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Committee representation

The Industry Standards Committee on Halal Standards (ISC I) under whose authority this Malaysian Standard was developed, comprises representatives from the following organisations:

Department of Islamic Development Malaysia
Department of Standards Malaysia
Department of Veterinary Services
Federation of Malaysian Manufacturers
Halal Industry Development Corporation Sdn Bhd
Institute of Islamic Understanding Malaysia
International Islamic University Malaysia
Malaysian Association of Standards Users
Institute of Quality Malaysia
Malaysian Agricultural Research and Development Institute
Ministry of Domestic Trade, Co-operatives and Consumerism
Ministry of Health Malaysia (Food Safety and Quality Division)
Ministry of Health Malaysia (National Pharmaceutical Control Bureau)
Ministry of International Trade and Industry
Muslim Consumers' Association of Malaysia
SIRIM Berhad (Secretariat)

Co-opted member:

Yayasan Ilmuwan

The Technical Committee on Halal Food and Islamic Consumer Goods which developed this Malaysian Standard consists of representatives from the following organisations:

Department of Agriculture Malaysia
Department of Fisheries Malaysia
Department of Islamic Development Malaysia (Halal Hub Division)
Department of Islamic Development Malaysia (Research Division)
Department of Veterinary Services
Federal Territory Mufti Office
Federation of Malaysian Manufacturers
Federation of Marketing Authority
Halal Industry Development Corporation Sdn Bhd
Institute of Islamic Understanding Malaysia
Malaysian Agricultural Research and Development Institute
Malaysian Association of Standards Users
Ministry of Agriculture and Agro-based Industry
Ministry of Domestic Trade, Co-operatives and Consumerism
Ministry of Health Malaysia (Food Safety and Quality Division)
Ministry of International Trade and Industry
Muslim Consumers' Association of Malaysia
Royal Customs of Malaysia
SIRIM Berhad (Secretariat)
SIRIM QAS International Sdn Bhd (Chemical Testing Section)
SIRIM QAS International Sdn Bhd (Product Certification Section)
Universiti Kebangsaan Malaysia
Universiti Putra Malaysia
Universiti Teknologi MARA

Co-opted members:

Department of Islamic Development Malaysia (Hub Halal Division)
Malaysian Organisation of Pharmaceutical Industries
Ministry of Health Malaysia (National Pharmaceutical Control Bureau)
Ministry of Health Malaysia (Pharmaceutical Services Division)
Pharmaceutical Association of Malaysia
Universiti Sains Malaysia

FOREWORD

This Malaysian Standard was developed by the Technical Committee on Halal Food and Islamic Consumer Goods under the authority of the Industry Standards Committee on Halal Standards.

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.

Halal pharmaceuticals - General guidelines

1 Scope

This Malaysian Standard describes the general guidelines in the manufacturing and handling of halal pharmaceuticals. It serves as a basic requirement for halal pharmaceuticals in Malaysia.

NOTE. This standard does not necessarily contain all requirements which may be required for certification. Halal certification may be sought by arrangement with the competent Islamic authorities in Malaysia.

2 Normative references

The following normative references are indispensable for the application of this standard. For dated reference, only the edition cited applies. For undated reference, the latest edition of the normative references (including any amendments) applies.

Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products[1]

Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guide to Good Manufacturing Practice for Medicinal Products Annexes[1]

3 Terms and definitions

For the purpose of this standard, the following terms and definition shall apply.

3.1 pharmaceuticals

Pharmaceutical products in finished dosage forms, and includes both prescription and non-prescription medicinal products for human use which is registered with the Drug Control Authority, Ministry of Health Malaysia.

NOTE. Examples may include biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products.

3.2 halal pharmaceuticals

Products that contain ingredients permitted under the *Shariah* law and fulfill the following conditions:

a) do not contain any parts or products of animals that are non-halal by *Shariah* law or any parts or products of animals which are not slaughtered according to *Shariah* law;

b) do not contain *najs* according to *Shariah* law;

c) safe for human use non-poisonous, non-intoxicating or non-hazardous to health according to prescribed dosage;

[1] From hereafter, these documents will be referred to as PIC/S GMP Guidelines and PIC/S Annexes.

d) not prepared, processed or manufactured using equipment contaminated with *najs* according to *Shariah* law;

e) do not contain any human parts or its derivatives that are not permitted by *Shariah* law; and

f) during its preparation, processing, handling, packaging, storage and distribution, the halal pharmaceutical products are physically separated from any other pharmaceutical products that do not meet the requirements stated in items a), b), c), d) or e) or any other items that have been decreed as non-halal and *najs* by *Shariah* law.

3.3 Shariah law

3.3.1 The order of Allah which relate to the action of the people who are being accountable (*mukallaf*) by obligation, option or *al wadh'u*[2].

3.3.2 *Shariah* law defined by Malaysia law means the laws of Islam in the *Mazhab* of Shafie or the laws of Islam in any of the other *Mazhabs* of Maliki, Hanafi and Hambali or *fatwa* issued by the Islamic Authority.

3.4 halal

Items or actions permitted by Shariah law without punishment imposed on the doer.

3.5 *najs*

3.5.1 *Najs* according to *Shariah* law are:

a) dogs, pigs, their descendents and derivatives;

b) halal pharmaceuticals that are contaminated with items that are non-halal;

c) halal pharmaceuticals that come into direct contact with items that are non-halal;

d) any liquid and objects discharged from the orifices of human beings or animals;

NOTES:

1. The examples are urine, blood, vomit, pus, placenta, excrement and sperm and ova of pigs and dogs except sperm and ova of other animals.

2. Milk, sperm and ova of human and animals, except dog and pig, are not *najs*.

e) *maitah* or carrion or halal animals that are not slaughtered according to *Shariah* law; and

f) *khamar*[3] and food or drink which contain or mixed with *khamar*.

3.5.2 There are three types of *najs:*

a) *mughallazah* which is considered as severe *najs* which are dogs and pigs *(khinzir)* including any liquid and objects discharged from their orifices, descendants and derivatives;

NOTE. Examples may include porcine derived gelatin, insulin and hormones.

[2] *Al wadh'u* is a requirement prior to the implementation of any action that permissible according to *Shariah* law, e.g. the usage of medicine via oral, apply, injection, drops or others are allowable as long as the medicine is free from najs.
[3] Such as alcoholic beverages and intoxicant.

b) *mukhaffafah* which is considered as light *najs*. The only *najs* in this category is urine from a baby boy at the age of two years and below who has not consumed any other food except his mother's milk; and

c) *mutawassitah* which is considered as medium *najs* which does not falls under severe or light *najs* such as vomit, pus, blood, *khamar*, carrion, liquid and objects discharged from the orifices.

3.6 competent authority

Agency which is entrusted by the government to carry out specified work according to prescribed requirements.

NOTE. In Malaysia there are various competent authorities which are responsible in respective areas such as Islamic affairs, halal certification, animal health, public health, drug regulatory control; etc.

3.7 manufacture

All operations starting from the sourcing of materials and products through to production, packaging, quality control, release, storage, and shipment (from storage related to the manufacturing site) of finished products, and the related controls. Manufacture shall also include re-packaging and re-labelling operations.

3.8 manufacturing premise

Any building or any other structure, permanent or otherwise together with the land on which the building, or other structure is situated and any adjoining land used in connection with the preparation, processing, handling, packaging, storage, and distribution of any halal pharmaceuticals.

3.9 materials

3.9.1 starting materials

Any substance used in the production of halal pharmaceuticals.

3.9.2 packaging material

Any material employed in the packaging of halal pharmaceuticals, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

4 Requirements

For the purpose of halal pharmaceuticals, the following requirements shall be incorporated with PIC/S GMP Guidelines and PIC/S Annexes currently being enforced by the relevant competent authority.

4.1 Quality management

The organisation shall ensure that the halal pharmaceuticals are manufactured according to halal requirements.

4.2 Management responsibility

The management shall ensure that the Halal Assurance System shall be comprehensively designed and correctly implemented by way of incorporating application of halal, Good Manufacturing Practice and Quality Control. The system shall be fully documented and the effectiveness monitored.

The senior management shall be responsible to ensure that the participation and commitment by staffs in many different departments and at all levels within the company, the company's suppliers and distributors are acquired.

4.3 Halal Assurance System

The Halal Assurance System shall be appropriate for the manufacturing of halal pharmaceuticals and shall be ensured that:

a) the pharmaceuticals are designed and developed in a way that comply with the requirements of halal and Good Manufacturing Practice;

b) the production and control operations are clearly specified and Good Manufacturing Practice adopted;

c) the processing line be operated for halal pharmaceuticals only and in the case of converting the processing line which contained or contaminated with *najs al-mughallazah* to a halal production line then the ritual cleansing method, refer to Annex A, by *Shariah* law shall be required.

4.4 Fundamentals for halal pharmaceuticals in GMP

The requirements describe in the PIC/S GMP Guidelines and PIC/S Annexes are integral part of the Standard and shall be referred to for Halal Pharmaceuticals.

4.4.1 The main control point is on the source of materials and utilities that come in-contact with the products

4.4.2 The requirements to Good Manufacturing Practice for halal pharmaceuticals are listed below:

a) All materials are clearly defined with evidence of complying with *Shariah* requirements.

b) All necessary facilities and resources for halal compliance are provided including availability of:

   i) appropriately qualified and trained personnel;

   ii) adequate premises, space and services;

   iii) dedicated equipment and line;

   iv) correct materials, containers and labels;

   v) approved procedures and instructions; and

   vi) dedicated storage and transport.

c) All records are made, manually and/or by recording instruments, during manufacture which shall demonstrate that all the steps required by the defined procedures and instructions were taken and that the quantity and quality of the product are as expected. Any significant deviations are fully investigated and documented.

d) All records of manufacturing including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.

e) The distribution of the products minimises any risk to their halal integrity.

f) A system is available to recall any batch of product, from sale or supply.

g) Any complaint about marketed products are examined and the causes of halal non-compliance investigated. The appropriate measures in respect of the non-compliance are taken and shall prevent re-occurrence.

4.5 Halal Quality Control

Halal Quality Control is to ensure all materials used are halal compliant. The purchase, handling and sourcing of chemicals, reagents, apparatus, equipment and other items required for sampling and testing shall not be made from any source that is decreed as non-halal by *Shariah* law.

4.6 Personnel and responsibility

4.6.1 The organisation shall ensure that there are sufficient qualified personnel available to establish and maintain a satisfactory Halal Assurance System. All personnel shall be aware of the principles of halal and receive initial and continues training relevant to their needs.

4.6.2 The organisation shall establish a committee which is led by a trained Muslim personnel. The committee shall consist of purchasing personnel and fulfill a minimum 2/3 Muslim quorum and they are responsible to ensure the effectiveness in the implementation of the Halal Assurance System.

4.7 Training

4.7.1 The organisation shall provide training for all personnel on the halal principles and its application.

4.7.2 Continues training shall be given, and its practical effectiveness shall be periodically assessed. The training programmes shall be available and approved by the halal committee. All training records shall be kept.

4.8 Personal hygiene

Strict personal hygiene is an integral requirement for halal and shall be adequately addressed and in compliance with the PIC/S GMP Guidelines and PIC/S Annexes.

4.9 Premise and equipment

4.9.1 The premise shall be situated in an environment which, when considered together with measures to protect the manufacturing process, presents no risk of causing contamination of non-halal materials or products. The layout and design shall conform to the requirements of the PIC/S guidelines.

4.9.2 The premise shall be effectively separated and well insulated from pig farm activities and others, in order to prevent cross contamination through air, water, sewerage, personnel and equipment.

4.9.3 The premise shall observe to an Islamic value and practice. The presence of non-conformance items shall be prohibited within the premise.

4.9.4 The premise and equipment used for processing halal pharmaceutical products shall not be made of or contain any materials that are decreed as non-halal and *najs* by *Shariah* law and shall be used only for manufacturing of halal pharmaceutical products.

4.9.5 The premise and equipment which were previously used or in contact with *najs al-mughallazah* shall be washed and ritually cleansed as required by *Shariah* law. Refer to Annex A for the method of washing and ritual cleansing according to *Shariah* law for *najs al-mughallazah*.

4.9.6 In the case of converting *najs al-mughallazah* line or processing line containing *najs al-mughallazah* into halal production line, the line shall be washed and ritually cleansed as required by *Shariah* law. This procedure shall be supervised and verified by the competent authority. Upon converting into halal production line, the line shall be operated for halal pharmaceutical products only. Repetition in converting the line to *najs al-mughallazah* line and back to halal line, shall not be permitted.

4.10 Production and storage areas

There shall be dedicated and self-contained facilities available for the production and storage of halal pharmaceutical products. This is important to prevent the risk of product contamination becoming non-halal.

4.11 Quality control areas

When handling and conducting quality control activities in the production area, the operations for control laboratories shall take precaution to prevent contamination on production line which may cause product to be non-halal.

4.12 Ancillary areas

4.12.1 Prayer rooms shall be provided and appropriately located.

4.12.2 Animal houses shall be well isolated from other areas, with separate entrance (animal access) and air handling facilities.

4.13 Documentation

The Halal Assurance System shall be documented including evidence of materials origin and shall be approved, signed and dated by authorised Muslim personnel. The documents required shall include but not limited to:

a) Halal certificates from recognised certification bodies;

b) Product data sheet which contain complete description on the materials source of origin and method of processing; and

c) Manufacturing formula and processing instructions.

NOTE. The documents shall be verified by the manufacturer.

4.14 Production

The production operations shall follow clearly defined procedures and comply with halal principles.

4.15 Materials

All materials used in manufacturing of halal pharmaceuticals include starting and packaging materials. Materials may be from synthetically or naturally derived sources.

All *najs* are prohibited.

4.15.1 Synthesized materials

The sources and processing of synthesized materials shall comply with halal requirements. The usage of synthetic alcohol is permissible.

4.15.2 Natural materials

The usage of all natural materials that are poisonous, intoxicating or hazardous to health may be used as allowed by the competent authority.

4.15.2.1 Plants

All types of plants and plant products and their derivatives are halal except those prohibited by the competent authority.

4.15.2.2 Animals

Animals can be divided into two categories and are described as follows:

a) Land animals

All land animals are halal for pharmaceutical purposes except the following:

i) animals with long pointed teeth or tusks which are used to kill prey such as tigers, bears, elephants, cats, monkeys, etc.;

ii) predator birds such as eagles, owls and etc.;

iii) pests and/or poisonous animals such as rats, cockroaches, centipedes, scorpions, snakes, wasps and other similar animals;

iv) animals that are forbidden to be killed in Islam such as bees (*al-nahlah*), woodpeckers (*hud-hud*), etc.;

v) creatures that are considered repulsive such as lice, flies, etc.;

vi) farmed halal animals which are intentionally and continually fed with *najs*;

vii) animals forbidden to be eaten in accordance to *Shariah* law such as donkeys and mules; and

viii) all of the above and other animals that prohibited by the competent authority.

b) Aquatic animals

All aquatic animals are halal except those prohibited by the competent authority. Animals that live both on land and water such as crocodiles, turtles and frogs are not halal.

Aquatic animals which live in *najs* or intentionally and/or continually fed with *najs* are not halal.

4.15.2.3 Minerals

Minerals are any non-organic homogenous solid substances of the earth's crust. All minerals are halal except those prohibited by the competent authority.

4.15.2.4 Micro-organisms

Microscopic organism are those of medical interest include bacteria, viruses, fungi and protozoa. All micro-organisms are halal except those prohibited by the competent authority

Any organism of microscopic size from 10^{-6} µ to 10^{-9} µ including bacteria, rickettsiae, viruses, fungi and etc.

4.15.2.5 Natural chemicals

All natural chemicals are halal except those prohibited by the competent authority.

4.15.2.6 Genetically modified organisms (GMO)

Products and/or by-products of genetically modified organisms (GMOs) or ingredients made by the use of genetic material of animals that are decreed as halal by *Shariah* law.

4.16 Packaging materials

4.16.1 The consumable and non-consumable packaging and printed materials shall be from any origin that is decreed as halal by *Shariah* law.

4.16.2 The packaging design, sign, symbol, logo, name and picture shall not be misleading and/or contravening the principles of *Shariah* law.

4.17 Contract manufacture and analysis

Contract manufacture and analysis shall be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of satisfactory quality and that is decreed as halal by *Shariah* law. There shall be a written contract between the contract giver and the contract acceptor which clearly establishes the duties of each party which include complying with the halal requirements.

4.18 Self inspection

Self inspections shall be conducted in order to monitor the implementation and compliance with halal and Good Manufacturing Practice principles and to propose necessary corrective and preventive measures.

4.19 Legal requirements

Halal pharmaceuticals shall in other aspects comply with legislation including other relevant requirements currently in force in Malaysia.

5 Compliance

For halal pharmaceuticals deemed to comply with this standard, it shall comply with Clause 4 of this standard. This shall be verified through site inspection as deemed necessary by the competent authority.

6 Halal certificates

The halal certificates shall be issued by the competent authority in Malaysia.

7 Halal certification mark

Upon approval by the drug control authority in Malaysia, each halal pharmaceutical may be marked with the halal certification mark of the Islamic authority.

Annex A
(normative)

Method of washing and ritual cleansing according to *Shariah* law for *najs al-mughallazah*

A1 General requirements

Method to cleanse n*ajs al-mughallazah* either visible[4] or invisible[5]:

a) it is required to wash seven times, one of which shall be water mixed with soil;

b) the first wash shall be to clear the existence of *najs*, even if a few washes are needed. The water from first cleaning shall not remain behind and the next wash shall be counted as the second wash;

c) the amount of soil used is just enough to sufficiently change the physical appearance of water from clear to turbid; and

d) the usage of cleansing agent containing soil is permitted.

NOTE. The ritual cleaning process may be performed by method of spraying or rinsing.

A2 Conditions of the soil

The conditions of the soil shall be:

a) free from *najs*;

b) free from contaminants; and

c) not *musta'mal* soil [which had been used for dry ablution (*tayammum*)] except after subject to heavy rain.

A3 Condition of the water

The conditions of the water are:

a) shall be natural (*mutlaq*);

b) not *musta'mal*[6]; and

c) free from najs.

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[4] Visible najs (*'ainiyah*) are najs that appearded pyysically present in the stool can be seen and touched

[5] Invisible najs (*hukmiyah*) are najs that have lost the physical form, dried or otherwise.

[6] *Musta'mal* water is the water that is less than two *qullah* (approximately 192 L) that had been used for cleansing.

A4 Validation

The ritual cleansing process shall be followed by cleaning procedures which is validated.

Acknowledgements

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