

BEYOND QUALITY ASSURANCE

How Halal-Certified
Pharmaceuticals
Benefit Everyone





Duopharma Biotech Berhad
[Registration No: 200001021664 (524271-W)]
is Malaysia's leading pharmaceutical company.
Duopharma Biotech products are certified halal
by the Department of Islamic Development
Malaysia (JAKIM), based on the MS2424:2012
halal pharmaceuticals standard – the first of its
kind in the world for over-the-counter (OTC) and
medicine products.

Misconceptions about halal pharmaceuticals

Who is it for?

... Halal products are only for Muslims

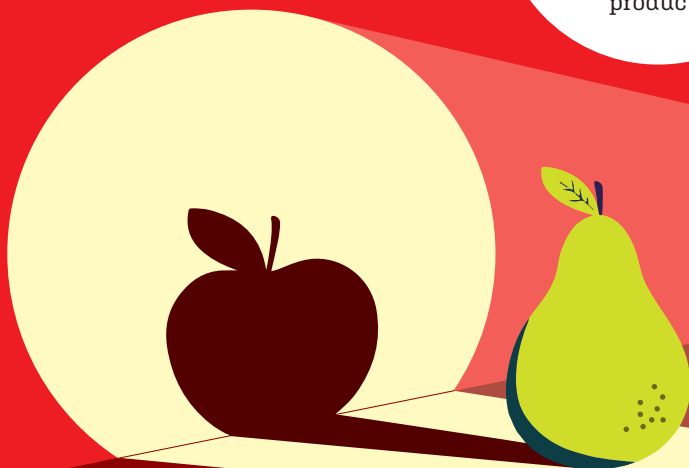
What does it mean?

... Halal just means it doesn't contain pork or alcohol

What about the quality?

... Not as good as branded, imported products

... FALSE!



Halal pharmaceuticals

– a quality alternative for all

Although drugs in the form of tablets are commonly associated with modern medicine, pills were actually invented more than 3,500 years ago. Ancient Egyptians made pills by pulverising various seeds, leaves and plant resins together. The powder was then mixed with honey or grease and shaped by hand into little spheres. The common ingredients were saffron, myrrh, cinnamon and other medicinal plants.

Since then, pharmaceuticals have come a long way. But for most consumers who don't have a background in medicine or pharmacy, the ingredients listed on the packaging of our medicine might as well be in Greek. How many of us know what the active pharmaceutical ingredient (API) is, or pay attention to the various binders, lubricants, glidants and disintegrants that make up 80% of the ingredients of the tablet?

DID YOU KNOW?

All production lines in Duopharma Biotech's pharmaceutical plants have adhered to halal requirements since 1998.

Many pharmaceutical products, for example, have trace amounts of alcohol to help the API — which makes up 10-15% of the pill — dissolve in the body when ingested. For most adults, small amounts of alcohol do not pose a problem. But for children or those with allergies to particular substances, it is worth paying attention to the ingredients.

In the case of halal pharmaceutical products, the use of alcohol as an excipient

is controlled within limits set by the Ministry of Health. In accordance with Fatwa requirements, the ingredient must be made of synthetic materials and not from the production of liquor.

The emergence of halal pharmaceuticals heralds a new era for consumers and healthcare providers alike. The stringent requirements of halal certification serve as an additional layer of quality assurance as all raw materials need to be screened, documented and verified. This applies to every step of the manufacturing process.

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

Assurance of quality

Pharmaceuticals have one of the highest standards of manufacturing, with established guidelines and required documentation making it one of the most stringent processes in the world.

As with all locally made pharmaceuticals, products must adhere to the high standards set by the Ministry of Health before they can be registered and allowed to be distributed in the market. This certification, known as the Good Manufacturing Practice (GMP), assures the public that the product is safe for consumption.

Understanding GMP

GMP guidelines are set according to World Health Organisation (WHO) requirements. In essence, it is a system that ensures products are consistently produced and controlled

according to quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

GMP requirements cover all aspects of manufacturing, testing and quality assurance. Each step of production – from the starting materials, premises and equipment to the training of staff – requires detailed, written procedures.

With the GMP system in place, manufacturers are required to provide documented proof that procedures are followed at each step of the process for each batch of products.

As different countries may devise their own GMP guidelines, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) is responsible for developing

uniform inspection procedures and harmonised standards among member countries.

The PIC/S is an international voluntary co-operative arrangement among regulatory bodies of 52 countries, including Malaysia's National Pharmaceutical Regulatory Agency under the Ministry of Health.

DID YOU KNOW?

According to the *State of the Global Islamic Economy Report 2018/19* by Thomson Reuters, the global halal pharmaceutical industry is expected to grow 8% year-on-year to reach US\$131 billion in 2023.

GMP Requirements for Pharmaceuticals

MATERIALS

→ All materials must be clearly defined

MANUFACTURING PREMISES

→ Must maintain controlled environmental conditions to prevent cross-contamination

PROCESSES

→ Must be clearly defined and controlled
→ Records must be made to demonstrate that all the required steps were taken and that the quantity and quality of the drug is as expected
→ Deviations must be investigated and documented

EQUIPMENT

→ Dedicated equipment and line

PERSONNEL

→ Must be trained to carry out and document procedures

STORAGE & TRANSPORT

→ Dedicated storage and transport
→ Distribution and storage of products must minimise any risk to quality

RECORDS

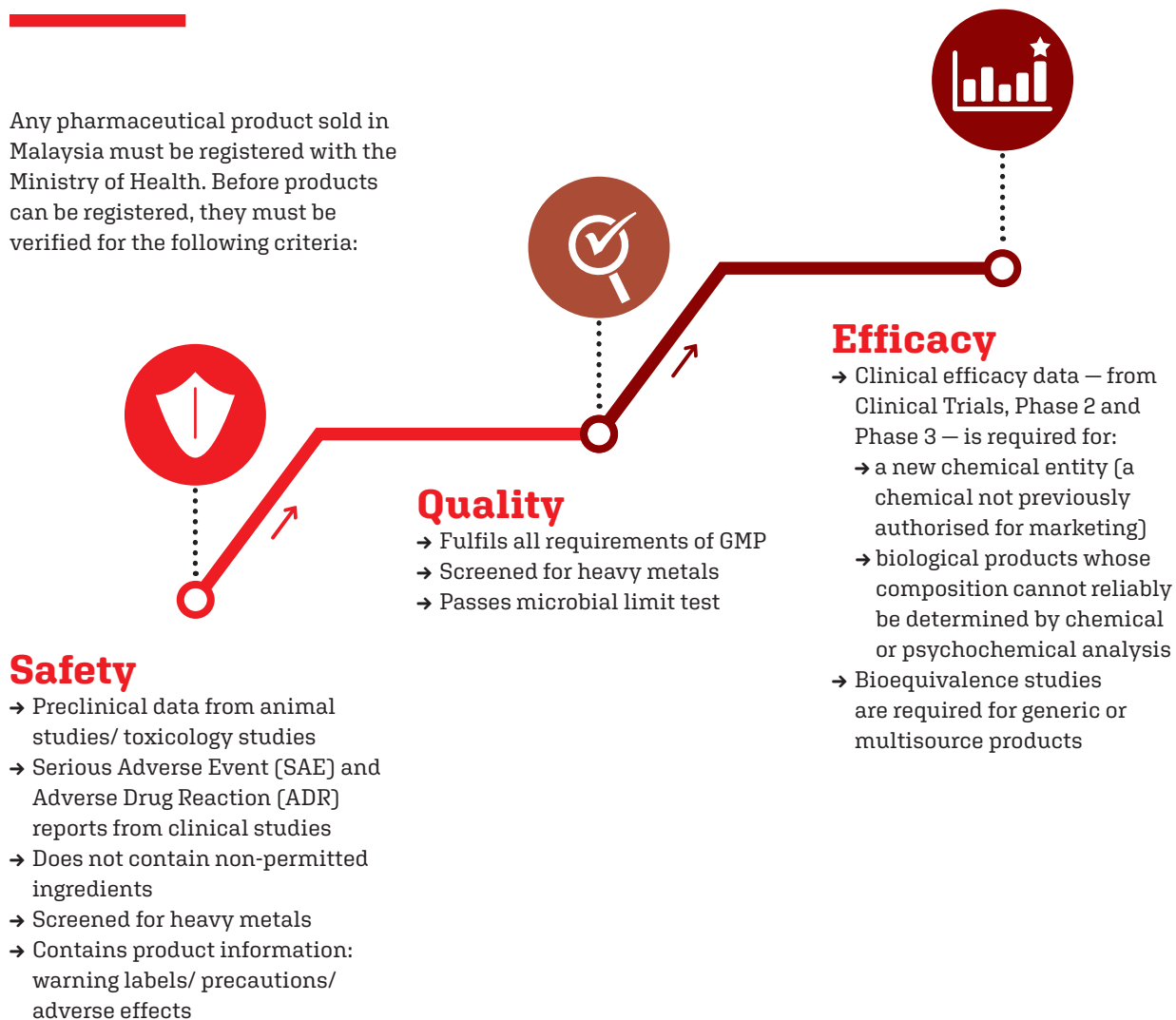
→ The complete history of a batch, from manufacture to distribution, must be easily traceable

RECALLS & COMPLAINTS

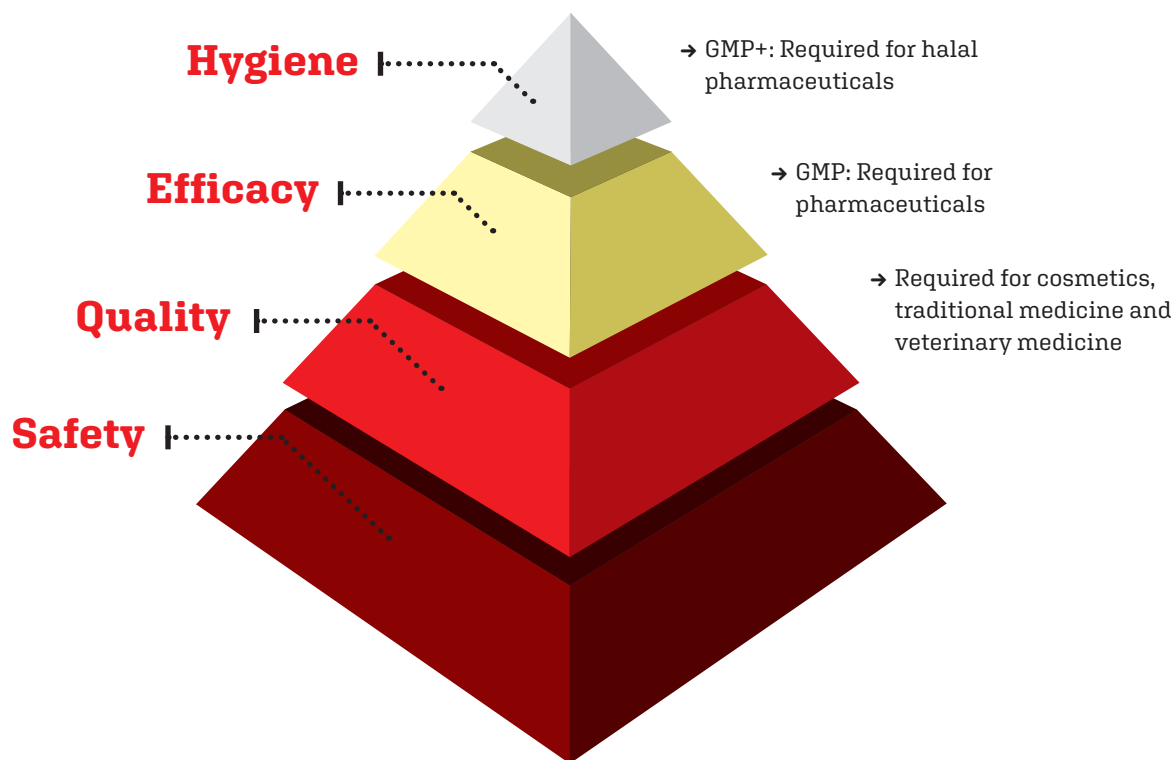
→ A system must be in place to recall any batch from sale or supply
→ Any complaint about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken to prevent recurrence

Ministry of Health requirements

Any pharmaceutical product sold in Malaysia must be registered with the Ministry of Health. Before products can be registered, they must be verified for the following criteria:



Halal certification goes beyond these requirements, providing an additional layer of assurance. The products must first fulfil the requirements of GMP before fulfilling additional prerequisites for halal certification, which set a higher benchmark for quality.



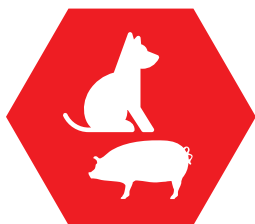
Requirements for locally manufactured medicinal products

Accountability and traceability

A common misconception of halal is that it simply contains no porcine products or alcohol. However, halal certification goes beyond this and actually involves:

1. Materials

Materials must not contain any parts or products of animals that are non-halal or are not slaughtered accordingly. They must not contain *najs*, or 'unclean' materials according to Shariah law. Materials categorised as *najs* are:



→ Products from dogs, pigs and their derivatives



→ Products contaminated or in direct contact with non-halal materials



→ Liquids discharged from humans and animals such as urine, blood, vomit, pus, placenta, excrement and sperm



→ Carrion as well as animals (including permitted animals) that are not slaughtered according to Shariah law

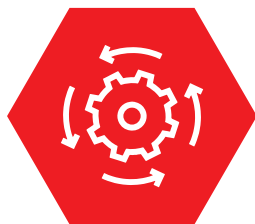


→ Khamar (fermented alcohol)

With halal pharmaceuticals, care must be taken to ensure everything that goes into the product is accounted for and documented. Traceability is an essential part of the halal certification process.

Let us take capsules as an example. To make capsules, a core ingredient is gelatine, which is extracted from the bones of animals. In a halal pharmaceutical process, suppliers of gelatine must ensure to use only the sources permitted, with every step verified and documented—meaning there are no hidden ingredients, such as ‘filler’ materials or byproducts of animals that are not slaughtered in compliance with Shariah requirements.

→ Processing



→ Packaging



→ Distribution



2. Process

Halal is not just about what goes into the product, but also how it is made. Pharmaceutical products that are certified halal cannot be prepared, processed or manufactured using equipment that has been contaminated with *najis*.

Manufacturers must ensure that their premises and facilities adhere to Shariah guidelines. Additionally, the products must not come into physical contact with any non-halal products; this includes during preparation, processing, handling, packaging, storage and distribution.

DID YOU KNOW?

In 2012, Malaysia became the first in the world to develop and enforce a national halal standard for pharmaceuticals called MS2424:2012.

Published by the Department of Standards Malaysia under the Ministry of Science, Technology and Innovation, the document outlines comprehensive guidelines for the application of halal certification for pharmaceutical products.



Duopharma Biotech: A pioneer of halal pharmaceuticals

Quality products **for all**

As the first halal pharmaceuticals manufacturer in the world, Duopharma Biotech has played a pioneering role in research and development. In 1996, Duopharma Biotech had a vision to produce quality generic pharmaceuticals – which refers to copies of brand-name drugs that have exactly the same pharmacological effects as their brand-name counterparts – at an affordable price for Malaysians.

“ The vision in 1996 was very simple: we wanted to produce good quality generic pharmaceuticals for Malaysians. Halal pharmaceuticals weren't the priority. But after we stabilised, we were very sure we were doing quality work. We were screening our raw materials and quality of ingredients to the highest international standard. That's when we decided to take it a step further.”

– Dr Leong Chuei Wei, Research & Development Consultant,
Duopharma Biotech

Backed by a strong technical research team recruited from Malaysian pharmacy PhD candidates studying overseas, Duopharma Biotech embarked on its halal pharmaceuticals journey that continues to set new standards of excellence today.

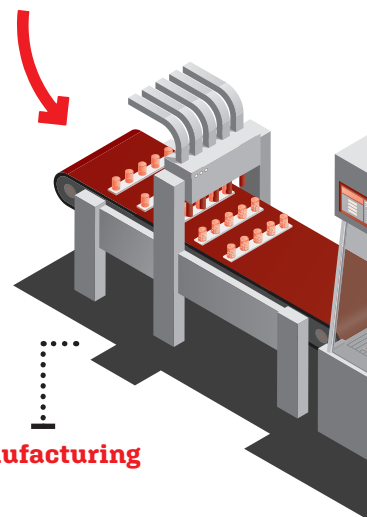
Duopharma Biotech's Halal Journey

- 1998** → Halal was integrated with GMP requirements for all production lines and manufacturing processes.
- 1999** → Health supplements under the brands CHAMPS, Flavettes, Proviton and Naturalle certified Halal by JAKIM in accordance with the Malaysian Standard MS 1500.
- 2008**
 - Formalisation of Halal Compliance Committee division for each manufacturing site.
 - A certified *sertu* (cleaning method) procedure for pharmaceutical plants was developed.
 - The first Halal Pharmaceutical Seminar was organised for non-food industry suppliers and other stakeholders.
- 2013** → Products under the over-the-counter (OTC) category certified Halal by JAKIM in accordance with Malaysian Standard MS 2424.
- 2014** → Products under the over-the-counter (OTC) category for the Indonesian market certified Halal by LPPOM MUI Indonesia.
- 2017** → Prescriptive (ethical) medicines certified Halal by JAKIM in accordance with Malaysian Standard MS 2424.
- 2018** → Formation of Halal Committee at Board level.

Research and development



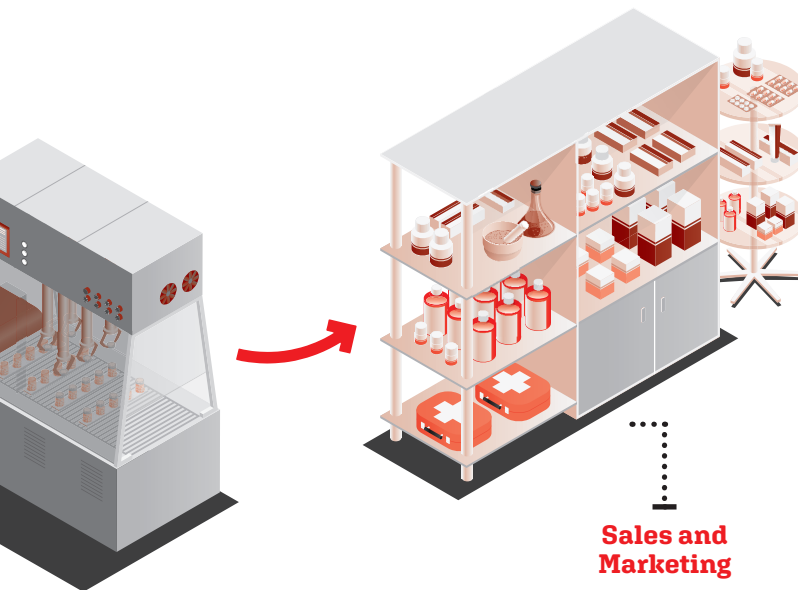
Manufacturing



Setting tone for pharmaceutical industry

“Duopharma Biotech is committed to providing safe, effective, quality and hygienic products to consumers. We started our adherence to halal requirements in 1998, and since then the company has achieved significant milestones in halal certifications.”

– Leonard Ariff Abdul Shatar, Group Managing Director, Duopharma Biotech



**Sales and
Marketing**

As Duopharma Biotech garnered more technical expertise and developed better procedure guidelines, the company decided it had a responsibility to share its knowledge with the Ministry of Health and relevant regulatory bodies to help push the industry forward.

In the 1990s, for example, bioequivalence testing — to ensure that generic pharmaceutical products are clinically interchangeable with brand-name drugs — was a voluntary requirement. Duopharma Biotech worked closely with the Centre for Product Registration, National Pharmaceutical Control Bureau under the Ministry of Health to develop guidelines for bioequivalence tests for generics.

Bioequivalence testing measures the blood levels of the active ingredient of both the brand-name drug and generic product. In both cases, the blood levels must be the same. This is to provide objective evidence that the generic product is therapeutically equivalent to the brand-name drug; there is no such thing as subjective proof such as “I feel better after taking this medicine.”

In 1999, the Ministry of Health enforced bioequivalence testing as a compulsory requirement for generic pharmaceutical products before it can be registered to be marketed and sold in the country.

Duopharma Biotech, **industry leader** ahead of its time


As a Malaysian company, it is no small feat for Duopharma Biotech to trailblaze the halal pharmaceutical path.

Duopharma Biotech work closely with the Department of Islamic Development Malaysia (JAKIM) to determine how the process of *sertu* (cleaning method) would be carried out and documented. In 2008, the company was the first to develop a certified *sertu* procedure for pharmaceutical plants, which later became part of Malaysia's national halal standard MS2424:2012.

In the manufacturing process of halal products, *sertu* is necessary to cleanse any surface — including skin, clothing and machinery — that has been contaminated by coming into contact with *najs mughallazah* (*severe impurity*), which refers to dogs, pigs and their products.

The process of *sertu* involves washing the surface of the machine seven times, one of which must be water mixed with soil.





Although it is not usually associated with cleaning, scientific research has shown clay to be an effective, natural cleansing agent that is free from harmful chemicals and able to kill 99.9% of bacteria borne by *najs mughallazah*.

“ It is important to note that the halal market is not exclusive to Muslims. It has gained increasing acceptance among non-Muslims too who associate halal with ethical consumption and other values such as social responsibility, stewardship of the earth, economic and social justice, animal welfare and ethical investment — in short, beyond its religious compliance.”

– Leonard Ariff Abdul Shatar,
Group Managing Director,
Duopharma Biotech

The research and development team at Duopharma Biotech oversees up to 60 products at any one time. The company believes halal pharmaceuticals offer an additional assurance of quality. In every new project it undertakes, the 50-strong research division is motivated by the simple premise that should they become consumers, they are assured of the products' safety, quality, efficacy and hygienic processes.

“ We all wear two hats; we have a vested interest in everything we do. One day, we will be consumers of this medication too — and we don't want to wonder, 'is it a good product?'"

– Dr Leong Chuei Wei,
Research & Development
Consultant, Duopharma Biotech

About Duopharma Biotech

Duopharma Biotech Berhad [Registration No: 200001021664 (524271-W)], Duopharma Biotech is a Malaysian-based investment holding company with the title Bumiputera Controlled Public Listed Company under the Ministry of International Trade and Industry.

As Malaysia's leading pharmaceutical company, its principal activities involve the manufacture, distribution, import and export of pharmaceutical products and medicines. Its Mission is to become a leading Healthcare Group providing quality and innovative solutions.

Duopharma Biotech is committed in the expansion of its manufacturing facilities with state-of-the-art technology to enhance compliance standards and capacity in supporting the growth of the industry. Duopharma Biotech facilities are accredited by Good Manufacturing Practice (GMP) standard, such as the

manufacturing licence by the National Pharmaceuticals Regulatory Agency (NPRA) which meets international guidelines of the Pharmaceutical Inspection Convention and Cooperation Scheme (PIC/S) and the requirements of the World Health Organisation (WHO).

Its range of products includes tablets, capsules, syrup, antibiotic, creams, haemodialysis solution, sterile irrigation solution, sterile powder injectables, small volume injectables, dental cartridges and eye drop preparations.

Duopharma Biotech's locally manufactured products are certified halal by the Department of Islamic Development Malaysia (JAKIM), based on the MS2424:2012 halal pharmaceuticals standard – the first of its kind in the world for the over-the-counter (OTC) and medicine products. Its products are exported around the world to countries including Vietnam,

Ethiopia, Sudan, South East Asia, Papua New Guinea, Pakistan, Bangladesh, Sri Lanka, Yemen, Singapore and Hong Kong.

Duopharma Biotech's halal initiatives are widely recognised, with its brands and products receiving numerous prestigious awards. The company embodies its vision of providing smarter solutions for a healthier life to create opportunities for high performance and sustainable growth for all stakeholders.

DID YOU KNOW?

All of Duopharma Biotech's pharmaceutical products are halal compliant. However, due to Ministry of Health regulations, the halal logo can only be displayed on over-the-counter products.

Duopharma Biotech **Products**

Consumer Healthcare (CHC) Brands

- Flavettes
- Proviton
- Uphamol
- Champs
- Naturalle
- Eye Glo
- Dermoplex
- Donna
- Alucid
- HemoRid
- Beacolytic
- Beacolux
- Oral Aid
- Vemizol



Prescriptive (Ethical) Medicines

There are more than 300 products produced in Duopharma Biotech halal-compliant facilities of the following therapeutic classes: Diabetes, Cardiovascular System, Renal, General Anti-infectives

Systemic, Hospital Solutions, Nervous system, Musculoskeletal System, Parasitology, Respiratory System, Sensory Organs, Alimentary Tract & Metabolism, Systemic Hormonal Preparations, Dermatological, Blood &

Blood-forming Organs.

Key brands include Sobenz, Nicol, Zolterol, Anikef, Omesec, Vascor, Zynomax, Acetan, Covasc, Atorvas, Prelica.

Milestones

Duopharma Biotech is the market leader in the pharmaceutical industry.

Our commitment to excellence has been recognised over the years.

Halal Certification

1999

First pharmaceutical company to obtain the Malaysian Halal certification - health supplements under the brands CHAMPS, Flavettes, Proviton and Naturalle – MS 1500

First pharmaceutical company to obtain the Malaysian Halal certification – MS 2424:2012 for OTC products



2013

2014

Obtain Halal certification from LPPOM MUI Indonesia

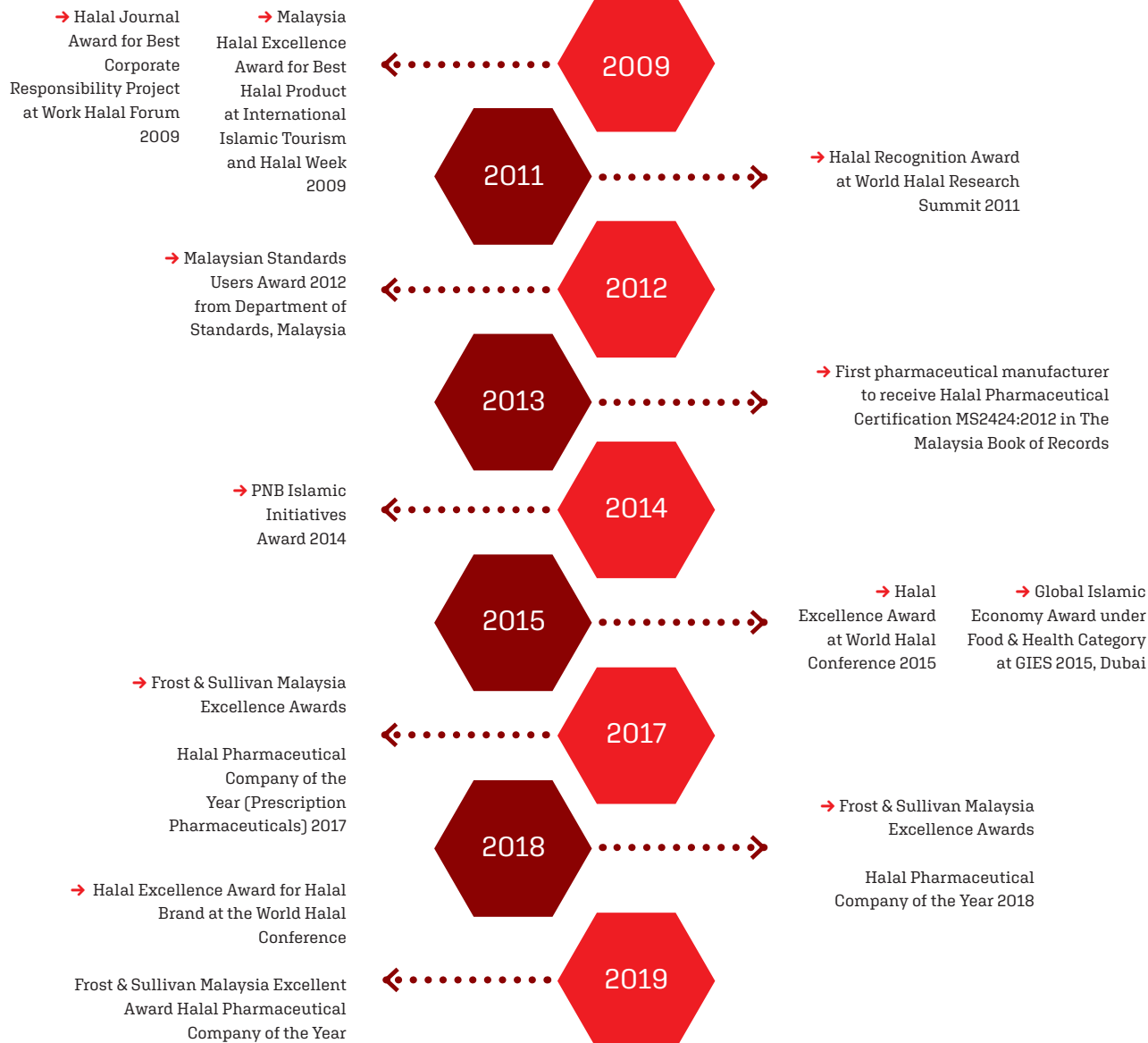


First pharmaceutical company to obtain the Malaysian Halal certification for Prescriptive Medicines based on MS 2424:2012



2017

Halal Accolades





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