



NPCB

# ***HALAL PHARMACEUTICALS: a regulator's perspective - MS 2424***

**Tajuddin Akasah**

*B. Pharm. Hons (USM), M. Phil., Ph. D (UK)*

National Pharmaceutical Control Bureau, MOH. Malaysia





# *THANK YOU*

To all of you who unselfishly dedicated,  
sacrificed your time & resources in  
improving the quality of life of others  
or our ummah



# Outlines

- Quality in Medicine
- Halal Pharmaceuticals - MS 2424
- What are the requirements?
- Compliance & Certification



# *QUALITY IN MEDICINE*

Tajuddin Akasah

*B. Pharm. Hons (USM), M. Phil., Ph. D (UK)*

National Pharmaceutical Control Bureau, MOH



*Question 1:* How do you feel if you were given a tablet which was not tested?



# Motorcar vs. Medicine - Similarity & Differences?

# Quality

- QC test is **destructive**
- Unable to do on **every tablet or lipstick**
- Require **sampling**



# What about the ones that we do not know or test?

*Cross-contamination*  
*Contamination*  
*Others*

*analgesic + anti-hypertensive*  
*analgesic + laxatives*



# Quality

- **Compliance** to GMP/GDP is crucial
- Quality being '**built-in**' from the start to finish and maintained till it reaches the patient/consumer
- We only test what we want [BP etc]
- *Halalness* being built in too rather than tested for

# Regulator's concern ....Pharmaceuticals

## Quality, Safety and Efficacy [Kualiti, Keselamatan dan Keberkesanan]

# *What do we mean ?*

Quality (meet specs, for intended use) and

Safety (Limits for Heavy metals & Microbial counts, no prohibited ingredients, ADR monitored)

Efficacy (proven clinically)

# ‘Quality is everybody’s responsibility’

*From the API manufacturers >  
pharma manufacturers >  
wholesalers > doctors >  
pharmacists > patients*



*Terima  
kasih*



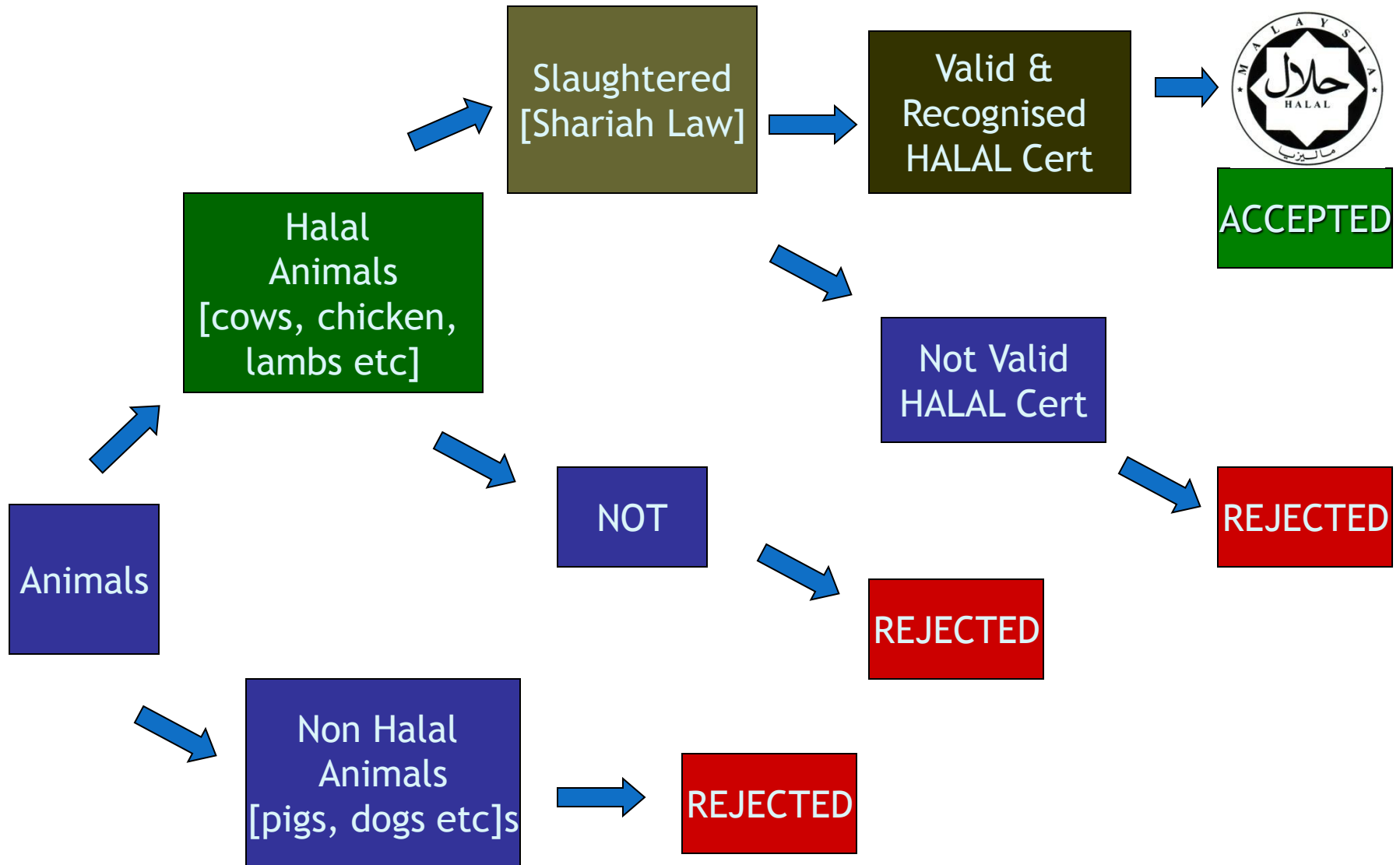
NPCB

# HALAL Pharmaceuticals: General Guidelines MS 2424 2012

---

# WHAT IS HALAL?

- **Halal** is an Arabic word meaning lawful. It refers to things or actions permitted by *Shariah* law (laws of Islam)
- to describe something that a Muslim is permitted to engage in, e.g. eat, drink or use
- The opposite of **halal** is haram, which is unlawful or prohibited.







# What is Halal Pharmaceuticals?

- 3.2 pharmaceutical products that contain ingredients permitted under the *Shariah* law & fulfill the following conditions:
- a) do not contain any parts or products of animals that are **non-halal** or any parts or products of animals which are not slaughtered according to *Shariah* law;
  - b) do not contain **najs**

# What is Halal Pharmaceuticals?

- c) **safe** for consumption, non-poisonous, non-intoxicating or non-hazardous to health according to prescribed dosage;
- d) not prepared, processed or manufactured using **equipment contaminated with *najs***;
- e) do not contain any **human parts or its derivatives** that are not permitted by *Shariah* law; and

# What is Halal Pharmaceuticals?

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.

# What are *Najs*?

## 3.5 *Najs*

- **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.

# What are *Najs*?

- b) **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) **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.

# MS 2424 2012

## 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.**

# MS 2424 2012

## 3.1 Pharmaceuticals

- products in **finished dosage forms**, & include both prescription and non-prescription medicinal products for human use (biopharmaceuticals, radiopharmaceuticals, traditional medicines and investigational medicinal products), which are **registered with the Drug Control Authority**, Ministry of Health Malaysia.



# MS 2424 2012 continues...

- 1.0 Scope
- 2.0 Normative references
- 3.0 Terms and definitions
  - 3.1 *pharmaceuticals*
  - 3.2 *Halal pharmaceuticals*
  - 3.3 *Shariah Law*
  - 3.4 *Halal*
  - 3.5 *Najs*
  - 3.6 *Competent Authority*





# MS 2424 2012 continues...

**3.7** *Manufacture*

**3,8** *Manufacturing premise*

**3,9** *Materials*

**4.0** *Requirements*

**4.1** *Quality management*

**4.2** *Management responsibility*

# MS 2424 2012 continues...

## 4.2 *Management responsibility*

Shall ensure that *Halal* Assurance System [HAS] comprehensively designed & correctly implemented, incorporating the application of GMP & QC

## 4.3 *Halal Assurance System*

*ensures that*

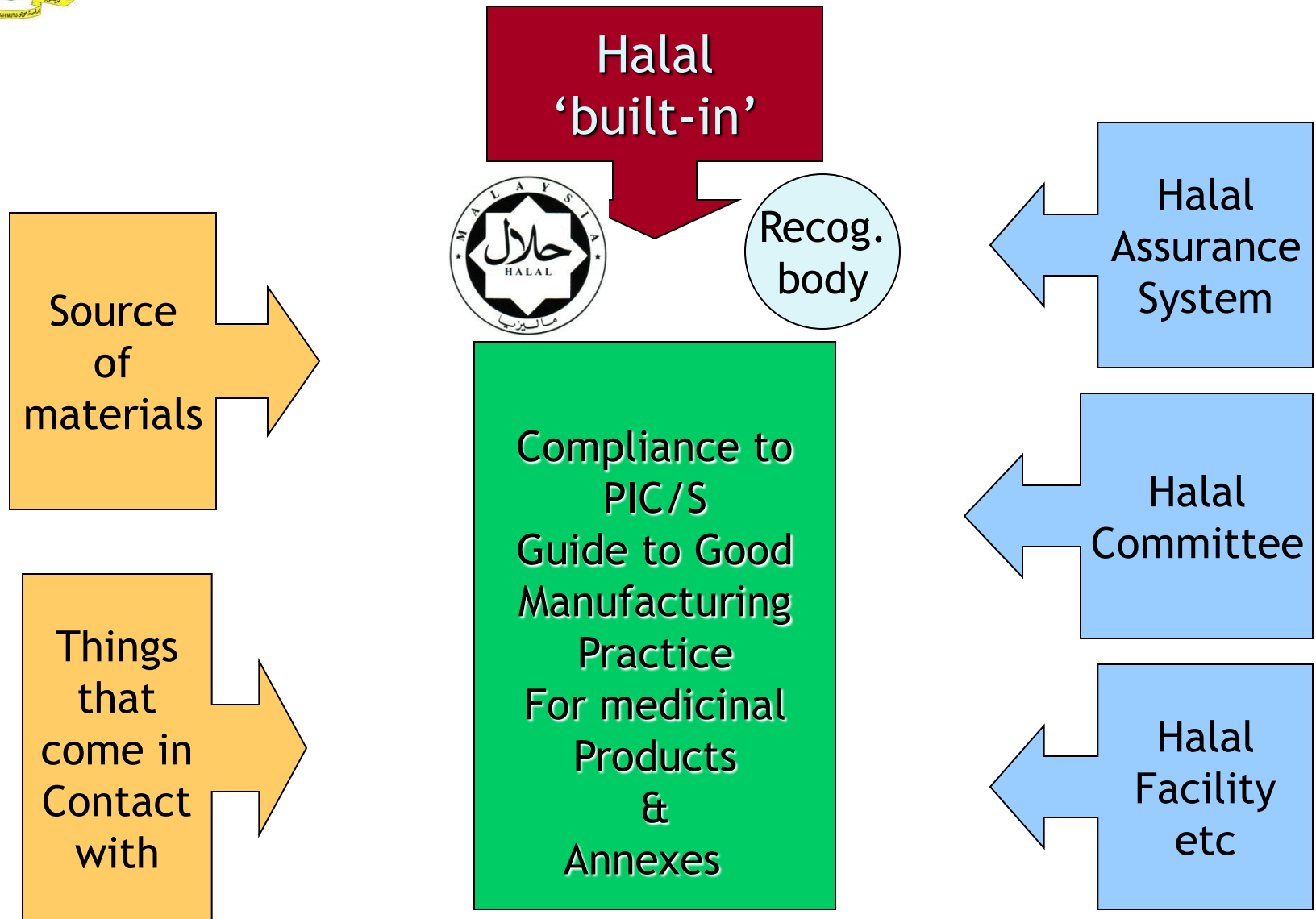
- The pharmaceuticals are designed and develop in a way that comply with the requirements of *halal* & GMP
- The processing line be operated for *halal* pharmaceuticals only
- if the processing line which contained or contaminated with *najs* then the ritual cleansing shall be required [Annex A]

## *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

- Ch. 1. Quality Management System
- Ch. 2. Personnel
- Ch. 3. Premises and Equipment
- Ch. 4. Documentation
- Ch. 5. Production
- Ch. 6. Quality Control
- Ch. 7. Contract Manufacture and Analysis
- Ch. 8. Complaint and Product Recall
- Ch. 9. Self Inspection
- Annexes 1-20 (specific)

**ELEMENTS OF PIC/S  
GMP**



# 1. QUALITY MANAGEMENT SYSTEM

- Quality Assurance
- Good Manufacturing Practice
- Product Quality Review
- [5 long Clauses]
- *Ensure halal pharma manufactured according to halal requirements [4.1]*

# QUALITY MANAGEMENT SYSTEM

- Developed, established, implemented
- Policies and objectives
- Organisational structure, functions
- Responsibilities, procedures
- QC and specifications



## 2. PERSONNEL [20]

- sufficient & qualified, separate people responsible for production and quality control (independent of each other)
- appropriately trained in GMP, regulatory requirements & understands their responsibilities

## 2. PERSONNEL [20]

- shall establish a **[Halal] committee** which is led by a trained Muslim
- shall consist of purchasing personnel and fulfill a minimum **2/3 Muslim quorum** & they are responsible to ensure the effectiveness in the implementation of the *Halal* Assurance System [4.6]

## 2. PERSONNEL [20]

- Continuous training on *Halal*, approved by H Committee, periodically assessed[4.7]
- **Strict personal hygiene** is an integral requirement for *halal* [4.8]

### 3. PREMISES & EQUIPMENT [44]

- Suitably located, designed, constructed and maintained to suit the operations
- The need to avoid
  - any risks of contamination from environment
  - cross-contamination, mix up
  - risk of contamination of non-*halal* [4.9]

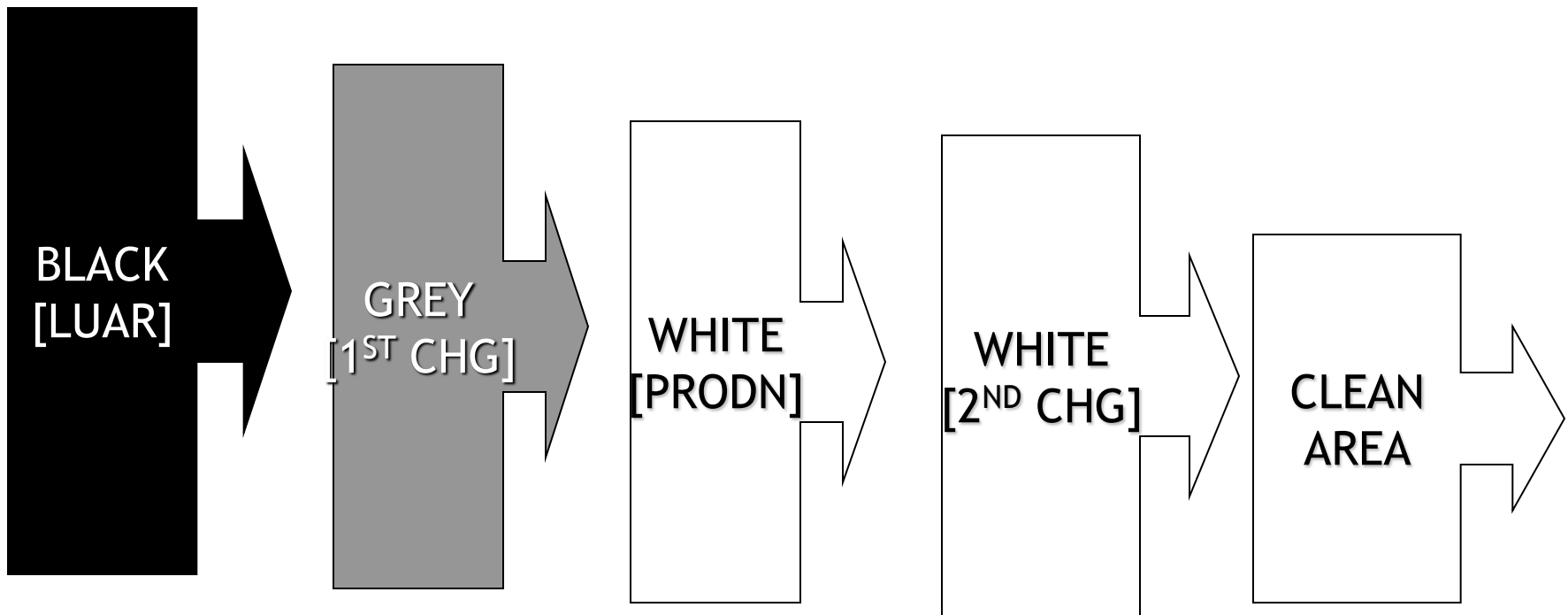
### 3. PREMISES & EQUIPMENT [44]

- Converting into *halal* production line [Annex A]
  - supervised & verified by Competent authority
- Shall be operated for *halal* pharmaceutical products only
- **Repetition in converting** the line to *najs* line and back to *halal* line shall **not be permitted** [4.9]
- Dedicated & self contained for *halal* products [4.10]

# Premises and equipment [4.9]

- effectively separated and well insulated from pig farm activities and others, in order to **prevent cross contamination** through air, water, sewerage, personnel and equipment
- shall observe to an Islamic value and practice

# AREA CLASSIFICATIONS





- Hormone Production



## 4. DOCUMENTATION [29]

- Complete history of each batch from starting material to finished products, **traceability [*Halal cert*]**
- Batch Processing Records or BMR, SOPs, Formulas etc
- **Evidence of materials origin, approved by authorised Muslim personnel [4.13]**



# 5. PRODUCTION [65]



# PRODUCTION

- Must follow clearly defined procedures
- & comply to *Halal* principles [4.14]
- must comply to the principles of GMP in order to obtain the product of requisite quality & in accordance with the manufacturing or marketing authorisations



# PRODUCTION - Starting materials

- Consistency of production is influenced by quality of starting materials & its specs
- The main control point is on **the source of materials and utilities that come in-contact** with the products, should be *Halal* compliance [4.4.2]



# Manufacturing Operations

Standard Operating Procedures (SOPs)  
Cleaning Procedures and Validations  
Right Formula

# Validation

The documented act of proving that any procedure, process, equipment, material, activity, or system actually leads to the expected results.

# Qualification or Validation ?

Qualify a system and/or equipment

- Validate a process
- Qualify an autoclave, whereas you validate a sterilisation process
- DQ, IQ, OQ, PQ

# Production

- actual & theoretical yield
  - abnormal discrepancy should be investigated
  - also in [4.4.2.c]



# Packaging & Labelling

- Line clearance
- Label reconciliation
- Independent checking by QC staff
- Correct materials, containers and labels
- Dedicated storage and transport. [4.4.2]

## Packaging materials [4.16]

- The consumable and non-consumable packaging and printed materials shall be from any origin that is decreed as *halal* by *Shariah* Law
- The packaging design, logo, symbol, name and picture shall not be misleading and/or contravening the principles of *Shariah* Law.

## 6. QUALITY CONTROL [33]

- Sampling, specifications, testing, documentation, release procedures which ensures the relevant test are carried out
- ensure all materials used are *halal* compliant
- shall not be made from any source that is decreed as non-*halal* by *Shariah* Law [4.5]

# Quality Control...

- Accuracy of therapeutic dose (content uniformity)
- Release of active substance (solubility, dissolution)
- Estimation of stability (stability studies, shelf life, storage conditions)
- take precaution to prevent *non-halal contamination* on production line [4.11]



## 7. CONTRACT MANUFACTURE & CONTRACT ANALYSIS [15]

# CONTRACT MANUFACTURE & CONTRACT ANALYSIS

- Must be correctly defined agreed and controlled in order to avoid misunderstandings
- Must clearly defines the duties of the giver and receiver [4.17]

## 8. COMPLAINTS AND PRODUCT RECALL [16]

- Complaints must be reviewed according to SOPs
- The causes of *halal* non-compliance investigated & appropriate measures taken to prevent re-occurrence [4.4.2]
- There should be a product recall procedure

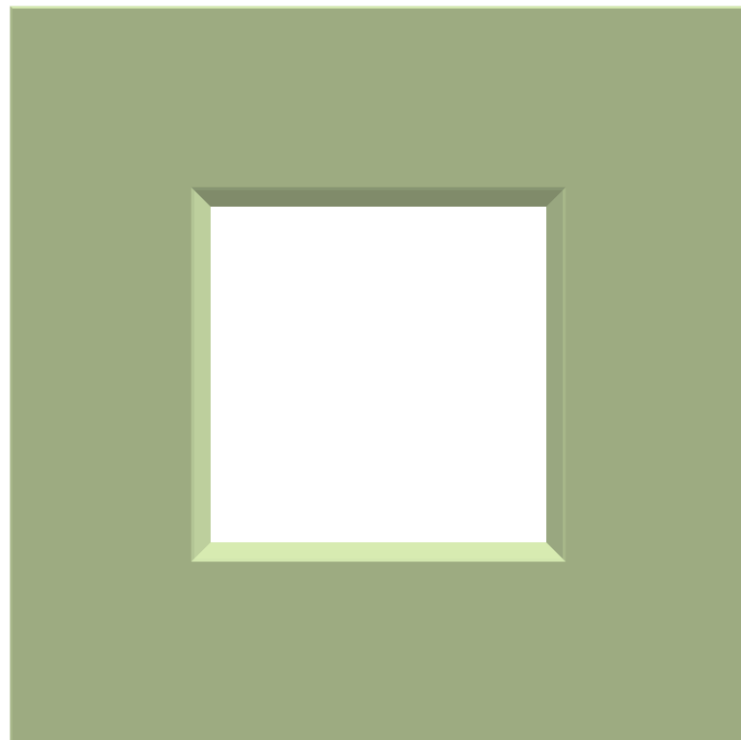
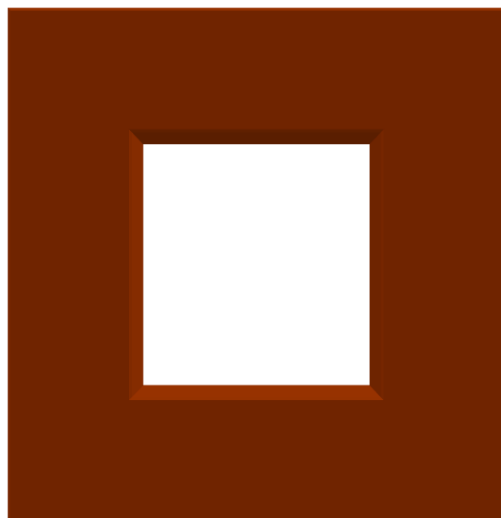
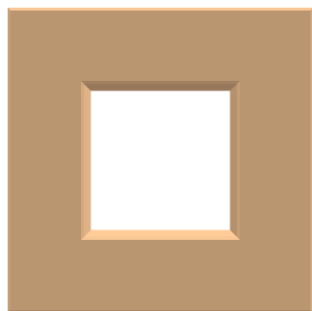
## 9. SELF INSPECTION [3]

- Conducted in order to monitor the implementation and compliance with GMP & *Halal* principles [4.18]
- To propose necessary corrective & preventive measures (CAPA)





NPCB



## 4.12 Ancillary areas

- Prayer rooms shall be provided and appropriately located
- Animal houses shall be isolated from other areas, with separate entrance (animal access) and air handling facilities

## 4.15 Materials

- All materials used in manufacturing of halal pharmaceutical include starting and packaging materials. Materials may be from synthetically or naturally derived sources.
- All najas are prohibited

## 4.15 Materials

### Synthesised materials

- The sources and processing of synthesised materials shall comply with *halal* requirement. The usage of synthetic alcohol is permissible

## 4.15 Materials

### 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 [3.2.c as prescribed dosage]

## 4.15 Materials

### Plants

- All types 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:

Land animals

Are *halal* for pharmaceutical purpose except the following

- Animal with long pointed teeth or tusks which are used to kill prey such as tigers, bears, elephants, cats, monkeys, etc

## 4.15.2.2 Land animals except...

- Predator birds such as eagles, owl and etc
- Pets and/or poisonous animals such as rats, cockroaches, centipedes, scorpions, snakes, wasps and other similar animal
- Animals that are forbidden to be killed in Islam such as bees, woodpeckers



## 4.15.2.2 Land animals except...

- Creatures that are considered repulsive such as lice, flies, etc
- Farmed *halal* animals which are intentionally and continually fed with najis
- Animals forbidden to be eaten in accordance to *Shariah* law such as donkeys and mules and
- All of the above and other animals that prohibited by the competent authority

## 4.15.2.2 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 - 2.6 Materials

Minerals, Micro-organisms & Natural chemicals

- are *halal* except those prohibited the competent authority

Genetically modified organism (GMO)

- Products and/or by products of GMOs or ingredients made by the use of genetic material of animals that are decreed as *halal* by *Shariah* Law

## 4.19 Legal requirements

- *Halal* pharmaceuticals shall in other aspects comply with legislation including other relevant requirement 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 [JAKIM] in Malaysia
- JAKIM - Dept of Islamic Development of Malaysia
- 71 recognised bodies in 29 countries

## 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 Islamic authority



# MS 2424 2012 - Annex A

- *Method of washing & ritual cleansing according to Shariah Law (samak) for najis*

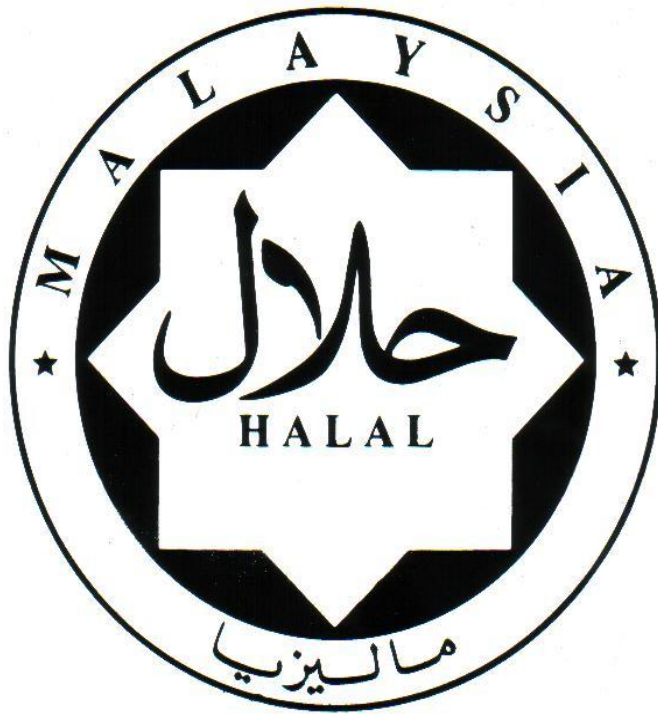




# *Take Home Message*

---

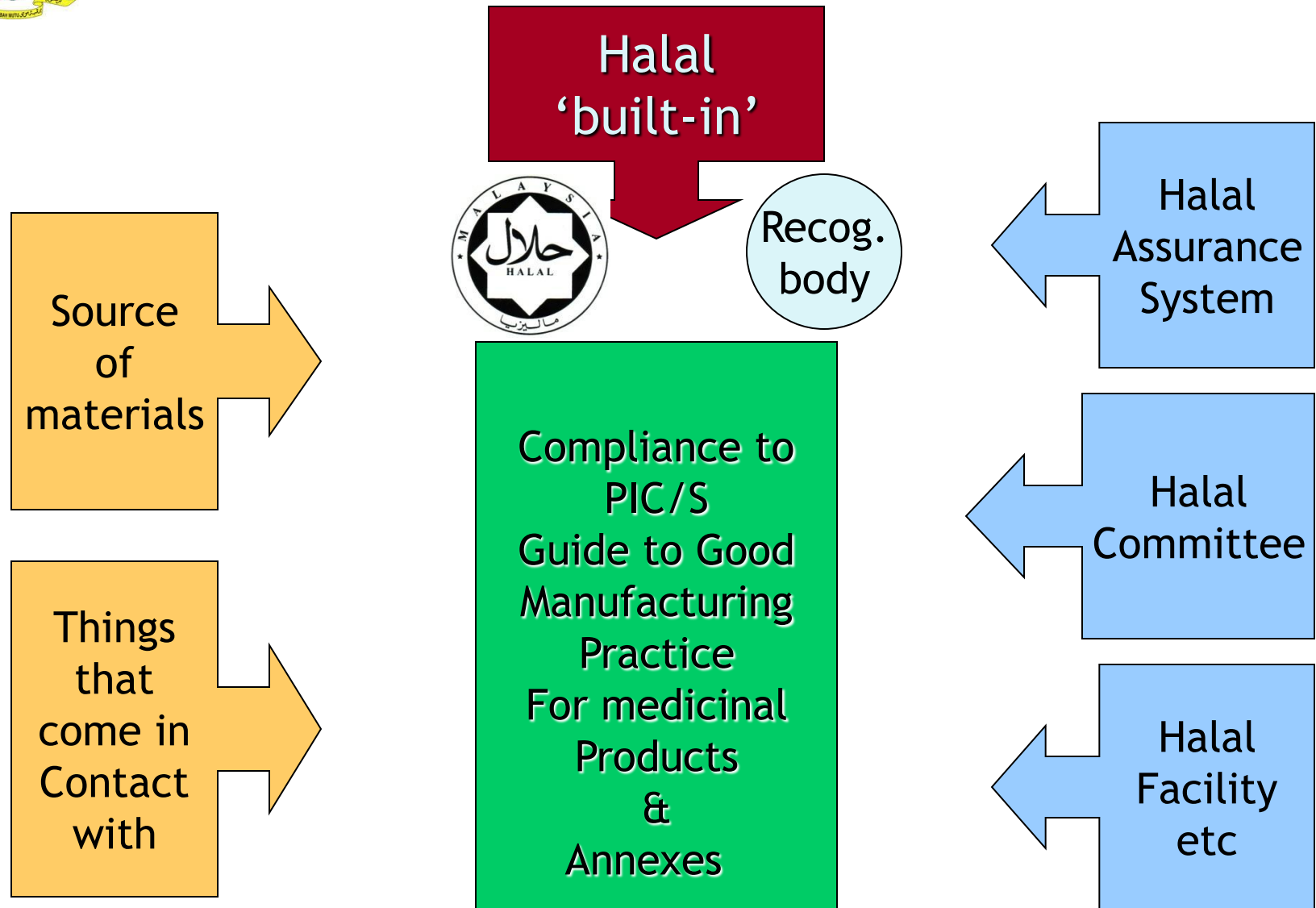
# ***Breaking News***



- MALAYSIA: First Malaysian *Halal* Pharmaceutical Standard for Better Healthcare - A First for the World

- Islamic principles
  - To protect life is top priority
  - In emergency or no choice, allowed to use *non-halal*
  - Continuous quest in search of *halal*

- MS 2424
  - PIC/S + HAS, Halal Committee, Dedicated Halal Facilities etc
  - Source of materials & what in contact with
  - *Halalness* being built in rather than tested to
  - its voluntary, it's a business decision





Product must  
be first  
registered or  
notified  
with DCA  
[Quality,  
Safety,  
Efficacy -  
already  
evaluated]

JAKIM  
conducts  
HALAL  
Pharma  
Audits

JAKIM issues  
HALAL  
Certificates  
[powers to  
issues or  
revoke  
Certifications]





NPCB

# We compliments each other!



[drtajuddin@bpfk.gov.my](mailto:drtajuddin@bpfk.gov.my)





# HALAL Pharmaceuticals: General Guidelines MS 2424 2012

## HALAL Cosmetics: General Guidelines MS 2200: Part 1: 2008





NPCB

# www.bpfk.gov.my


**BPFK** - Mozilla Firefox

File Edit View History Bookmarks Tools Help

[http://portal.bpfk.gov.my/index.cfm?menuid=34](#) Google

Most Visited Getting Started Latest Headlines

BPFK

**National Pharmaceutical Control Bureau**  
Biro Pengawalan Farmaseutikal Kebangsaan  
Ministry of Health Malaysia / Kementerian Kesihatan Malaysia

[HOME](#) | [SITEMAP](#) | [CONTACT US](#)

Learn more about the  
NATIONAL  
PHARMACEUTICAL  
CONTROL BUREAU (NPCB)

WHO Collaborating Centre

Drug Control Authority (DCA)

QUEST2

QUEST3

MADRAC  
(Adverse Drug Reactions)

Regulatory Information

New Products Approved

Template / Guide for Product  
Information for Generic  
Products

Bioequivalence (BE)

## New Procedure for Control of Cosmetic Products in Malaysia

**Overview:**

Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations 1984. From year 2002 to the end of year 2007, the control of cosmetic products was through pre-market registration; where the company which is responsible for placing the product in the local market submit product details and relevant certificates for review and registration by the National Pharmaceutical Control Bureau (NPCB) before the product can be manufactured, imported or sold in the country.

### Download Documents

[Guidelines for Control of Cosmetic Products in Malaysia](#)

[Flow Chart for Notification Procedure for Cosmetic Products](#)

[Guidelines on Good Distribution Practice \(GDP\)](#)

[ASEAN Test Methods](#)

[FAQ's on Cosmetics](#)

[News & Announcements](#)

Done



# *Some Tips*



## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Gelatin	Capsules, emulsifier, filler	<ol style="list-style-type: none"><li>1. Skin, bones, joints (bovine, porcine). Collagen derivatives.</li><li>2. Vegetables</li></ol>



## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Glycerine Glycerol	Diluent, antibacterial, sweetener, preservatives (found in syrup, toothpaste, soaps, shampoo etc)	1. Lard 2. Vegetables 3. Byproducts of biodiesel productions





## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Alcohol (ethanol - drinks)  (methanol- reagent)	Solvent, Antiseptic	1. Fermentations 2. Chemicals



## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Stearates, e.g Magnesium, Stearic acid, calcium	Lubricants Binder	<ol style="list-style-type: none"><li>1. Animal Fats, Lard or fatty acids from pig's stomach)</li><li>2. Vegetable (palm oil. Coconut, soybean, castpr oil, sunflower)</li></ol>



## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Enzymes e.g. Trypsin	Media for microbial growth (TSB)	1. Pig's Pancreas
ACTH	Hormones, corticotrophin	2. Pig's Pituitary Gland





## *Commonly used*

SUBSTANCE	FUNCTION	SOURCES & COMMENTS
Heparin	<p>Anti-Clotting Agent</p> <p>Also used in 'coating' in medical devices e.g. catheter, heart transplant devices</p>	<ol style="list-style-type: none"><li>1. Pig's intestine</li><li>2. Bovine</li></ol>

