



MALAYSIAN HERBAL MONOGRAPH



10 Mac 2015
National Pharmaceutical Control Bureau (NPCB)

- **The Importance of Malaysian Herbal Monograph (MHM)**
- **MHM volume 1,2 and 3**
- **National Key Economic Area (NKEA)
Malaysian Herbal Monograph**
- **Institution Involved**
- **Workflow in development of MHM**
- **Content of MHM**



- Invaluable source of scientific information on herbal medicines
 - Regulators, manufacturers, academia, researchers, health professionals & others
 - Authorities information
 - Therapeutic uses of herbal medicines
 - Summaries of pharmacological, clinical & toxicological data
 - Guidance for authentication of plant material
 - Guidance for quality control profile for herbal materials and products
 - Ensuring the quality and right raw material goes into the product
 - correct species
 - correct part
- (Authentication is the most basic quality step)



- Malaysian Herbal Monograph (MHM)
 - Volume 1 (1990)
 - Volume 2 (2009)
 - Volume 3 (2013)

-20 monograph/species in each volume. (Total :60)
-based on voluntarily work by institution



- National Key Economic Area(NKEA) Malaysian Herbal Monograph (MHM)

- 2013 - 10 monograph/species
- 2014 -15 monograph/species

-www.globinmed.com

-Budget allocated for this project and with key performance indicator (KPI).



- Institution involved in development of Malaysian Herbal Monograph (MHM)
 - Institute of Medical Research (IMR)
 - National Pharmaceutical Control Bureau (NPCB)
 - Forest Research Institute Malaysia (FRIM)
 - Malaysian Agriculture Research and Development Institute (MARDI)
 - Local Universities such as UKM, UPM and USM
- Technical/Scientific Committee
-Main Committee.



WORKFLOW (By INSTITUTION)

COLLECTION OF MEDICINAL PLANTS

PROCESSING OF MEDICINAL PLANTS

STUDY OF MEDICINAL PLANTS

LITERATURE REVIEW

- Definition
- Synonym & vernacular names
- Medicinal uses
- Dosage
- Storage

IDENTIFICATION

- Plant morphology:
photography, macroscopy, microscopy
- Characters
- Colour tests
- Chemical constituents

PURITY TESTS

- Foreign matter
- Ash contents - *Total ash, acid-insoluble ash, water-soluble ash*
- Loss on drying
- Extractive value

SAFETY TESTS

- Heavy metals limit
- Microbial limit
- Test for specific pathogen

SAFETY INFORMATION

- Preclinical toxicology
- Acute toxicity test

DATA VERIFICATION BY NPCB

CONDUCT BY IMR

DATA VERIFICATION & PRESENTATION
(Technical Committee review, Industry review, Main Committee review)

PREPARATION OF MHM & PUBLICATION

▪ Content of Malaysian Herbal Monograph (Vol. 2, 2009)

1.0 Definition

2.0 Synonym

2.1 Latin name

2.2 Vernacular name

3.0 Character

4.0 Identification

4.1 Macroscopic

4.2 Microscopic

4.3 TLC

4.4 Colour test

5.0 Purity test

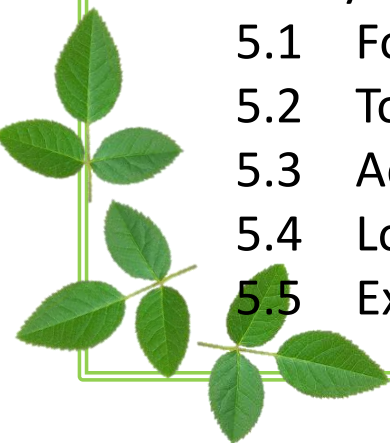
5.1 Foreign matter

5.2 Total ash

5.3 Acid insoluble ash

5.4 Loss on drying

5.5 Extractive value



- **Content of Malaysian Herbal Monograph (Vol. 2, 2009)**

- 5.6 Heavy metals

- 5.7 Microbial limit

- 5.8 Test for specific pathogens

- 6.0 Storage

- 7.0 Uses

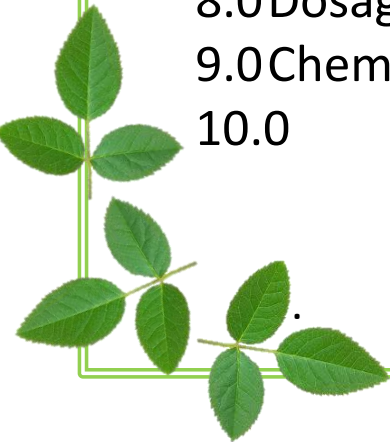
- 7.1 Uses described in folk medicine, not supported by experimental or clinical data

- 7.2 Biological activity

- 8.0 Dosage

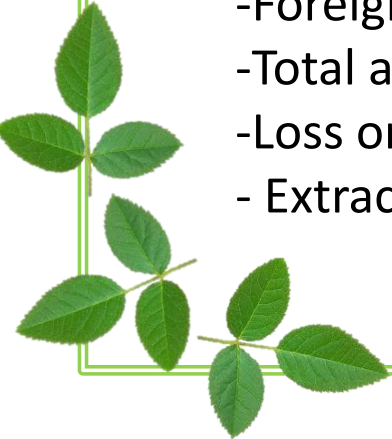
- 9.0 Chemical constituents

- 10.0 References



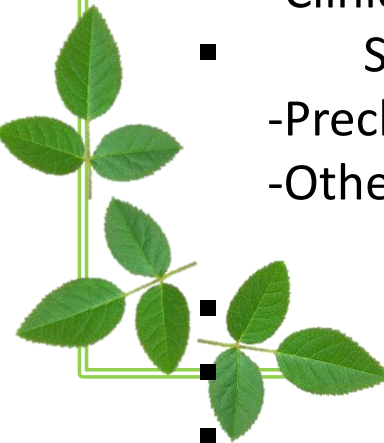
Content of Malaysian Herbal Monograph (NKEA)

- Definition
- Synonym
- Character
- Identification
 - Plant Morphology
 - Microscopy
 - Colour test
 - TLC
 - HPLC
- Purity test
 - Foreign matter
 - Total ash
 - Loss on drying
 - Extractive value



Content of Malaysian Herbal Monograph (NKEA)

- Safety Test
 - Limit of Heavy metals
 - Microbial limit test
 - Test for specific pathogens
- Chemical constituents
- Medicinal Uses
 - Uses described in folk medicine, not supported by experimental or clinical data
 - Biological and pharmacological activity supported by experimental data
 - Clinical studies
- Safety Information
 - Preclinical studies (Toxicology studies)
 - Others (Adverse reaction, contraindication, side effect, warning and precautions)
- Dosage
- Storage
- References



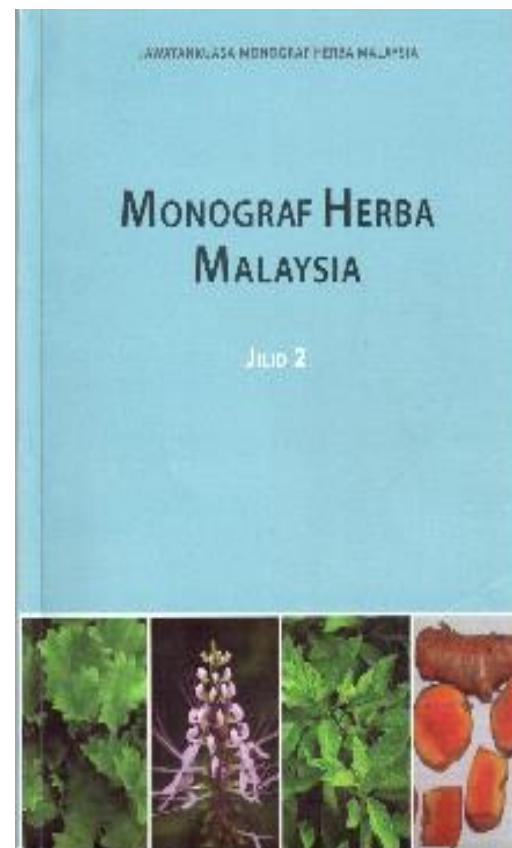
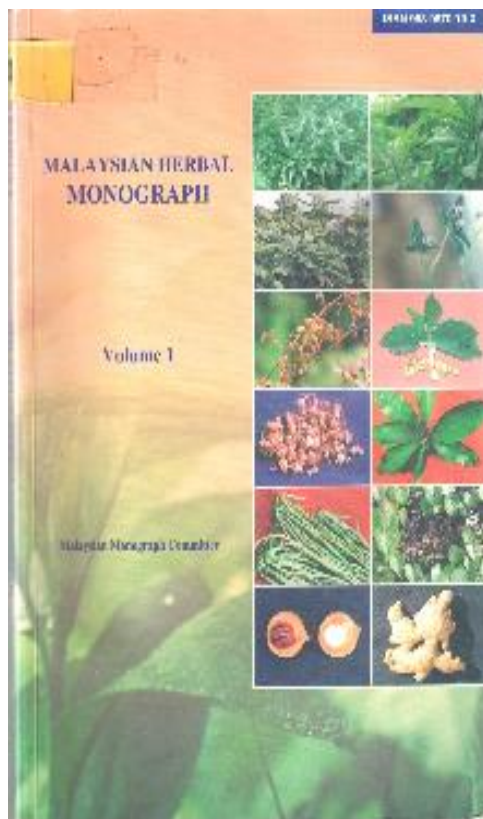
NKEA Monographs 2013 (Plants List)

No	Plants	Scientific Name
1	Tongkat ali root	<i>Eurycoma longifolia</i>
2	Kacip fatimah root	<i>Labisia pumila</i>
3	Misai kucing leaf	<i>Orthosiphon aristatus</i>
4	Dukung anak herb	<i>Phyllathus niruri</i>
5	Hempedu bumi herb	<i>Andrographis paniculata</i>
6	Pegaga herb	<i>Centella asiatica</i>
7	Halia rhizome	<i>Zingiber officinale</i>
8	Mengkudu fruit	<i>Morinda citrifolia</i>
9	Roselle calyx	<i>Hibiscus sabdariffa</i>
10	Mas cotek leaf	<i>Ficus deltoidea</i> var. <i>deltoide</i>

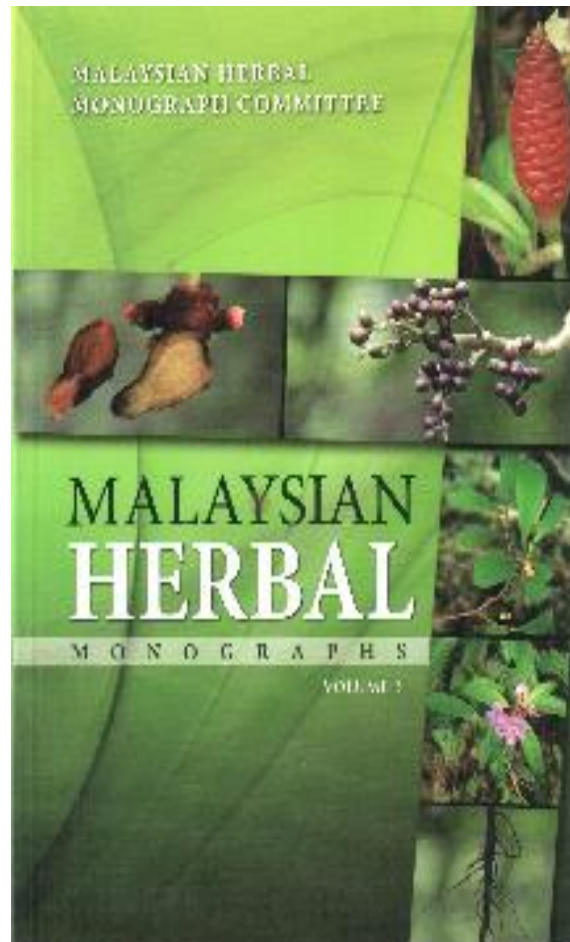
NKEA Monographs 2014 (Plants List)

No	Plants	Scientific Name
1	Senduduk leaves	<i>Melastoma malabathricum</i>
2	Kesum leaves and twigs	<i>Persicaria minor</i>
3	Ulam raja leaves	<i>Cosmos caudatus</i>
4	Sireh leaves	<i>Piper betle</i>
5	Temu lawak rhizome	<i>Curcuma xanthorrhiza</i>
6	Kaduk leaves	<i>Piper sarmentosum</i>
7	Kelapa sawit leaves	<i>Elaeis guineensis</i>
8	Sambung nyawa leaves	<i>Gynura procumbens</i>
9	Belalai gajah leaves	<i>Clinacanthis nutans</i>
10	Merunggai leaves	<i>Moringa oleifera</i>
11	Gelenggang leaves	<i>Senna alata</i>
12	Patawali stem	<i>Tinospora crispa</i>
13	Lempoyang rhizome	<i>Zingiber zerubet</i>
14	Halia bara	<i>Zingiber officinale</i>
15	Selasih	<i>Ocimum basilicum</i>

The Malaysian Herbal Monographs Vol. 1 & 2.



The Malaysian Herbal Monographs Vol. 3.



MALYSIAN HERBAL MONOGRAPH

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Background

The development of Malaysian Herbal Monograph (MHM) is one of the government's plans and it is identified as one of entry point projects (EPP) under the National Key Economic Areas (NKEA).

MHM is a crucial reference to establish good quality of raw material herbs for herbal or traditional products. It provides valuable information for both herbal or traditional manufacturers and regulators such as identification of herbs, quality control requirements, medicinal usage and safety information.

- The production of quality products can promote greater confidence among consumers both inside and outside the country, thus leading to increase usage and exports which will contribute to the country's economic development
- MHM ensure productions of local and traditional products are safe, of high quality, competitive and comply to international standards.

MALYSIAN HERBAL MONOGRAPH TECHNICAL COMMITTEE

Herbal Development Office (HDO), Ministry of Agriculture

- Institute for Medical Research (IMR)
- National Pharmaceutical Control Bureau (NPCB)
- Forest Research Institute Malaysia (FRIM)
- Malaysian Agricultural Research and Development Institute (MARDI)
- National University of Malaysia (UKM)
- Science University of Malaysia (USM)
- Putra University of Malaysia (UPM)

ACHIEVEMENTS

- Publication of Malaysian Herbal Monograph Volume 1 (1999)
- Publication of Malaysian Herbal Monograph Volume 2 (2010)
- Publication of Malaysian Herbal Monograph Volume 3 (15 April 2013)
- Launching of top ten NKEA Malaysian Herbal Monograph 2013 (15 April 2013)

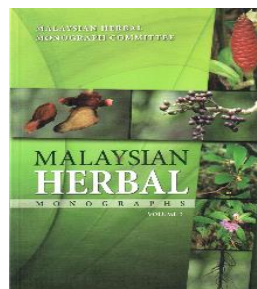
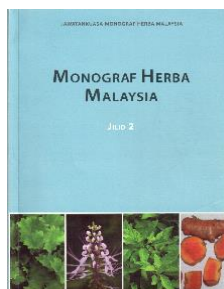
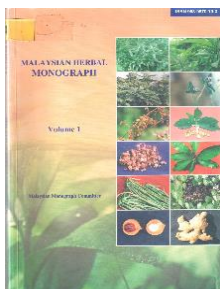
ROLE OF NPCB (PHYTOCHEMISTRY UNIT, CENTRE FOR QUALITY CONTROL)

- Verification of developed methodology for quality control of herbal raw material
- Method development for quality control of herbal raw material using Thin Layer Chromatography (TLC) and High Performance Liquid Chromatography (HPLC) - Including pesticide testing
- Provide training and seminar to local herbal or traditional product manufacturers on quality control of herbal raw material.

All the top ten plants under NKEA can be search at http://www.globinmed.com/index.php?option=com_content&view=category&id=209&Itemid=143



The Malaysian Herbal Monographs Vol. 1, 2 & 3.



NKEA TOP TEN PLANTS

1. Halia Rhizome (*Zingiber officinale*)



2. Dukung anak Herb (*Phyllanthus niruri*)



3. Misai kucing Leaf (*Orthostichon aristatus*)



4. Mengkudu Fruit (*Morinda citrifolia*)



5. Kacip Fatimah Root (*Labisia pumila var. alata*)



6. Roselle Calyx (*Hibiscus sabdariffa*)



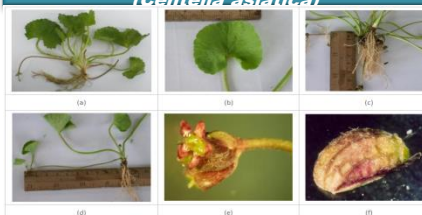
7. Mas cotek Leaf (*Ficus deltoidea var. deltoidea*)



8. Tongkat Ali Root (*Eurycoma longifolia* Jack)



9. Pegaga Herb (*Centella asiatica*)



10. Hempedu bumi Herb (*Andrographis paniculata*)



***THANK YOU FOR
YOUR ATTENTION***

