HALAL PHARMACEUTICALS
- Regulatory Perspectives

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to all of you who unselfishly dedicated, sacrificed your time & resources in improving the quality of life of others

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

• MALAYSIA: First Malaysian Halal Pharmaceutical Standard for Better Healthcare - A First for the World
Halalan [allowable] & Toyyiban [safe]

Toyyiban (DCA)
- Quality, Safety & Efficacy
- GMP, Pre & Post Registration requirements, GDP
- Policies etc

Halalan (JAKIM)
Regulator’s concern
....Pharmaceuticals

Quality, Safety and Efficacy
[Kualiti, Keselamatan dan Keberkesan]
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)
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 issue or revoke Certifications]
Current DCA’s Policy on HALAL

Allows HALAL labels on:
- Cosmetics, Traditional Med
- Health Supplements
- OTC [2013] IV parenterals

Why?
- There is a choice

Halal Certification is voluntary
Must label if it is from animal source either bovine or porcine
Feqah Principles

• To protect life is top priority
• When in *darurat* [emergency or when there is no choice] using of *non-halal* is *harus*
• Continuous quest in search of *halal*
HALAL Pharmaceuticals: General Guidelines 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.
What is Halal Pharmaceuticals?

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.
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)
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
Recognised Halal Bodies in JAPAN

1. **Japan Muslim Association**  
   3-4-14, Kohinata, Bunkyo-ku,  
   Tokyo 112-8585, Japan  
   Chairman Prof. Hideomi MUTO (Tayeb)  
   Tel: +81 33947940  
   Fax: +81 339479416  
   Email: jma@mc.neweb.ne.jp  
   TayebM@aol.com

2. **Japan Halal Association (JHA)**  
   547-0035, Osaka Shi Hirano-Ku,  
   Nishiwaki 1-1-2 Miyako Sansai  
   Tel: 81 6 6704 7080  
   Fax: 81 6 6704 9505  
   Email: info@jhalal.com
HALAL BUILT-IN
Not tested for
Halal ‘built-in’

Source of materials

Things that come in Contact with

Compliance to PIC/S Guide to Good Manufacturing Practice For medicinal Products & Annexes

Recog. body

Halal Assurance System

Halal Committee

Halal Facility etc

Source of materials

Things that come in Contact with

Compliance to PIC/S Guide to Good Manufacturing Practice For medicinal Products & Annexes

Recog. body

Halal Assurance System

Halal Committee

Halal Facility etc
We compliments each other!

drtajuddin@bpfk.gov.my
Terima kasih
Take Home Message
Halal ‘built-in’

Compliance to PIC/S Guide to Good Manufacturing Practice For medicinal Products & Annexes

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