precautions/drug interactions/adverse effects

L-ARGININE

Arginine is not recommended for patients following a heart attack

CHITOSAN, CHONDROITIN, FISH OIL

Derived from seafood

GINSENG

Contraindicated in pregnant women. Safe use in lactating women and children has not been established. Do not exceed the stated dose. Safety on long term use has not been established.

ASPARTAME

Unsuitable for phenylketonurics



QUALITY CRITERIA

- Compliance to Good Manufacturing Practice (GMP)
- Product freely sold in country of origin
- Certificate of analysis (COA) of raw material
- In Process Quality Control
- Finished Product Quality Control
- COA Finished Product
- Stability studies
- Protocol analysis



Certificate of Good Manufacturing Practice (GMP)

- Name and address of manufacturer
- Validity of GMP
(e.g. inspection date, issuing & expiry date)
- GMP standard/regulation used
- GMP compliance of the manufacturer



Certificate of Free Sale (CFS)

Must be issued by the competent authority of the:

- Country of **manufacturer**, or
- Country of **product owner**

To provide the following information:

- Product name
- Name and address of manufacturer
- Validity of CFS (e.g. issuing & expiry date)
- The free sale status in the exporting country

“This product is freely sold in ...”



GMP certificate/CFS template

Authority name, address, country

Type of certificate

Company name (product owner/ manufacturer)

Product name

Product formulation if available

Dosage form

Statement of freely sold (similar meaning) if for CFS certificate

Standard of GMP and compliance status if for GMP certificate

Duration of certification

Name, signature and designation of authorized personnel

Date of signature

Note: The certificate must be in English or translated into English
(certified true by issuance or embassy or notary public)



CPP /GMP & CFS

- New issuing body
(Email : issuebody_hs@npra.gov.my)
- If CPP is given → CFS & GMP **not required**
- If CFS & GMP are given → CPP **not required**

Certificate of Analysis of Active Ingredient

- COA of raw material for all active ingredients must be submitted pre-registration.
- To confirm the COA contains the following information:

☐ Correct active ingredient

☐ Complete test results which comply with the specifications

☐ Chemical assays of active ingredient which support the label claims
(e.g. elemental strength of vitamins & minerals, total viable cells of probiotic, enzyme potency, fatty acids profile, extraction ratio of herbal ingredient, percentage of actual active ingredient etc)

☐ Name, post and signature of authorized person

In Process Quality Control

- Summary of the tests performed
- Stages at which they are done
- The frequency of sampling
- Number of samples taken each time
- Specifications for quality assurance

Company Name/ Address:

Applicant/ Client Name/ Address:

Date:

In-Process Quality Control: Test performed during manufacturing process

No.	Test Done (example)	Stage Done (example)	Frequency of testing (example)	Quantity sample taken (example)	Specifications (example)	Method (example)
1.	Appearance	Before weight, after encapsulation	2	10 gram	Blue like orange	Organoleptic test
2.	Disintegration	After compression	2	10 tablet	NMT 30 minutes	Equipment etc
3.	Uniformity of weight	After tableting, Packaging	4	20 Tablets	1 gram/tab	
4.	Microbiology	Final Stage	1			
5.	Heavy metal	Final stage	1			

* Declaration (if any)

Signature (authorized personnel)

Name:

Designation:

*** The above parameters are only as an example; other test may be required for specific product.**

Finished Product Quality Control

COA of Finished Product

- To give details of quality control specifications including a list of tests (for both release and expiry specifications, if they are different) and state the limits of acceptance.
- Reference of each test method must be stated
- Results must meet the specification

**Finished Product Quality Control (FPQC) - Finished product Specification/
Specification Sheet**

Company name/Address:

Product Name:

Batch no.

Dosage form:

Packaging:

Date of manufacture:

Date of expiry:

No.	Test	Method	Specification	Reference
1.	Appearance/ Organoleptic: Odour Colour	Ex: Macroscopic/ Microscopic	To describe the characteristic	In-house/ pharmacopoeia (e.g. BP/USP etc)
2.	Assay: List the active ingredients	HPLC/ GC/ MS/ UV	To specify	To specify
3.	Disintegration/Dissolution	To specify	DRGD	DRGD
4.	Uniformity of weight	To specify		
5.	Water content	To specify		
6.	Microbial contamination TAMC, TYMC, specified microorganism	To specify	DRGD	DRGD
7.	Heavy Metal Contamination: Lead, Arsenic, Cadmium, Mercury	To specify	DRGD	DRGD
8.	Etc:			

Signature:

Name:

Designation: (At least by Quality Assurance Manager or equivalent)

Date of signature:

*** The above parameters are only as an example; other test may be required for specific product.**



1. Limit Test for Heavy Metals

- a) Lead : NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)
- b) Arsenic : NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)
- c) Mercury : NMT 0.5 mg/kg or 0.5 mg/litre (0.5ppm)
- d) Cadmium : NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)

** Required for products with ingredients from natural sources.*

4. Tests for Microbial Contamination, as shown in Table 14 below:

Route of Administration	TAMC (CFU/g or CFU/ml)	TYMC (CFU/g or CFU/ml)	Specified micro-organisms
Non-aqueous preparations for oral use	NMT 2×10^3	NMT 2×10^2	Absence of <i>Escherichia coli</i> (1 g or 1 ml)
Aqueous preparations for oral use	NMT 2×10^2	NMT 2×10^1	Absence of <i>Escherichia coli</i> (1 g or 1 ml)
Special Ph. Eur. provision for oral dosage forms containing raw materials of natural (animal, vegetal or mineral) origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/g or CFU/mL.	NMT 2×10^4	NMT 2×10^2	Not more than 10^2 CFU of bile-tolerant gram-negative bacteria (1 g or 1 ml) Absence of <i>Salmonella</i> (10 g or 10 ml) Absence of <i>Escherichia coli</i> (1 g or 1 ml) Absence of <i>Staphylococcus aureus</i> (1 g or 1 ml)

Notes:

TAMC : Total Aerobic Microbial Count

TYMC : Total Yeasts & Moulds Count

NMT : Not more than

[Reference: British Pharmacopoeia 2012]



Stability Data

- To be conducted in accordance with the current **ASEAN Guidelines on Stability Study**
- Real time stability study:
 - Storage condition: ZON IVB $30\pm 2^{\circ}\text{C}/75\pm 5\%\text{RH}$
 - Testing frequency: 0, 3, 6, 9, 12, 18, 24 months and annually for the proposed shelf life.



Stability Data: Required data

- 2 batches submitted
- Company name (holder/ manufacturer/ 3rd party lab)
- Product name
- Dosage form
- Packaging particulars (e.g. material, pack size, etc)
- Storage condition (e.g. temperature, humidity)
- Frequency of testing
- Period of stability study
- All tests required for each dosage form should be conducted
- Specifications (acceptance limit)
- Results for each test
- Approval from authorized person (name and designation)



Stability Data: Required data

Testing Parameters of Stability Study for each type of dosage forms are shown in **Table** below:

Testing Parameters Dosage Form	Appearance/ organoleptic (odor, color, taste)	Assay*	Hardness/ friability	Disintegration or dissolution rate	Moisture content	Viscosity	pH	Microbial content	Granules/ Particle Size variation	Re-suspendingability
Oral powder	√	√			√			√		
Hard capsule	√	√		√	√			√		
Soft capsule	√	√		√				√		
Coated and Uncoated Tablet	√	√	√ (uncoated)	√	√			√		
Coated and Uncoated Pill/ Pellet	√	√		√	√			√		
Suspension	√	√				√	√	√	√	√
Solution	√	√				√	√	√		
Emulsion	√	√				√	√	√		
Granules	√	√			√			√	√	



Formerly known as National Pharmaceutical Control Bureau (BPFK)
NATIONAL PHARMACEUTICAL REGULATORY AGENCY
AGENCI REGULATORI FARMASI NEGARA | KEMENTERIAN KESIHATAN MALAYSIA

MINISTRY OF HEALTH MALAYSIA / KEMENTERIAN KESIHATAN MALAYSIA

Post-Registration Changes



Variation

- ❑ Definition:
 - ❑ change of particulars of a registered product.



Variation

- ❑ Throughout the registration validity period of a product, the product registration holder is responsible for the product that is placed in the market and to make any amendments to the registration dossier based on any technical and scientific progress regarding the product
- ❑ Such amendments have to be approved by NPRA



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Variation

Malaysian Variation Guideline for Natural (Traditional Medicine & Homeopathy) and Health Supplement Product
2016



Lampiran 1



**NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH MALAYSIA**

**MALAYSIAN VARIATION GUIDELINE FOR
NATURAL (TRADITIONAL MEDICINE& HOMEOPATHY)
AND HEALTH SUPPLEMENT PRODUCTS
(ABRIDGED EVALUATION)
2016**

First Edition – July 2016

LIST OF CONTENTS

	Page
1 INTRODUCTION	4
2 SCOPE OF THIS GUIDELINE	4
3 DEFINITION	4
3.1 Major Variation (MaV)	4
3.2 Minor Variation (MiV)	4
4 PROCEDURE AND TIMELINE	5
5 CHANGES LEADING TO A NEW PRODUCT REGISTRATION	7
6 OTHERS	8
7 MAJOR VARIATION (MaV)	
MaV-1 Change and/or addition of indication/dosing regimen/patient population	9
MaV-2 Change of product labeling (subject to labeling requirements as per Drug Registration Guidance Document)	9
MaV-3 Change of the specification of drug substance(active ingredient)	10
a)Widening of limits	
b)Removal of test parameter	
MaV-4 Change of the manufacturing site of the drug product	10
MaV-5 Replacement of site for primary packaging (direct contact with drug product)	11
MaV-6 Change in the manufacturing process for drug product	11
MaV-7 Change of the specification of drug product	12
a)Widening of limits	
b)Removal of test parameter	
MaV-8 Qualitative or quantitative change of excipient	13
MaV-9 Change in colour, size and/or source of hard capsule shell	14
MaV-10 Change in primary packaging material	14
a) Qualitative and quantitative composition and/or	
b) Type of container and/or	
c) Inclusion of new primary packaging material	
MaV-11 Change of overage of drug substance (active ingredient)	15
MaV-12 Change of shelf-life of the drug product	15
MaV-13 Change of storage conditions of the drug product	16
8 MINOR VARIATION PRIOR APPROVAL (MiV-PA)	
MiV-PA1 Change of drug product name	17
MiV-PA2 Change of Consumer Medication Information Leaflet (RiMUP)	17
MiV-PA3 Change and/or addition of manufacturer/ manufacturing site/ supplier of	17



LIST OF CONTENTS

Page

	a) Drug substance (active ingredient)	
	b) Excipients in premixed form	
MiV-PA4	Change of the specification of drug substance (active ingredient)	18
	a) Tightening of limits	
	b) Addition/replacement of new test parameter	
MiV-PA5	Replacement of the company or party responsible for batch release	18
MiV-PA6	Change of the specification of drug product	19
	a) Tightening of limits	
	b) Addition/replacement of new test parameter	
MiV-PA7	Change of the specification of drug substance (active ingredient)/drug product within compendial limits	19
MiV-PA8	Change of in-process controls applied during the manufacture of the drug product (including tightening and addition of new in-process test)	19
MiV-PA9	Change of batch size of drug product	20
MiV-PA10	Change of imprints, bossing or other markings on tablets or printing on capsules including addition or change of inks used for product marking	20
MiV-PA11	Change in the test procedure of the drug product (including replacement or addition of a test procedure)	21
MiV-PA12	Replacement of a manufacturer for secondary packaging/repacker	21
MiV-PA13	Change of pack size/fill volume/carton pack sizes and/or change of shape or dimension of container or closure	21
MiV-PA14	Change in secondary packaging or any part of the primary packaging material not in contact with the finished product formulation such as colour of flip-off caps	22
MiV-PA15	Addition or replacement of measuring device for oral liquid dosage forms and other dosage form	22
MiV-PA16	Change of dimensions and/or shape of tablets, suppositories or pessaries without change in qualitative and quantitative composition and mean mass	22
9	MINOR VARIATION NOTIFICATION (MiV-N)	
MiV-N1	Change of details of product registration holder	23
MiV-N2	Change of importer and/or store address	23
MiV-N3	Change of product owner	24
MiV-N4	Change in ownership of manufacturer	24
MiV-N5	Change of the name or address (for example: postal code, street name) of the manufacturer of drug product	25
MiV-N6	Change of the name or address (for example: postal code, street name) of the company or manufacturer responsible for batch release	25

LIST OF CONTENTS

Page

MiV-N7	Withdrawal/deletion of the alternative manufacturer/ manufacturing site/ supplier of drug substance (active ingredient)	26
MiV-N8	Deletion of pack size for a drug product	26
10	GLOSSARY	26
11	REFERENCES	26



Variation

The following changes require new product registration (for health supplement products):

1. Changes to the active ingredient.

- Change of an active ingredient to a different active ingredient.
- Inclusion of an additional active ingredient to the product.
- Removal of an active ingredient from the product.
- Change in the strength of one or more of the active ingredients including change in the percentage of standardized extract and assay of the principal active constituent/s (exception for vitamins and minerals as per pharmacopoeia).
- Increase in overage (exception for vitamins and minerals as per pharmacopoeia).



Variation

The following changes require new product registration (for health supplement products):

2. Changes to the dosage form.
3. Changes in the route of administration.
4. Addition of a new manufacturer to a registered product.
5. Change from a currently approved contract manufacturer or own plant (local or overseas) to another overseas contract manufacturer not under crisis situation.
6. Changes from general claims to functional claims or general claims/ functional claims to disease risk reduction for HS.



Challenges for HS registration

- ☐ New active ingredients
- ☐ Products of new combinations of active ingredients
- ☐ New claims
- ☐ New technology (e.g. bilayer technology)
- ☐ New invention (e.g. new dosage form, extended release/slow release)

THANK YOU

References

Drug Registration Guidance Document
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