



UNIVERSITI TEKNOLOGI MARA

AGA265: SAFETY AND QUALITY CONTROL OF HERBAL PRODUCTS

Course Name (English)	SAFETY AND QUALITY CONTROL OF HERBAL PRODUCTS APPROVED
Course Code	AGA265
MQF Credit	3
Course Description	This course will introduce students to the fundamental principles, terminologies, definitions and classification of medical plants based on their effect of the risk of herb-drug interaction. An introduction into aspects related to safety, quality and efficacy of herbal medicinal products that include techniques for quality control of starting and finished products and ensuring batch to batch consistency, specification of concepts and relevant international guidelines are given.
Transferable Skills	Knowledge gained from lectures via discussions with lecturers and practical skills from Laboratory Work
Teaching Methodologies	Lectures, Blended Learning, Case Study, Discussion, Self-directed Learning
CLO	<p>CLO1 Describe the actions of herbs on the human body and the indications for their medicinal/ healthcare use</p> <p>CLO2 Carry out laboratory experiments relating to toxicology of herbal plants and on quality control of herbs as medicines/herbal medicinal products/ foods/ healthcare products</p> <p>CLO3 Demonstrate an understanding of safety and quality requirements for herbal products</p>
Pre-Requisite Courses	No course recommendations
Topics	
1. WHO Guidelines on Safety Monitoring of Herbal Medicines 1.1) Objectives 1.2) Terms Relating to Herbal Medicines 1.3) Terms Relating to Safety Monitoring of Medicinal Products 1.4) Challenges in Usage of Herbal Medicines and Products 1.5) Safety Monitoring on Herbal Medicines	
2. Malaysian Traditional and Complementary Malaysian Policy 2.1) Introduction to National Policy on Traditional and Complimentary Medicine 2.2) Definition of Terms in the Policy 2.3) Objectives of Policy 2.4) Strategies to Achieve Objectives of the Policy	
3. General Principles of Toxicity Evaluation 3.1) Definition of Toxicology 3.2) Sub-discipline and Common Terminology 3.3) Toxicological Concept 3.4) Dose Response Relationship 3.5) Types of Toxicity Testing 3.6) Globally Harmonized System of Classification and Labelling of Chemical (GHS)	
4. Important of Microbiology 4.1) Definition of Microbiology 4.2) Examples of Microbial Agent/Toxin Related to Herbal Product (Bacteria, Fungi and Aflatoxin) 4.3) Source of Microbial Contamination 4.4) Causes of Microbial Contamination 4.5) Effect of Microbial Contamination on Human Health, Economy and Social	

5. Importance of Inorganic Compounds 5.1) Definition of Inorganic Compounds 5.2) Examples of Inorganic Compounds Related to Herbal Products (Heavy Metals, Pesticides Residue, Sulphur dioxide) 5.3) Sources of Inorganic Compounds Contamination 5.4) Causes of Inorganic Compounds Contamination 5.5) Effect of Inorganic Compound Contamination on Human Health, Economy and Social
6. Quality Control of Herbal Products 6.1) Definition of Quality and Quality Control 6.2) Importance of Quality Control 6.3) Objectives of Quality Control 6.4) Responsibility of a Quality Control Department in the Organization 6.5) Quality Control Measures (Raw Materials, Process Control, Finished Product Control, Packaging Control, Storage Control and Product Recall) 6.6) Quality Control Techniques (Important of Sampling, Sampling Plan, Sampling Techniques)
7. Quality Assurance 7.1) Definition of Quality Assurance and Total Quality Management 7.2) Differences between Quality Control and Quality Assurance 7.3) Theories and Application 7.4) Functions of Quality Assurance Programs

Assessment Breakdown		%
Continuous Assessment		60.00%
Final Assessment		40.00%

Details of Continuous Assessment				
	Assessment Type	Assessment Description	% of Total Mark	CLO
	Assignment	Assignment	20%	CLO3
	Test	Online Test	20%	CLO1
	Written Report	Virtual Laboratory Writing Report	20%	CLO2

Reading List		
	Recommended Text	
	<ul style="list-style-type: none"> • Mark Blumental, Senior Editor, American Botanical Council, Integrative Medicine Communication, Boston 1998, <i>The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines.</i> • <i>General guidelines for Methodologies on Research and Evaluation of Traditional Medicine.</i> Geneva, World Health Organization, 2000 (WHO/EDM/TRM/2000.1) • Herbal Medicinal Research Centre. 2002 <i>Compendium of Medicinal Plants Used in Malaysia Volumes 1 and 2.</i> Institute for Medical Research • Khatijah Hussin 2006, <i>Anatomical Atlas of Malaysian Medicinal Plants Used in Malaysia</i>, Volume 1 Ed., UKM, Universiti Kebangsaan Malaysia • Khadijah Hussin and Mohamad Ruzi Abdul Rahman 2006, <i>Anatomical Atlas of Malaysian Medicinal Plants</i>, Volume 2 Ed., UKM, Universiti Kebangsaan Malaysia • 2007, <i>National Policy of Traditional and Complementary Medicine</i>, 2nd Edition Ed., Ministry of Health Malaysia • Muhamad Zakaria and Mustafa Ali Mohamad 2010, <i>Traditional Malay Medicinal Plants</i>, Institut Terjemahan Negara Malaysia Berhad • <i>WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.</i> Geneva, World Health Organization, 2003 	
Article/Paper List	This Course does not have any article/paper resources	
Other References	This Course does not have any other resources	