



Bridging

Halal to Health

The Awareness and Insights





Duopharma Biotech Berhad

is Malaysia's leading pharmaceutical company.

Duopharma Biotech's products are certified halal by the Department of Islamic Development Malaysia (JAKIM), based on the MS2424:2019 halal pharmaceuticals standard - the first of its kind in the world for over-the-counter (OTC) and medicine products.



Emergence of Halal Pharmaceuticals

The global halal industry is making headlines worldwide as one of the most lucrative markets, worth US\$ 2 trillion in 2022 and US\$ 2.8 trillion by 2025. Although halal is commonly associated with food and beverages, there is growing interest and demand for halal pharmaceuticals and cosmetics. Halal food dominates the halal industry market share, but halal pharmaceuticals takes second place, which is 26% of the global halal market.

The global halal pharmaceuticals market is projected to reach US\$100 billion in 2021 based on Muslims spend on pharmaceuticals. It is expected to grow at a CAGR 6.7%, US\$129 billion in 2025. In terms of geography, Asia Pacific is likely to remain the largest region comprising a high Muslim populace, followed by the Middle East, Africa, Europe, and the Americas.

Malaysia has gained widespread recognition in the halal market as the first country in the world to publish a national standard that specifies guidelines and requirements for producing, handling, and storing halal food. The Malaysian Standard on Halal Food, MS 1500, is a global reference, not only for halal food but others, including pharmaceuticals. However, this guideline was not comprehensive enough to govern the pharmaceutical industry adequately. This is because pharmaceutical products deal with a wider variety of ingredient components, and the whole manufacturing process is more complicated than food.

The Malaysian Standard for halal pharmaceuticals, MS 2424 was introduced in response to this. The latest version applied is MS 2424:2019, halal pharmaceuticals – General requirements (First revision).

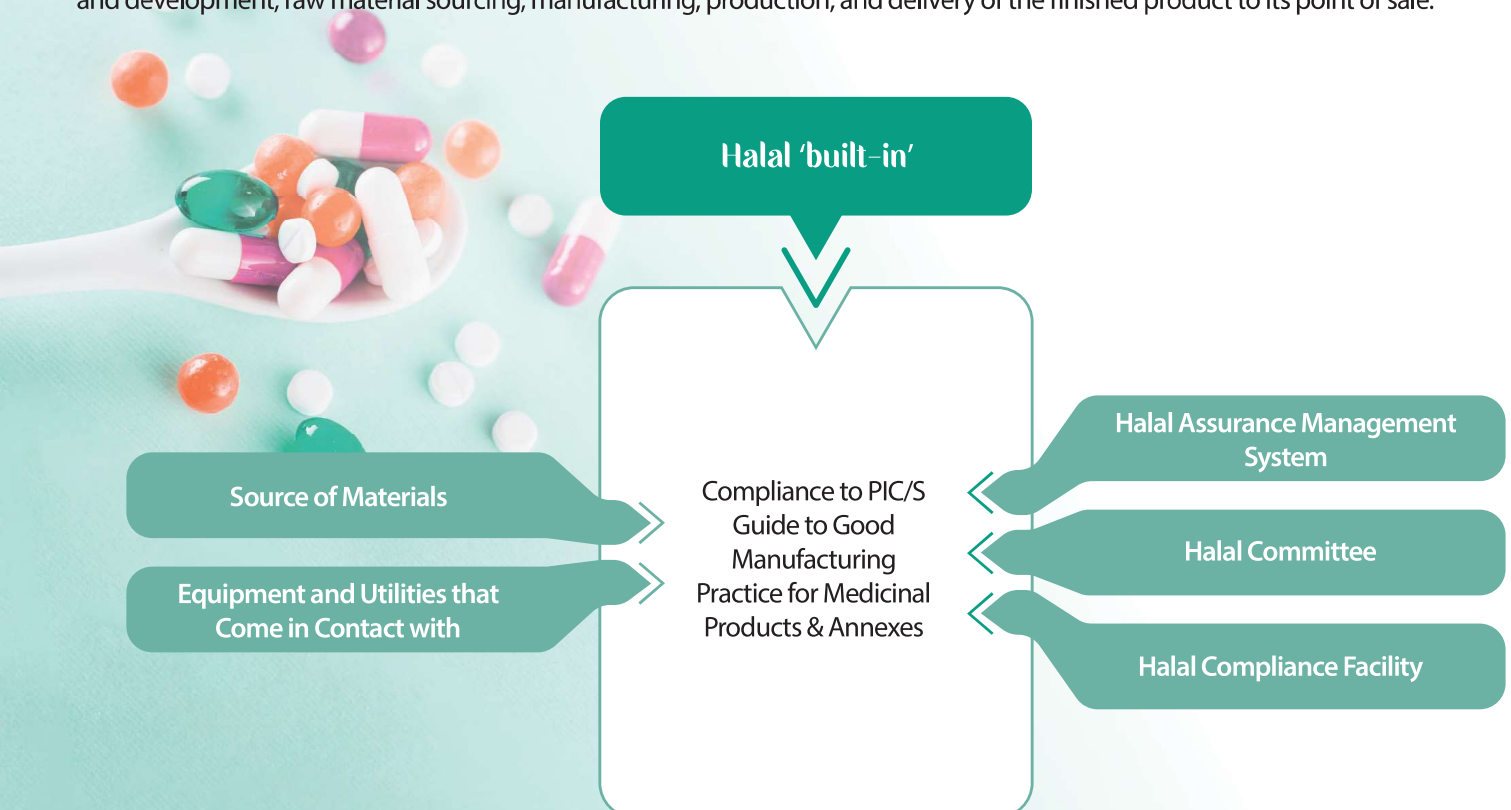


Halal Pharmaceuticals – It's more than just the ingredients!

GMP for Halal Pharmaceuticals: "The Halal Built-In, Not Tested For" Concept

"Halal built-in, not tested for" is a concept that approaches the development and production of halal products holistically and systematically incorporated into the industry's best practices or regulated guidelines. The MS 2424 recognises and applies the guidelines of the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

At the same time, this principle considers halal requirements integrated into every single process. It is from strategy to planning, research and development, raw material sourcing, manufacturing, production, and delivery of the finished product to its point of sale.



Good Manufacturing Practices (GMP) in Halal Pharmaceuticals

01 Quality management

- A halal pharmaceutical company must have a comprehensive design of a Halal Assurance Management System, Good Manufacturing Practice (GMP), and Quality Control (QC).
- A halal pharmaceutical company provides the necessary facilities and resources for halal compliance, which includes approved procedures and instructions for screening materials (including starting materials, reagents, solvents, process aids, intermediates, APIs, packaging and labelling materials); ensuring processing and handling, packaging, storage and distribution adhere to Shariah guidelines.

02 Personnel and responsibility

- A halal pharmaceutical company must ensure sufficient qualified personnel to establish and maintain a satisfactory Halal Assurance Management System.
- All personnel must be aware of the principles of halal and have gone through extensive training programs relevant to their needs.
- A Halal Committee is established, responsible for ensuring the effectiveness of implementing the company's Halal Assurance Management System.
- Hygiene requirement is applied to personnel, premises, equipment and relating materials in halal pharmaceuticals.
- The premises involved in the production of halal pharmaceuticals must be in an environment that presents no risk of causing contamination of non-halal materials or products.
- The layout and design of the premises must conform to the requirements of the PIC/S guidelines.

03 Production and storage

- A halal pharmaceutical company provides the necessary facilities and resources for halal compliance, which includes approved procedures and instructions for screening materials (including starting materials, reagents, solvents, process aids, intermediates, APIs, packaging and labelling materials).
- The processing and handling, packaging, storage and distribution must be ensured to adhere to Shariah guidelines.
- All halal products are dedicated to self-contained facilities to prevent the risk of contamination.
- Self-inspection is conducted to monitor implementation and compliance with halal and GMP principles

Following are the ingredients, processes, and products permitted under the Shariah guidelines with specific conditions



Ingredients

- ★ Do not contain any parts or products of animals that is non-halal
- ★ Do not contain *Najs, according to Shariah
- ★ Do not contain any human parts or their derivatives that are not permitted by Shariah



Process

- ★ Not prepared, processed or manufactured using equipment contaminated with *Najs, according to Shariah
- ★ During its preparation, processing, handling, packaging, storage, distribution, the products are physically separated from any other products that are decreed as non-halal and *Najs by Shariah



Product

- ★ Safe for consumption, non-poisonous, non-intoxicating or non-hazardous to health according to the prescribed dosage

*Najs according to Shariah guidelines are :

- a) dogs, pigs, their descendants 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;
- e) halal animals that are not slaughtered according to Shariah guidelines; and
- f) khamar and food or drink which contain or is mixed with khamar.



Halal Traceability Improves Consumer Trust

Halal traceability is an absolute necessity to demonstrate the integrity of the halal supply chain in the halal pharmaceutical industry. The implementation of a traceability and halal tracking system not only mitigates the risk associated with non-halal ingredients but all other activities related to manufacturing and handling of halal pharmaceutical products. In addition, it is to function as a communication tool to make information available throughout the supply chain process.

In conclusion, halal traceability emerged as an essential area in the halal pharmaceutical industry. Ultimately, halal traceability is established with one goal in mind, which is to improve transparency in the production chain. The more halal transparency will increase consumer trust in medicine because of advanced information on, among other things, production processes and control of food safety as a result of good information flow along the chain.





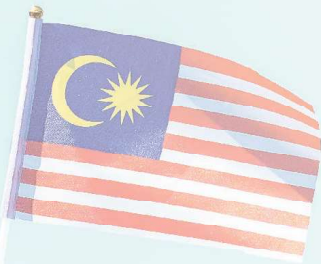
Halal Governance in Malaysia

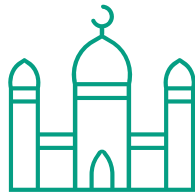
The halal industry in Malaysia has been growing rapidly since four decades ago. The growth of the halal sector was contributed mainly by two main factors: firstly by Muslim needs, awareness and demands, and secondly, by the support from the authority, especially in regulating the halal independent assurance processes. As a result, the Halal Malaysia Certification is one of the areas which received the most attention by industry players and consumers in Malaysia.

The establishment of the Malaysian Standard on halal for food (MS 1500) in 2004 was a highlight milestone for Malaysia as the first country to have a documented and systematic Halal Assurance System.

All halal certification applications for food and products in Malaysia are through the Department of Islamic Development, Malaysia (JAKIM), a government agency that administers Islamic affairs in Malaysia. The halal certificate is issued after the applicant has been verified to fulfil all the procedures and requirements stipulated in the guidelines.

The Halal Malaysia logo is globally recognised and symbolises the halal status awarded by a competent government agency administering Islamic affairs in Malaysia, JAKIM.





Primary Government Agencies in Malaysia Halal Ecosystem

The halal industry promotes the socio-economic growth of the country. Therefore, the Malaysian government has put in many efforts to improve governance, capacity building, and promotion. Besides ensuring halal supply chain integrity, including planning, developing, implementing, and regulating, promoting halal education among industrial players and consumers is critical. The government has also set up agencies and monitoring bodies to authorise and regulate any aspect related to halal certification, auditing and guidelines.

Department of Islamic Development Malaysia (JAKIM) is the designated competent authority for Halal Malaysia Certification, prescribed under the Trade Description (Certification and Marking of 'Halal') Order 2011. JAKIM also serves as the country's regulatory body, overseeing the implementation of halal laws.

Department of Standards Malaysia (DSM) is an agency under the Ministry of International Trade and Industry (MITI) responsible for developing and promoting Malaysian Standards (MS) including 35 MS under the halal industry sector.

Halal Development Corporation Berhad (HDC) is an agency under MITI, that spearheads the development of Malaysia's integrated and comprehensive halal ecosystem and infrastructure.

Malaysia External Trade Development Corporation (MATRADE) is an agency under MITI responsible for promoting trade and Malaysia's export through trading platforms, including the annual Malaysia International Halal Showcase (MIHAS).



Malaysian Halal Pharmaceutical Standards for Better Healthcare



"In 2012, Malaysia – a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) – became the first country in the world to develop a national standard on halal pharmaceutical products: Malaysian Standards MS 2424:2012. "



The Department of Standards Malaysia (DSM), managed the development of MS 2424. The standard was developed by a Committee with balanced representation, including JAKIM, the National Pharmaceutical Regulatory Agency, the Halal Development Corporation, the Malaysian Organization of Pharmaceutical Industries, and many more, through consensus.

The MS 2424 describes the conditions that drug manufacturers must meet for their products to be halal-certified. Each provision is incorporated with the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Good Manufacturing Practice for Medicinal Products. In 2019, the standard was updated and included additional improvements, including vaccines.





Why Halal Pharmaceutical?

Health is considered one of the greatest blessings from Allah SWT. Therefore, taking care of our health is a priority. People will live happily in this world when they are healthy, peaceful and have their basic needs fulfilled. Muslims are also guided on the preservation of well-being based on the five principles of Maqasid al-Shari'ah, namely religion, life, intelligence, progeny, and wealth.

'Halal' is an Arabic word which means permissible, permitted, or lawful. All things created by Allah (God) are Halal, with few exceptions that are specifically prohibited.

Halal pharmaceuticals are essentially medicines made from sources that are legal to use and that are prepared, manufactured, and extracted in accordance with Shariah guidelines. In addition to meeting the standards of Shariah, a number of other factors, including "Safe for consumption and usage," "Assurance on product efficacy," "Quality in production, ingredients and materials," and "Cleanly processed," significantly contribute to Toyibban (wholesomeness).

Muslim and non-Muslim consumers alike benefit from the halal certification of pharmaceutical products as they provide quality alternative products for consumers to make an informed choice.



"The Halal concept also includes a broad spectrum of basic human needs, embracing vital areas for the world, spanning green manufacturing practices to preserve our planet, to basic needs of mankind in terms of hygiene, sanitation and safety"

**- Tan Sri Datin Paduka Siti Sa'diah Binti Sh Bakir,
Chairman of Duopharma Biotech Berhad**





“Halal Pharmaceutical is Health For All”

The universal
benefits and value of halal

that accentuate

safety,

hygiene,

quality, and

wholesomeness,

have changed the perception and acceptance of
all consumers towards halal product
consumption.

As a result, **halal products**
are trending as a **healthy lifestyle.**





Duopharma Biotech: A Global Frontier of Halal Pharmaceutical Products

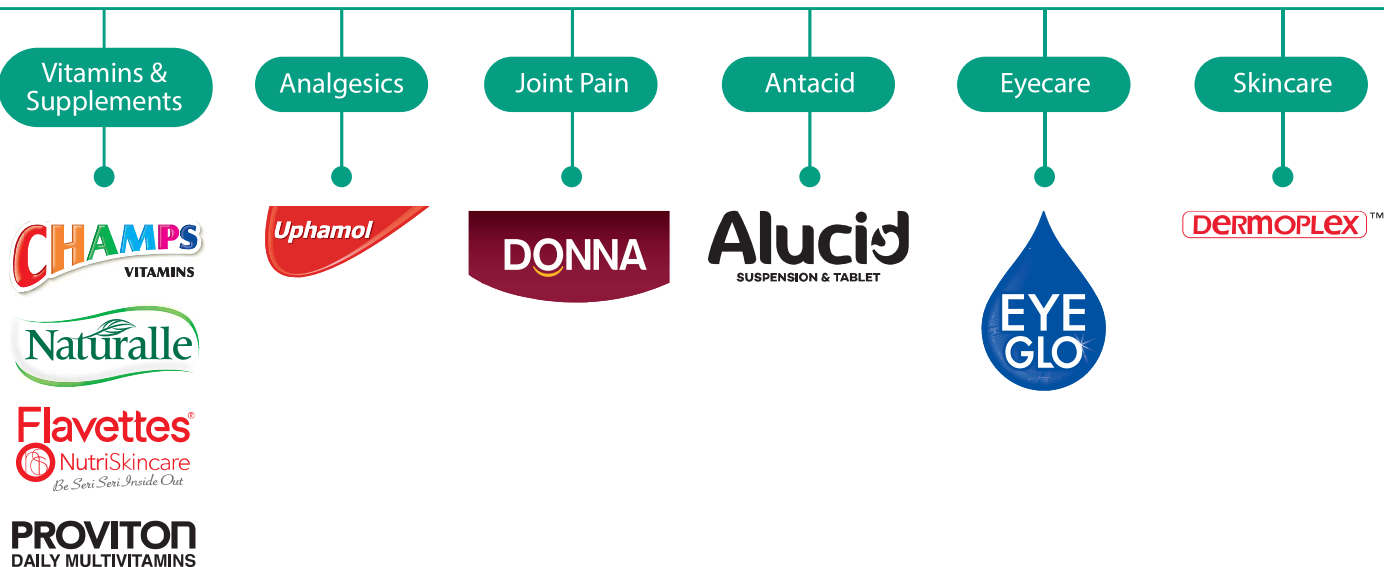
As part of fardh kifayah (communally obligatory); a legal obligation that Muslims must discharge, Duopharma Biotech upholds its commitment as the market leader in halal pharmaceuticals. Our halal products are safe for consumption and use, assured of their effectiveness, with high-quality ingredients and production standards, and processed hygienically. We will continue to grow our presence in the halal pharmaceutical space and directly ensure the growth of the halal pharmaceutical industry in Malaysia and around the world.

As a halal pharmaceutical company, it is no small feat for Duopharma Biotech to trailblaze the halal pharmaceutical path. Duopharma Biotech incorporates the principle of "Halal Built-In, Not Tested for" as part of the Company's good manufacturing practices. This principle is applied in everyday operations, from management responsibility to research and development (R&D), personnel, equipment, material sourcing, and production, right up to the delivery of the finished products to its points of sale. Our halal pharmaceutical products include Consumer Healthcare (CHC) ranges from health supplements, vitamins to over-the-counter medicines such as painkillers and analgesics, eye drops, cough mixtures, and ointments for wounds/cuts/bruises, creams for rash/itchiness and many more.



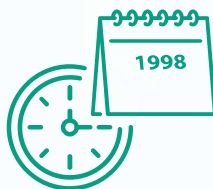
Duopharma Biotech Products

We manufacture and distribute more than 70 Consumer Healthcare products to cater for the demand in Malaysia, ASEAN and other countries. Amongst the products are as below:



We manufacture and distribute pharmaceutical products which consist of more than 300 generic drugs in various therapeutics including:

Respiratory	Uphadyl, Carin [™] , Sobenz, Simtec, Caridine
Musculo-Skeletal System	Zolterol [™] , Anarex
Nervous System	Acugesic, Prelica
Systemic Hormones	Prednisyn, Penatone
Alimentary Tract & Metabolism	Oral Aid Lotion, Hyomide
Systemic Anti-Infectives	Zynomax, Flonoxin
Dermatology	Aqua Cream
Sensory	Neo Deca, Nicol Eye Drops, Latacom, Latanost
Cardiovascular	Vascor, Acetan, Covasc [™] , Crystorvas, Bezartan, Vytan, Valsartan, Vytocor
Renal care	ERYSAA [®] , Unihepa, Ranofer, Bi-Haemosol and Haemosol



Our Halal Journey & Milestone

1998

All production lines dedicated for producing halal pharmaceuticals.

Consumer Healthcare products under the brands CHAMPS, Proviton, Flavettes and Naturalle were the first to attain Halal Malaysia Certification based on MS1500:2009 Malaysian Standard on Halal Food.

1999

2011


Received the Halal Recognition Award at the World Halal Research Summit 2011 by HDC.

Awarded by the Malaysia Book of Records as the first pharmaceutical manufacturer to receive Halal Malaysia Certification based on MS 2424:2012 Malaysian Standard on Halal Pharmaceuticals.

2013

2015

- Received the Halal Excellence Award at World Halal Conference 2015 by HDC.
- Received the Global Islamic Economy Award under Food & Health Category at Global Islamic Economy Summit 2015, Dubai hosted by the Dubai Chamber, the Dubai Islamic Economy Development Centre (DIEDC), and Thomson Reuters.



The inauguration of the Company's Thought Leadership platform, the Halal Pharmaceutical Symposium.

2016

2017

- Received the recognition by JAKIM as the first manufacturer to have attained Halal Certification for Prescriptive Medicine Based on MS2424:2012.
- Received the Frost & Sullivan Malaysia Excellence Awards Halal Pharmaceutical Company of the Year (Prescription Pharmaceuticals) 2017.

- Received the Frost & Sullivan Malaysia Excellence Awards Halal Pharmaceutical Company of the Year 2018.
- Establishment of Halal Committee at the Board level providing stewardship to the Company's Halal Pharmaceuticals Agenda.

2018

2019

- Received the Halal Excellence Award for Halal Brand at World Halal Conference 2019 by HDC.
- Received the Frost & Sullivan Malaysia Excellence Awards Halal Pharmaceutical Company of the Year 2019.

Received the Halal Healthcare Excellence Award at the World Halal Excellence Award 2021 by HDC.

2022



Frequently Asked Questions (FAQ)

What does
Halal mean



Halal is an Arabic word for lawful. It refers to things or actions permitted by Shariah guidelines (laws of Islam) to describe something that Muslims can engage in, e.g. eat, drink or use.

What does
Non-Halal mean



In contrast to Halal, Non-Halal or haram means forbidden. Non-Halal designates prohibited objects such as food products and actions.

What is Halal
Certification



Halal Certification is a third party assurance by a Halal Certification Body attesting that the products and services provided conformed to halal requirements.

What is Halal
pharmaceuticals



Pharmaceutical products in finished dosage forms include prescription and non-prescription medicinal products for human use registered with the Drug Control Authority, or local health authority that contain ingredients permitted under the Shariah guidelines and fatwa.

Refer to page 5 for more information on the ingredients and processes that is in line with Shariah guidelines.





Halal is a Universal Value Taking a Step Beyond Quality



Safety & Quality

The Halal mark and certificate are an additional layer of assurance that the source of ingredients is of approved sources.



Healthy Consciousness

Halal gaining acceptance as a standard of best practices and preferred choice by all associated with healthy eating and lifestyle.



Cleanliness

Cleanliness and hygiene is very important in Islam and part of the religion's foundation. As quoted by Prophet Muhammad SAW, "Cleanliness is half of faith."



Trust

The "Halal Logo" on the packaging is an assurance that the manufacturing process adheres to the prescribed requirements of safety and wholesomeness quality.



Environment & Animal Welfare

Halal certification is an additional measure of safety to consumers that products are produced based on Shariah law which covers the principles of more than just GMP. Halal also stands for animal welfare and a sustainable environment.



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