

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, eye drops, ear drops, and nose drops.

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