MALAYSIAN STANDARD

MS 2424:2019

Halal pharmaceuticals – General requirements (First revision)

ICS: 11.120.99

Descriptors: halal, pharmaceutical, requirements, manufacturing, handling, certification

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Committee representation

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

Department of Chemistry Malaysia
Department of Islamic Development Malaysia
Department of Standards Malaysia
Department of Veterinary Services
Federal Agricultural Marketing Authority
Federation of Malaysian Manufacturers
Halal Industry Development Corporation Sdn Bhd
Institute of Islamic Understanding Malaysia
Institute of Quality Malaysia
International Islamic University Malaysia
Malaysian Agricultural Research and Development Institute
Malaysian Association of Standards Users
Ministry of Domestic Trade, Co-operatives and Consumerism
Ministry of Health Malaysia (Food Safety and Quality Division)
Ministry of Health Malaysia (Medical Device Authority)
Ministry of Health Malaysia (National Pharmaceutical Regulatory Agency)
Ministry of International Trade and Industry
Muslim Consumers' Association of Malaysia
National Metrology Institute of Malaysia
Royal Customs Department
Universiti Sains Islam Malaysia

The Technical Committee on Halal Pharmaceuticals which supervised the development of this Malaysian Standard consists of representatives from the following organisations:

Department of Islamic Development Malaysia (Halal Hub Division)
Department of Islamic Development Malaysia (Fatwa Division)
Department of Standards Malaysia (Secretariat)
Federation of Malaysian Manufacturers
Halal Industry Development Corporation
Malaysian Organisation of Pharmaceutical Industries
Malaysian Pharmaceutical Society
Ministry of Defence Malaysia, Malaysian Armed Forces Headquarters (Health Services Division)
Ministry of Health Malaysia (National Pharmaceutical Regulatory Agency)
Ministry of Health Malaysia (Pharmacy Policy and Strategic Planning Division)
Muslim Consumers' Association of Malaysia
Pharmaceutical Association of Malaysia
Universiti Kebangsaan Malaysia (Faculty of Pharmacy)
University of Science Malaysia (School of Pharmaceutical Sciences)
University Malaya Medical Centre

The Working Group on Revision of MS 2424 - Halal Pharmaceuticals which developed this Malaysian Standard consists of representatives from the following organisations:

Ain Medicare Sdn Bhd
AJ Pharma Holding Sdn Bhd
Duopharma Biotech Bhd
Cyberjaya University College of Medical Sciences
Department of Islamic Development Malaysia (Halal Hub Division)
Department of Standards Malaysia (Secretariat)
Department of Veterinary Services Malaysia
Halal Industry Development Corporation

Committee representation (continued)

International Islamic University Malaysia (Kulliyyah of Pharmacy)
Malaysian Pharmaceutical Society
Malaysian Vaccine & Pharmaceutical Sdn Bhd
Ministry of Defence Malaysia, Malaysian Armed Forces Headquarters (Health Services Division)
Ministry of Health Malaysia (Pharmacy Policy and Strategic Planning Division)
National Pharmaceutical Regulatory Agency (Centre of Compliance and Licensing)
National Pharmaceutical Regulatory Agency (Centre of Quality Control)
Pharmaniaga Berhad
Universiti Kebangsaan Malaysia (Faculty of Pharmacy)
University of Science, Malaysia (School of Pharmaceutical Sciences)

Foreword

This Malaysian Standard was developed by the Working Group on Revision of MS 2424 – Halal Pharmaceuticals- General requirements under the authority of the Industry Standards Committee on Halal Standards.

Major modifications in this revision are as follows:

a) the title of this Malaysian Standard has been replaced with "*Halal Pharmaceuticals - General requirements*;

b) incorporation of definition on "*activated saccharide", "adjuvant", "carrier protein", "cell culture", "filling lot", " non-halal", "Halal competent authority", "internal halal committee", "manufacturing area/facility", "master cell bank", "master seed lot", "fatwa",* "*Active Pharmaceutical Ingredients (API)", "API Starting Materials", "buffer", "excipients", "growth medium", "intermediates", "materials", "preservatives", "process aids", "purified polysaccharide", "raw materials*", *"sertu",* "s*olvents*" and "*stabiliser*", *"vaccine", "working cell bank" and "working seed lot"*;

c) amendment on clause "*Quality management*" to "*Halal pharmaceutical quality system or quality management*";

d) amendment and improvement on clause "*Management responsibility*";

e) amendment and improvement on clause "*Manufacturing premise and equipment*";

f) amendment and improvement on clause "*Halal Assurance System*" to *"Halal Management System*";

g) amendment and improvement on clause "*Production and storage areas*" to "*Manufacturing and storage areas*";

h) amendment on clause "*Production*" to *Manufacturing*";

i) incorporation of new requirements on "*Transportation*";

j) incorporation of new requirements on "*Synthetic materials*";

k) amendment and improvement on clause "*Packaging materials*" to "*Packaging and labelling*";

l) amendment and improvement on clause "*Contract manufacture and analysis*" to "*Outsourced activities*;

m) incorporation of new Annex B; and

n) amendment and improvement on various clauses for clarity.

This Malaysian Standard cancels and replaces MS 2424:2012, Halal pharmaceuticals - General guidelines.

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

