CHEST

CENTRE FOR HERBAL STANDARDIZATION

USM UNIVERSITI SAINS MALAYSIA

# PROSPECTUS 2016/2017

# Prospectus

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## FOREWORD

Herbal products are gaining increasing importance and general acceptability in Malaysia as nutritional supplements, medicines or as essential ingredients in cosmeceuticals. This popularity is the result of the recognition of the unique biochemistry and therapeutic potential of the herbals as well as acceptance of Malaysian government to promote local herbal products globally through entry point project (EPP) under the National Key Economic Areas (NKEAs).

Unfortunately, the escalating use of herbal product has also given rise to the abuse and adulteration of the herbal substances. Standardization of the herbal material is therefore of upmost importance to ensure reproducibility in the manufacturing of herbal products. Standardization and the practice of good quality assurance would lead to development of products which are of high quality, safety and efficacy enabling penetration of the global market.

Centre for Herbal Standardization (CHEST) is the leading centre in USM with the state-of-the-art facilities to focus in herbal research and services. This centre is one of the research institutions, local universities and government agencies in Malaysia which was given the responsibility to develop Malaysian Herbal Monograph. The monographs serve as a comprehensive reference and provide requisite information in its bid to increase the value of local herbals. In turn, this would elevate the status of the Malaysian herbal industry.

We are devoted to providing services that consistently meet high quality and performance standards. Prompted by our institution's mission and vision, we are working hard to secure ISO/IEC 17025 accreditation to assist testing and calibration in our laboratories.

We look forward to serve you.

**Prof. Dr. Sabariah Ismail**
Director
*January 4, 2016*

# INTRODUCTION

It is often claimed indigenous knowledge including the 'know-how' in the usage of plants for medicinal purposes are not in alignment with hi-tech drug development. As per now, a venue where indigenous knowledges and drug discoveries are being combined together are scattered and almost non-existence. Understanding the need to bridge this together, Universiti Sains Malaysia in a joint effort with Biotropics Malaysia Berhad established the Centre for Herbal Standardization in the year of 2011. Also known as CHEST, the centre located at Science & Art Innovation Space (sains@usm) provides a platform where natural products drug discovery guided by traditional knowledge can be accomplished. In the last five years, CHEST has placed increasing emphasis in providing solutions and benefits to various corporate as well as government sectors.

## Vision

To be the world leader in herbal service provider, research and development.

## Missions

To lead in research & services in the aspect of quality, safety and efficacy of herbs.
To achieve recognition in quality laboratory management system. To contribute towards higher national sustainable development by nurturing herbal research expertise.

## Values

**QUALITY** Create and expect excellence.

**INTEGRITY** and **HONESTY** Be honest and have integrity in all we do.

**PASSION** Be passionate, positive and proud with our roles.

**ACCOUNTABILITY** Honour expectations and obligations.

**PROFESSIONALISM** It is our priority.

# HERBAL MONOGRAPH DEVELOPMENT SERVICES

The purpose of the monographs is to provide scientific information on the safety, efficacy, and quality control/quality assurance of widely used medicinal plants, in order to facilitate their appropriate use. Contents of monograph are:

| Part 1 (Experimental) | Part 2 (Literature Review) |
|---|---|
| • Botanical features<br>• Distribution<br>• Identity tests<br>• Purity requirements<br>• Chemical assays<br>• Active or major chemical constituents | • Clinical applications<br>• Traditional applications<br>• Pharmacology<br>• Contraindications<br>• Warnings and precautions<br>• Potential adverse reaction<br>• Posology |

## References

1. Medicinal Herbs and Plant Database, Globinmed – Malaysian Herbal Monograph. Available at *http://www.globinmed.com/index.php?option=com_content&view=category&id=209&Itemid=143*

# STABILITY STUDY SERVICES

To provide evidence on how the quality of an active substance or medicinal product varies with time under the influence of a variety of environmental factors such as temperature and humidity and to establish a shelf life for the drug/herbal product and recommended storage conditions.

CHEST is offering real time (long term) and accelerated (short term) stability storage. storage conditions are as per requirements for zone IVb.

## Real Time

- Condition: 30°C ± 2°C / 75% RH ± 5% RH.
- Duration: 24–36 months.
- Testing points: up to 8 (0-month, 1–month, 3–month, 6–month, 9–month, 12–month, 24–month and 36–month).
- Tests: As per regulation/request.

## Accelerated Time

- Condition: 40°C ± 2°C / 75% RH ± 5% RH.
- Duration: 6 months.
- Testing points: 4 (0–month, 1–month, 3–month and 6–month).
- Tests: As per regulation/request.

# DRUG–DRUG & HERB–DRUG INTERACTION SERVICES

Drug-drug and herb-drug interactions are important safety and regulatory issues. These metabolic interactions may occur through inhibition or induction of drug metabolizing enzymes. These interactions may cause increased or decreased drug exposures when two or more drugs are co-administered or when herb and drugs are taken together.

CHEST provides the following services:

1. Luminescence-based Cytochrome P450 inhibition assay in CYP1A2, 2C9, 2C19, 2D6 and 3A4 isoforms.
2. Luminescence-based UDP-glucuronosyltransferase (UGT) inhibition assay in UGT1A1, 1A4, 1A6, 3A4 and 2B7 isoforms.
3. Glutathione S-transferase (GST) inhibition assay.
4. HPLC-based Cytochrome P450 inhibition assay in microsomal fractions or recombinant isoforms.
5. HPLC-based UDP-glucuronosyltransferase (UGT) inhibition assay in microsomal fractions or recombinant isoforms.
6. Data interpretation: half maximal inhibitory concentration (IC50) and inhibitory constants (Ki) value will be determined.

## References


1. Mohd Salleh, N., Ismail, S. and Mohamad Ibrahim, M. N. (2015). Radical scavenging activity of lignin extracted from oil palm empty fruit bunch and its effect on glutathione S-transferase enzymes activity. Asian Journal of Pharmaceutical and Clinical Research, 8(3), 81-87.
2. Haron, M., Ismail, S. (2014). Effects of mitragynine and 7-hydroxymitragynine (the alkaloids of Mitragyna speciosa Korth) on 4-methylumbelliferone glucuronidation in rat and human liver microsomes and recombinant human uridine 5'-diphospho-glucuronosyltransferase isoforms. Pharmacognosy Research, 7(4), 341-349.
3. Hanapi, N. A., Azizi, J., Ismail, S. and Mansor, S. M. (2010). Evaluation of selected malaysian medicinal plants on phase I drug metabolizing enzymes, CYP2C9, CYP2D6 and CYP3A4 activities in vitro International Journal of Pharmacology, 6(4), 494-499.

# EXTRACTION AND ISOLATION / FRACTIONATION SERVICES

## Extraction

- Extraction is a separation process consisting in the separation of a substance(s) from a matrix (such as plant materials).
- Extraction services available are accelerated solvent extraction (ASE), reflux, soxhlet, maceration and sonication.
- We accept dried grinded plant materials. Please enquire for more details acceptable on material.

## Isolation/ Fractionation

- Isolation/Fractionation is the physical separation of a chemical substance(s) of interest from foreign or contaminating substances. Isolate(s) obtained is in semi-pure form.
- Combination or individual techniques of filtration, centrifugation, drying, flash chromatography, liquid fractionation (liquid-liquid extraction) and semi-prep HPLC are available.

## Drying

- Drying is a process of removing solvent(s) or solvent residue(s) to obtain dry materials.
- Currently vacuum drying and freeze drying services are available.

# PHYSICOCHEMICAL TESTING SERVICES

## Carbon Hydrogen & Nitrogen (CHN) Determination

- Carbon, Hidrogen and Nitrogen Elemental Analysis is an analytical method is based on the complete and instantaneous oxidation of the sample by “flash combustion”, which converts all organic and inorganic substances into combustion products.
- Equipment: Leco TruSpec CHN.

## Differential Scanning Calorimetry (DSC) Analysis

- Differential scanning calorimetry (DSC) is a thermoanalytical technique in which the difference in the amount of heat required to increase the temperature of a sample and reference is measured as a function of temperature. The basic principle underlying this technique is that when the sample undergoes a physical transformation such as phase transitions, more or less heat will need to flow to it than the reference to maintain both at the same temperature.
- Data such as melting point can be obtained from heat flow–temperature curve produced by DSC.
- Equipment: Perkin Elmer DSC 4000.

## Thermogravimetric (TGA) Analysis

- Thermogravimetric analysis (TGA) is a method of thermal analysis in which changes in physical and chemical properties of materials are measured as a function of increasing temperature (with constant heating rate), or as a function of time (with constant temperature and/or constant mass loss).
- Data obtained from TGA analysis are moisture content, total ash content, volatile content, decomposition temperature and curve etc.
- Equipment: Leco TGA 701.

# SPECTROSCOPIC SERVICES

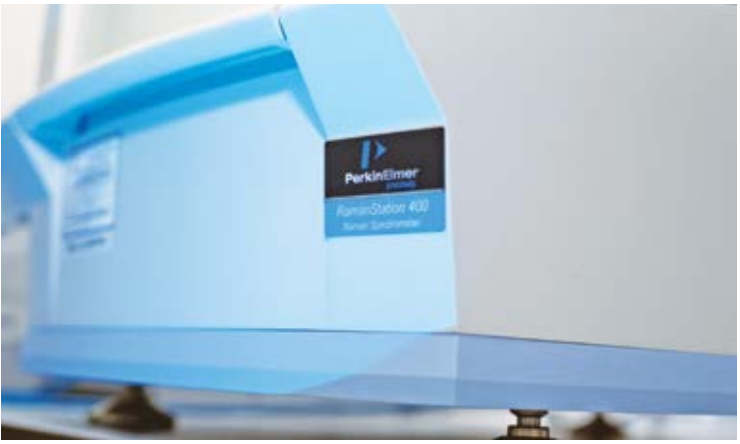
## Ultraviolet–Visible (UV–VIS) Spectroscopy


- Ultraviolet-visible (UV-Vis) spectroscopy can identify certain organic functional groups, determine whether containers are appropriately light-proof, and perform quantitative analysis of dyes or functionalized compounds of interest.
- CHEST is offering full UV-visible spectrum scan, custom-made quantitative methods, total phenolic content assay, total flavonoid content assay, antioxidant (DPPH) assay and total protein assay; in conventional cuvette or micro-well plate format.
- Equipment: Perkin Elmer Lambda 25 and VICTOR X5.

## Fourier Transform Infrared (FTIR) Spectroscopy

- Infrared spectroscopy techniques such as Fourier Transform Infrared (FTIR) spectroscopy can identify specific functional groups, polymers, and additives through spectral matching, and certain techniques can test samples by touch in a non-destructive manner.
- CHEST is offering full spectrum profile scan and functional group identification; in conventional KBr pellet or by ATR.
- Equipment: Perkin Elmer Spectrum 400.

## Raman Spectroscopy




- Raman spectroscopy is a technique used to observe vibrational, rotational, and other low-frequency modes in a system; commonly used in chemistry to provide a fingerprint by which molecules can be identified.
- CHEST is offering full spectrum profile scan.
- Equipment: Perkin Elmer Raman Station 400.


# CHROMATOGRAPHIC SERVICES

## High–Performance Liquid Chromatography (HPLC)

- High-performance liquid chromatography (HPLC) is a form of liquid chromatography to separate compounds that are dissolved in solution.
- CHEST is offering profiling, method development, method validation and individual sample analysis. Currently, only reverse phase applications will be entertained.
- Equipment: Dionex Ultimate 3000RS system with DAD and fluorescence detector.

## High–Performance Thin–Layer Chromatography (HPTLC)

- High-Performance Thin-Layer Chromatography (HPTLC) is the most advanced form of TLC and comprises the use of chromatographic layers of utmost separation efficiency and the employment of state-of-the-art instrumentation for all steps in the procedure: precise sample application, standardized reproducible chromatogram development and software controlled evaluation.
- CHEST is offering method development and individual sample analysis.
- Equipment: Camag HPTLC system with autosampler, visualizer and scanner.

## Liquid Chromatography–Mass Spectrometry (LCMS) Screening

- Liquid Chromatography-Mass Spectrometry (LCMS) screening is a service offered by CHEST whereby samples undergo chromatographic separation and eluted compounds are detected using mass spectrometer. Tandem mass spectrum data is available. A generic (5%–100% MeOH) gradient will be employed unless requested otherwise.
- Acceptable sample: Dry or dissolved samples are acceptable. Suitable solvents to prepare the samples would be aqueous, methanol, acetonitrile, ethanol and isopropanol. Compounds must be amenable to ESI ionization.
- Equipment: Dionex Ultimate 3000RS coupled with Bruker microTOF Q II.

## Liquid Chromatography–Mass Spectrometry (LCMS)

- Liquid chromatography–mass spectrometry (LCMS) is an analytical chemistry technique that combines the physical separation capabilities of liquid chromatography (or HPLC) with the mass analysis capabilities of mass spectrometry (MS).
- CHEST is offering tandem MS (LCMSMS) method development, method validation and individual sample analysis. For details, please enquire.
- Equipment: Dionex Ultimate 3000RS coupled with Bruker microTOF Q II.

## Gas Chromatography–Mass Spectrometry (GCMS)

- Gas chromatography–mass spectrometry (GCMS) is an analytical method that combines the features of gas-chromatography and mass spectrometry to identify different substances within a test sample.
- CHEST is offering EI-based method development, method validation and individual sample analysis. National Institute of Standards and Technology (NIST) Mass Spectral Library is available. For details, please enquire.
- Equipment: Leco Pegasus (TOF type MS).

# MASS SPECTROMETRIC SERVICES

## Flow Injection–Mass Spectrometry (FIMS)

- Flow Injection-Mass Spectrometry (FIMS) is a service offered by CHEST whereby samples are directly introduced to mass spectrometer without any chromatographic separation. Only single stage mass spectrum data is available.
- Acceptable samples: Preferably purified compounds (dry or solution form). Suitable solvents to prepare the samples would be aqueous, methanol, acetonitrile, ethanol and isopropanol. Compounds must be amenable to ESI ionization.
- Equipment: Dionex Ultimate 3000RS coupled with Bruker microTOF Q II.

# GENERAL SERVICES TERMS AND CONDITIONS

## Pricing & Payment

1. Quoted prices will be valid for 30 days. Unless otherwise agreed by CHEST, in its acceptance of any order, payment of invoices is due within 30 days of the invoice date set forth on each invoice. All overdue payments are subject to interest charges of 1.5% per month from the due date until the date of payment.
2. In the event any unforeseen problems or expenses arise in the course of carrying out the services, CHEST shall endeavour to inform Client and shall be entitled to charge additional fees to cover extra time and cost necessarily incurred to complete the services.

## Acceptance

1. The Client wishes to be provided with the Services by CHEST and CHEST agrees to provide the Services to the Client on the terms and conditions of this Acceptance Letter.
2. ‘Services’ shall have the meaning of all technical and facilities support to complete the task specified by the Client.
3. The Client is solely responsible for the proper delivery of samples sent to CHEST for testing.
4. The samples or materials shall be in a condition that makes analyses and preparation of reports possible without difficulty.

## Turnaround Time

Delivery dates and turnaround times are estimates and are provided to the Client for information only. CHEST will use reasonable efforts to meet agreed upon delivery dates and turnaround times.

## Repeat Testing

1. CHEST will conduct a limited review if the Client raises any objection to any test result reported by CHEST. CHEST may conduct the test if experimental controls warrant a retest.
2. A repeat test can only be performed if the conditions of the sample or goods to be sampled make such retesting possible.
3. Objections to the test result are allowed within a period of one month, counting from the time the result is received by the Client.

## Non-Disclosure and Intellectual Rights

CHEST does not disclose any Clients information unless required by law. CHEST does not make any intellectual claims on any data obtained from test materials provided by Clients.

## Disclaimers

1. The Client is aware and acknowledges that the testing methods and reports may not always yield a 100% exact and, or relevant result.
2. CHEST will be responsible only for providing the means (laboratories, equipment) for carrying out the testing requested. CHEST undertakes to use reasonable care in the analysis, having regard to its level of experience in the test methods required, the price being paid by the Client and the overall circumstances of the testing.
3. CHEST accepts no responsibility for any loss or damage, which may occur to any sample in transit. CHEST shall return the samples to The Client if the samples received were not in good condition (open, damage, dented, wet) after visual inspection. The Client will at all times be liable for the security, packaging and insurance of the sample from its dispatch until it is delivered to the offices of the laboratories of CHEST.
4. CHEST will use reasonable care in handling and storing samples, but CHEST shall also not be held responsible for any loss or destruction of samples even after their receipt at its laboratories. The Client warrants and represents to CHEST that all samples sent to CHEST for analysis are safe and in a good condition. The Client must inform CHEST in writing prior to shipment and label the packaging, samples and, or containers appropriately, if the samples are of dangerous nature.
5. CHEST shall not be responsible for any result generated by 3rd party laboratories.

## Contact Information

You are welcome to enquire our customer service for service pricing and details. Our team is committed to your success.

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