



THE RELIGIOUS COUNCIL  
NEGARA BRUNEI DARUSSALAM

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# GUIDANCE DOCUMENT

## BRUNEI DARUSSALAM GUIDELINES FOR MANUFACTURING AND HANDLING OF HALAL MEDICINAL PRODUCTS, TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS

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NEGARA BRUNEI DARUSSALAM

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**The Religious Council  
Negara Brunei Darussalam**

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FOR MANUFACTURING AND HANDLING  
OF HALAL MEDICINAL PRODUCTS,  
TRADITIONAL MEDICINES AND HEALTH  
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Attention is drawn to the fact that this Brunei Darussalam Standard/Guidelines does not confer any immunity from legal obligations in any contract for compliance to the Standard.

The Brunei Darussalam Standards/Guidelines are subjected to periodical review according to the current needs of the local *halal* medicinal products, traditional medicines and health supplements industries to keep abreast of progress in the industries concerned. Suggestions of amendments will be recorded and in due course brought to the notice of the committees concerned.

Amendments issued since publication

Amendment No.	Date of Issue	Text Affected

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## COMMITTEE REPRESENTATION

The Technical Committee on the Development of National Halal Standards and/or Guidelines for Halal Medicinal Products, Traditional Medicines and Health Supplements that developed this guidelines consists of representatives from the following organisations:

Attorney General's Chambers, Prime Minister's Office

Brunei Economic Development Board

Construction, Planning and Research Unit, Ministry of Development

Department of Agriculture and Agrifood, Ministry of Industry and Primary Resources

Department of Pharmaceutical Services, Ministry of Health

Department of Religious Council, Ministry of Religious Affairs

Department of Syariah Affairs, Ministry of Religious Affairs

Halal Food Control Division, Department of Syariah Affairs, Ministry of Religious Affairs

Islamic Legal Unit, Ministry of Religious Affairs

National Standards Centre, Ministry of Industry and Primary Resources

Representatives from Private Sectors

State Mufti's Office, Prime Minister's Office

Universiti Brunei Darussalam

Universiti Islam Sultan Sharif Ali

## WORKING GROUP REPRESENTATION

The Working Group on Guidelines for Halal Medicinal Products, Traditional Medicines and Health Supplements drafted the Brunei Darussalam Guidelines for Manufacturing and Handling of Halal Medicinal Products, Traditional Medicines and Health Supplements, consists of representatives from the following organisations:

Brunei Economic Development Board

Department of Agriculture and Agrifood, Ministry of Industry and Primary Resources

Department of Pharmaceutical Services, Ministry of Health

Department of Religious Council, Ministry of Religious Affairs

Halal Food Control Division, Department of Syariah Affairs, Ministry of Religious Affairs

Islamic Legal Unit, Ministry of Religious Affairs

State Mufti's Office, Prime Minister's Office

## PREAMBLE

The Brunei Darussalam Guidelines for Manufacturing and Handling of Halal Medicinal Products, Traditional Medicines and Health Supplements was prepared by The Technical Committee on the Development of National Standards and/or Guidelines for Halal Medicinal Products, Traditional Medicines and Health Supplements, under the authority of the Religious Council, Brunei Darussalam.

The guidelines are published to address the requirements for the manufacturing and handling of *halal* medicinal products, traditional medicines and health supplements to fulfil the religious duty of collective obligation (*Fardhu Kifayah*) by making available *halal* medicinal products, traditional medicines and health supplements and also with the purpose of enhancing trade and business in Brunei Darussalam.

The major areas encompassed by the guidelines include sourcing of starting material(s), manufacturing, packaging, transportation and storage of *halal* medicinal products, traditional medicines and health supplements. The guidelines are designed not to compromise the Good Manufacturing Practice requirements for medicinal products, traditional medicines and health supplements adopted by the Brunei Darussalam Medicines Control Authority or relevant drug regulatory authority in respective countries.

## 1. Scope

The scope of the Brunei Darussalam Guidelines for Manufacturing and Handling of Halal Medicinal Products, Traditional Medicines and Health Supplements are as follows:

- 1.1 To recommend measures to be taken on the sourcing of starting material(s), manufacturing, packaging, transportation and storage of *halal* medicinal products, traditional medicines and health supplements.
- 1.2 To use the term *halal* in accordance with *Hukum Syara'* on the certification and labelling of *halal* medicinal products, traditional medicines and health supplements.

It is intended to supplement the Guide to Good Manufacturing Practice for Medicinal Products that is internationally recognized including from the World Health Organization (WHO), Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and do not supersede any prohibition contained therein.

## 2. Definition

For the purpose of these guidelines, the following definitions apply:

### 2.1 Arabic Script

To avoid any doubts as to the identity or definition of any of the words and expressions used in these Guidelines and listed in the first column of **Annex A**, reference can be made to the original form in Arabic script with respect to the words and expressions in the second column of the Annex.

### 2.2 Brunei Darussalam Medicines Control Authority

An authority established under Section 5 of the Medicines Order, 2007 where its functions are as mentioned under Section 6 of the Medicines Order, 2007.

### 2.3 Competent Authority

Competent authority shall be the agency which is entrusted by the Government of Brunei Darussalam to carry out specified work according to prescribed requirements.

### 2.4 Enzyme

A protein that catalyzes chemical reactions of other substances without itself being destroyed or altered upon completion of the reaction.

### 2.5 Finished Product

A medicinal, traditional medicine or health supplement product that has undergone all stages of manufacture, including packaging in its final container and labelling.