



# Quality Control Aspects for Herbal Product with High or Medium Claim

**Noraida Mohamad Zainoor**

BSc (Hons) Pharm (UK), M.Sc. (KUL), Ph.D (UK)

National Pharmaceutical Control Bureau (NPCB), MOH. Malaysia

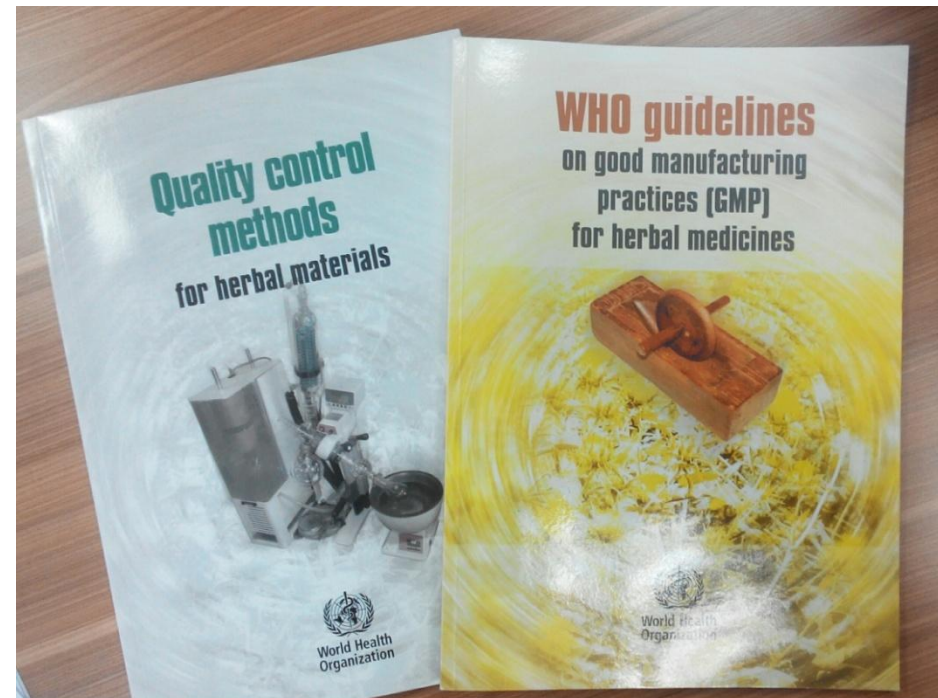


# Outlines

- ✓ Quality Management System
- ✓ Claims for Herbal Product
- ✓ Routine Tests for Herbal Product with General Claim
- ✓ Quality Control Tests for Herbal Product with High or Medium Claim
- ✓ Summary

# References

1. WHO Quality Control Methods for Herbal Materials, 2011.  
<http://apps.who.int/medicinedocs/en/d/Jh1791e/>
2. WHO Guidelines on GMP for Herbal Medicines, 2007.
3. PICs, Guide To GMP For Medicinal Products Part I, 1 Sept 2009.





# Quality Management System

- ✓ To produce high quality medicinal products, manufacturers must ensure that:-
  - a. their medicinal products are fit for their intended use.
  - b. comply with the regulatory requirements.
  - c. do not place consumers or patients at risk due to inadequate safety, quality or efficacy.
  
- ✓ And therefore, to achieve that goals, is crucial for medicinal manufacturers to implement a Quality Management System (QMS).



# Quality Management System

- ✓ The QMS should be a comprehensively designed system that incorporating with Quality Assurance (QA), Good Manufacturing Practice (GMP) and Quality Control (QC).





# Quality Control

- ✓ Quality Control (QC) is:-
  - A part of GMP
  - Concerned with sampling, specifications, testing, organisation, documentation and release procedure.
  - QC is responsible to ensure that materials for medicinal production are not released for use, nor medicinal products released for sale or supply, until their quality has been judged satisfactory.





# Claims

## ✓ General Claims

- Herbal Product can promote good health and general well-being (physical and mental) by providing nutrition, enhancing body structure or function and relieving physiological discomfort.

Example: Herbal product helps to maintain good health



# Claims

## ✓ Medium Claims

- Herbal Product can reduce the risk of a disease or disorder.

Example: Herbal product used for improving bowel movement.

## ✓ High Claims

- Herbal Product can treat or cure or management of any serious disease or disorder.

Example: Herbal product used to treat diabetes





# *Routine Tests*

- ✓ Type of routine QC tests (pre and post registration) for Herbal Product with General Claim are :-
1. Limit Test for Heavy Metals (Hg, As, Pb and Cd)
  2. Disintegration Test.
  3. Test for Uniformity of Weight (For Tablets and Capsules Only).
  4. Tests for Microbial Contamination.



# *Routine Tests*

- ✓ Type of routine QC tests (pre and post registration) for Herbal Product with General Claim are :-
- 5. Testing for Specific Ingredient such as screening of *Monacolin-K* in Traditional herbal medicines containing Red Yeast Rice (*Monascus purpureus*)-  
*<1% w/w or <10 mg per day.*
- 6. Any possible adulterants (pharmaceutical drug) based on product claimed.



# *Routine Tests*

However, WHO Guidelines on GMP for Herbal Medicines, 2007, testing for herbal medicines should also include the following tests:-

- ✓ Other contaminants such as pesticide residues, radioactives and aflatoxins.
- ✓ Other physical tests such as water content and loss on drying.
- ✓ Identity tests such as fingerprint chromatograms

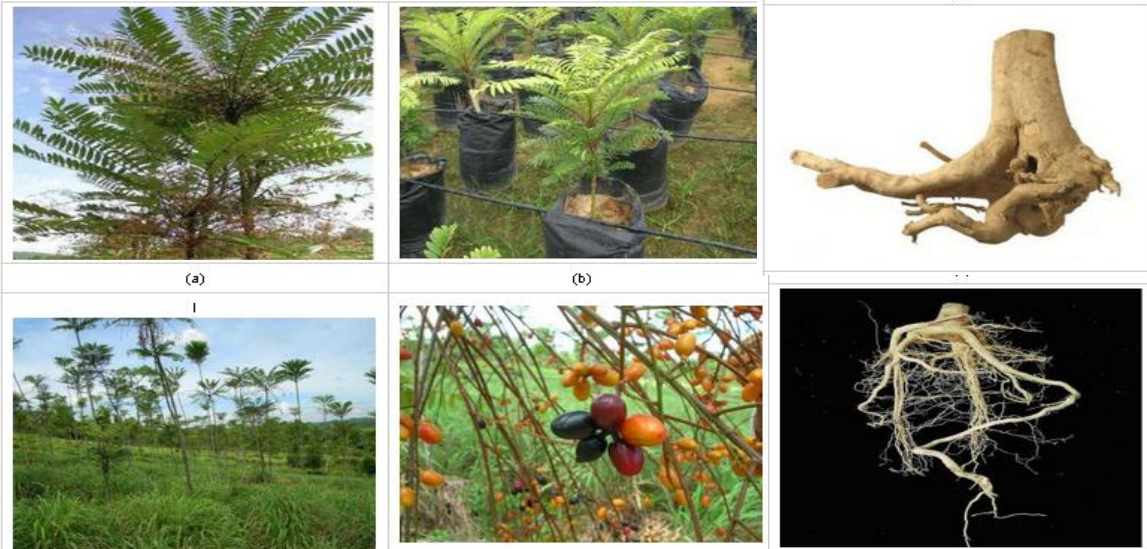


# *Quality Control Testing for Herbal Product with High or Medium Claim*

- ✓ Raw material(s)-Identification, safety
- ✓ Intermediate product- IPQC
- ✓ Finish product
- ✓ Stability Study - determine shelf life



# Quality Control Testing for Herbal Product with High or Medium Claim



## Tongkat Ali (*Eurycoma longifolia*)

e.g. Chemical Constituent, 10mg of Eurycomanone can treat diabetes.



# *Quality Control Testing for Herbal Product with High or Medium Claim*

- ✓ Raw material
  - Sampling to get representative sample (raw material and finished products).
  - Sampling according to approved written procedure.

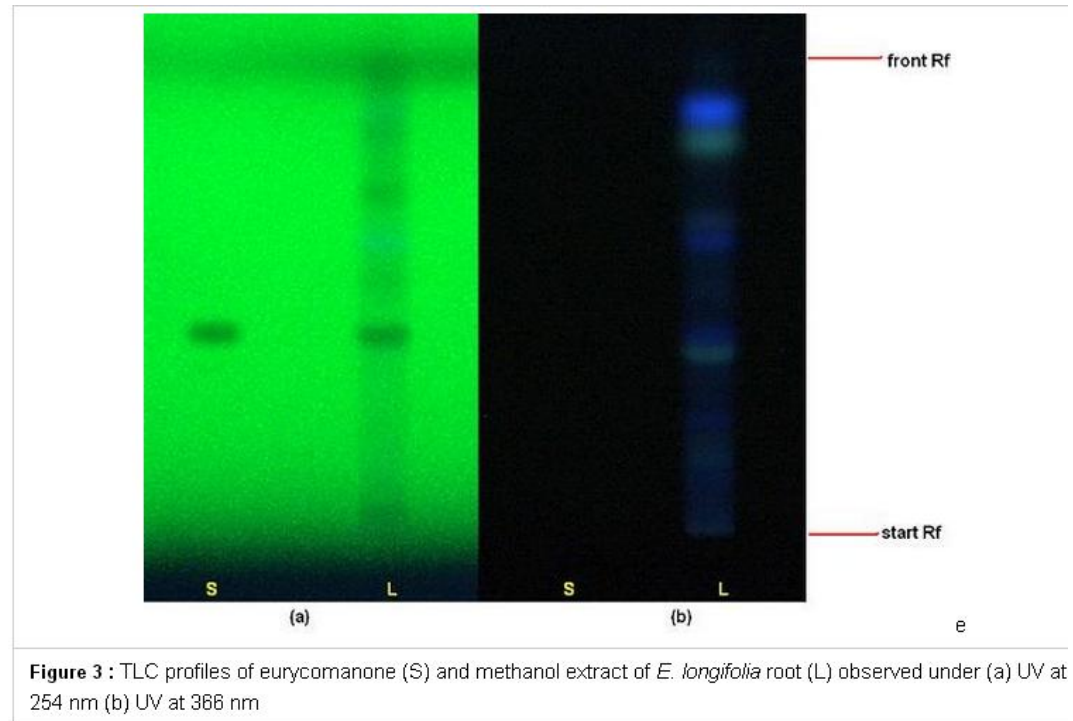
# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Raw material

### a. IDENTIFICATION

- Macroscopy
- Microscopy
- Colour tests
- Thin Layer

Chromatography  
(TLC)-no more fingerprint



Tongkat Ali (*Eurycoma longifolia*)  
e.g. Chemical Constituent, 10mg of Eurycomanone can treat diabetes.



# *Quality Control Testing for Herbal Product with High or Medium Claim*

## ✓ Raw material

### b. PURITY TESTS

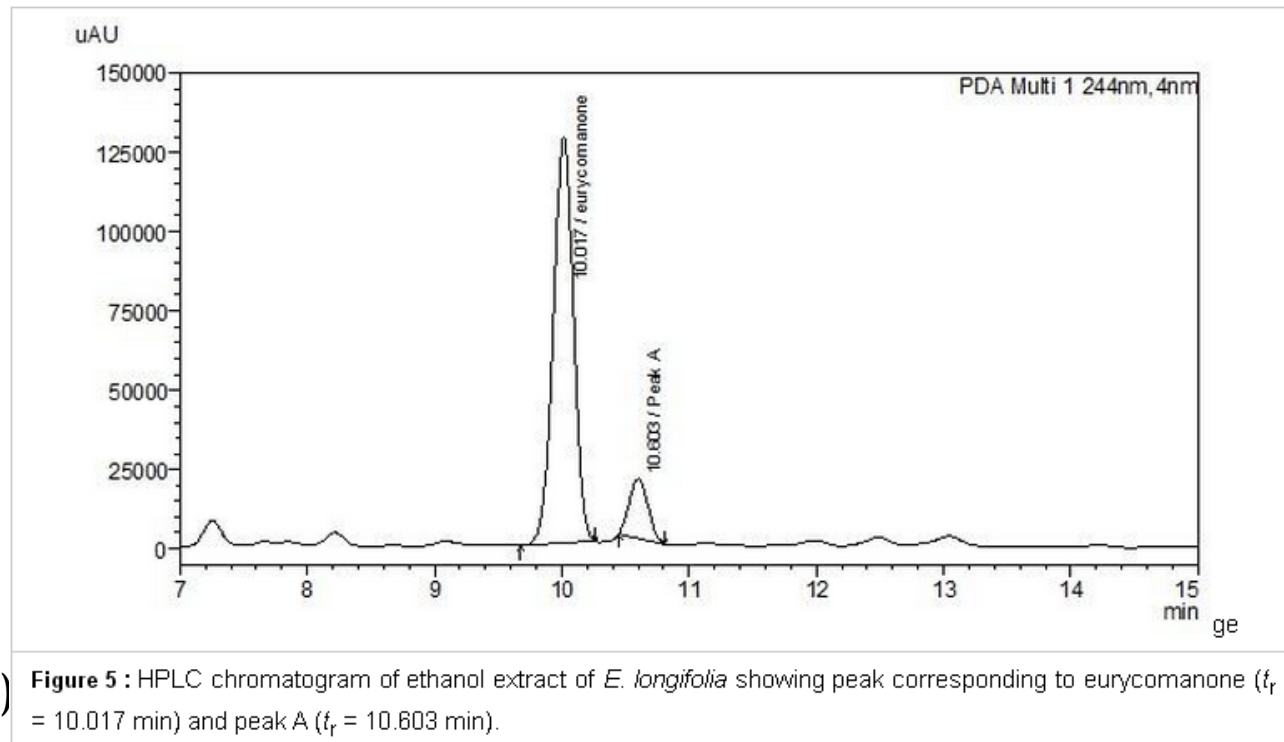
- Foreign Matter - Not more than 2%
- Ash Contents
  - Total ash
  - Acid-insoluble ash
- Loss on Drying
- Extractive Values-Water-soluble extracts
  - Ethanol-soluble extracts





# Quality Control Testing for Herbal Product with High or Medium Claim

- ✓ Raw material
  - c. ASSAY TEST (HPLC)- Active Ingredient Content e.g > 20%w/w of eurycomanone (Compared with Ref Std)





# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Raw material

### d. SAFETY TESTS

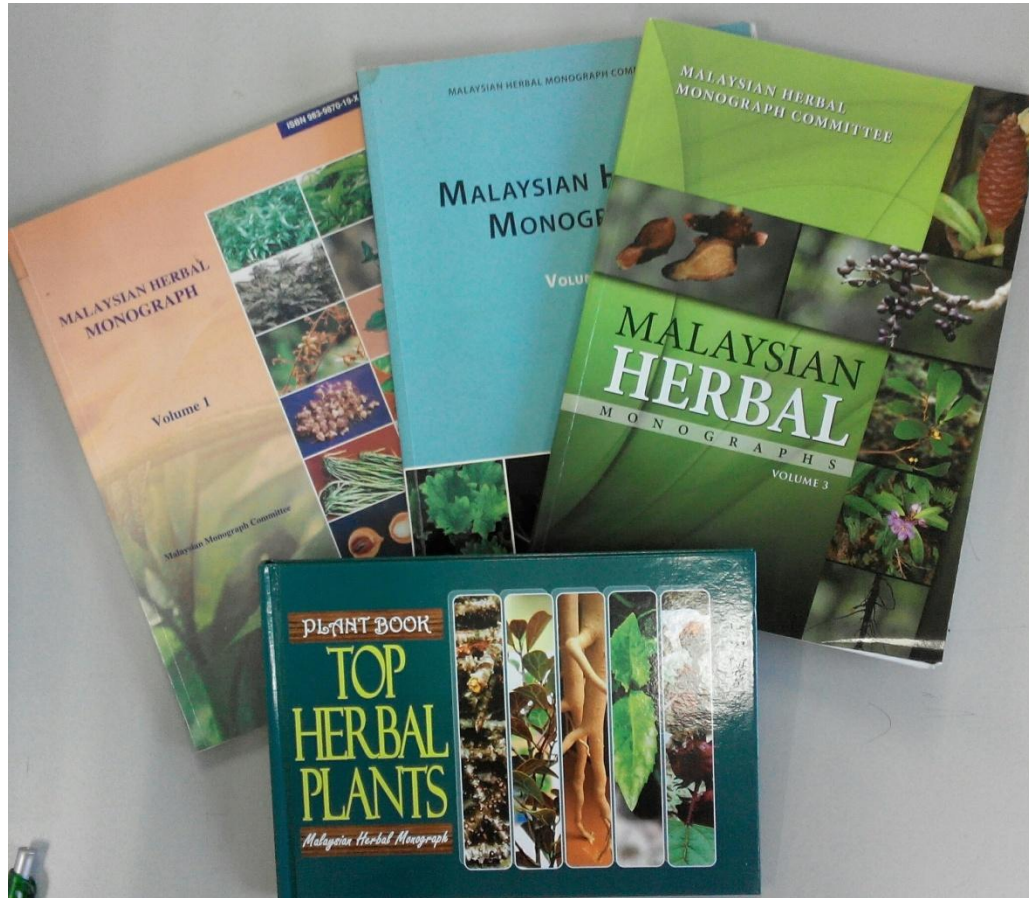
- Heavy Metals
- Microbial Limits
- Specific Pathogens
- Pesticide Residues
- Aflatoxins





# Quality Control Testing for Herbal Product with High or Medium Claim

- ✓ Raw material





# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Raw material

www.globinmed.com/index.php?option=com\_content&view=article&id=102022:eurycoma-longifolia-jack&catid=20

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Eurycoma longifolia Jack

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**MALAYSIAN HERBAL MONOGRAPH**

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**Tongkat Ali Root**

*Eurycoma longifolia* Jack

Simaroubaceae



# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Finished Product

### a. PHYSICAL TESTS

- Appearance-colour, shape
- Uniformity of weight-dosage consistency-(under/overdose)



### b. IDENTIFICATION using Chemical Marker (e.g for Tongkat Ali - eurycomanone)

- Thin Layer Chromatography (TLC)
- HPLC



# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Finished Product

### c. PURITY TESTS

d. LOSS ON DRYING OR WATER CONTENT - related to microbial growth.

### e. ASSAY TEST (HPLC)- Active Ingredient Content

Tongkat Ali (*Eurycoma longifolia*) e.g. Chemical Constituent, 10mg of Eurycomanone can treat diabetes. Specification- quality evaluation (to release or reject) e.g 90-110% of labeled claim of eurycomanone.



# Quality Control Testing for Herbal Product with High or Medium Claim

## ✓ Finished Product

f. IMPURITIES TEST-during processing and storage

- Related/Degradated Substances
- Solvent Residues

g. DOSAGE PERFORMANCE TESTS

- Friability
- Disintegration
- Dissolution





# *Quality Control Testing for Herbal Product with High or Medium Claim*

## ✓ Finished Product

### h. SAFETY TESTS

- Heavy Metals
  - Microbial Limits
  - Specific Pathogens
- ❖ It is responsible for Herbal manufacturers to make a complete protocol analysis and certificate of analysis of raw material(s) and finished product available for registration.





# *Quality Control Testing for Herbal Product with High or Medium Claim*

## ✓ Stability Study

- To determine shelf life (expiration dating period, conformance period) of Finished Product (FP).
- The time period during which a FP is expected to remain within the approved shelf-life specification, provided that it is stored under the conditions defined on the container label.



# *Quality Control Testing for Herbal Product with High or Medium Claim*

## ✓ Stability Study

### ■ Formal stability studies

- Long term and accelerated studies.
- Stress testing (forced degradation) to assess the effect of severe conditions (e.g. temperature, photostability and humidity)
- Identification, Impurities and assay testing must be stability indicating and validated method.



# Summary

- ✓ The QC for herbal product with high or medium claim must:-
  - start at initial stage of manufacturing up to the storage of Finished Product.
  - have qualified personnel to conduct all the tests and to interpret the analytical data.
  - have validated testing methods and using calibrated and well maintained of analytical equipment.
  - Have suitable laboratory facilities to run chemical and microbiological testing. Have proper documentation, SOPs and records



***THANK YOU  
FOR  
YOUR ATTENTION***