

MALAYSIAN STANDARD

MS 2409:2011

PHYTOPHARMACEUTICAL ASPECT OF FREEZE DRIED WATER EXTRACT FROM TONGKAT ALI ROOTS - SPECIFICATION

ICS: 67.040

Descriptors: tongkat ali, roots, phytopharmaceutical aspect, freeze dried, water extract

© Copyright 2011

DEPARTMENT OF STANDARDS MALAYSIA

DEVELOPMENT OF MALAYSIAN STANDARDS

The Department of Standards Malaysia (STANDARDS MALAYSIA) is the national

standards and accreditation body of Malaysia.

The main function of STANDARDS MALAYSIA is to foster and promote standards,

standardisation and accreditation as a means of advancing the national economy,

promoting industrial efficiency and development, benefiting the health and safety of

the public, protecting the consumers, facilitating domestic and international trade and

furthering international cooperation in relation to standards and standardisation.

Malaysian Standards (MS) are developed through consensus by committees which

comprise balanced representation of producers, users, consumers and others with

relevant interests, as may be appropriate to the subject at hand. To the greatest

extent possible, Malaysian Standards are aligned to or are adoption of international

standards. Approval of a standard as a Malaysian Standard is governed by the

Standards of Malaysia Act 1996 [Act 549]. Malaysian Standards are reviewed

periodically. The use of Malaysian Standards is voluntary except in so far as they are

made mandatory by regulatory authorities by means of regulations, local by-laws or

any other similar ways.

STANDARDS MALAYSIA has appointed SIRIM Berhad as the agent to develop,

OR

distribute and sell the Malaysian Standards.

For further information on Malaysian Standards, please contact:

Department of Standards Malaysia

Ministry of Science, Technology and Innovation Level 1 & 2, Block 2300, Century Square

Jalan Usahawan 63000 Cyberjaya Selangor Darul Ehsan

MALAYSIA

Tel: 60 3 8318 0002 Fax: 60 3 8319 3131

http://www.standardsmalaysia.gov.my

E-mail: central@standardsmalaysia.gov.my

SIRIM Berhad

(Company No. 367474 - V) 1, Persiaran Dato' Menteri Section 2, P.O. BOX 7035 40700 Shah Alam

Selangor Darul Ehsan

MALAYSIA

Tel: 60 3 5544 6000 Fax: 60 3 5510 8095

http://www.sirim.my

E-mail: msonline@sirim.my

CONTENTS

		Page
Committee representationii		
Forewordii		
1	Scope1	
2	Normative references	
3	Terms and definitions	
4	Water extraction	
5	Drying	
6	Formulation	
7	Standardisation	
8	Stability of extract	
9	Application	
10	Storage, packaging and labelling of extract	
11	Compliance with the standard	
12 Legal requirements		
Table 1		Specification of freeze dried water extract of Radix Eurycomae
Table B1		The ratio of mobile phase between phosphoric acid (Solvent A) and acetonitrile (Solvent B)
Table C	3	Storage condition for stability studies
Annex A		Production flow chart of freeze dried Radix Eurycomae extract - commercial scale
Annex B		Qualitative and quantitative determination of marker compounds 5
Annex C		Stability testing of herbal substances and products
Bibliography		

Committee representation

The Industry Standards Committee on Food and Food Products (ISC U) under whose authority this Malaysian Standard was developed, comprises representatives from the following organisations:

Department of Agriculture Malaysia Department of Chemistry, Malaysia Department of Standards Malaysia Federal Agricultural Marketing Authority Federation of Malaysian Manufacturers Malaysian Agricultural Research and Development Institute Malaysian Association of Standards Users Malaysian Institute of Food Technology Malaysian Palm Oil Association Malaysian Palm Oil Board Ministry of Agriculture and Agro-Based Industry Ministry of Health Malaysia Ministry of International Trade and Industry Ministry of Science, Technology and Innovation (National Biotechnology Division) Universiti Kebangsaan Malaysia Universiti Putra Malaysia

The Technical Committee on Herbs which supervised the development of this Malaysian Standard consists of representatives from the following organisations:

Alterni (M) Sdn Bhd
Applied Chemie Sdn Bhd
Department of Agriculture Malaysia
FA Herbs Sdn Bhd
Forest Research Institute Malaysia
Institute for Medical Research
Malaysia Agricultural Research and Development Institute
Malaysian Herbal Corporation
Ministry of Health Malaysia (National Pharmaceutical Control Bureau)
SIRIM QAS International Sdn Bhd
Universiti Kebangsaan Malaysia
Universiti Malaysia Sabah
Universiti Sains Malaysia
Universiti Teknologi Malaysia (Institute of Bioproduct Development)

The Working Group on Phytopharmaceutical Aspect of Herbs which developed this Malaysian Standard consists of representatives from the following organisations:

Forest Research Institute Malaysia
Institute for Medical Research
Nestle Manufacturing (M) Sdn Bhd
Nova Laboratories Sdn Bhd
Phytes Biotek Sdn Bhd
SIRIM Berhad (Secretariat)
TPM Biotek Sdn Bhd
Universiti Kebangsaan Malaysia
Universiti Teknologi Malaysia (Chemical Engineering Pilot Plant)

FOREWORD

This Malaysian Standard was developed by the Working Group on Phytopharmaceutical Aspect of Herbs under the authority of the Industry Standards Committee on Food and Food Products.

This Malaysian Standard is based on Malaysian Herbal Monograph, 1999 (FRIM) and findings by reliable research institutions.

Compliance with a Malaysian Standard does not of itself confer immunity from legal obligations.