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**Gmp Asean Guideline Ministry Of**  
ASEAN Guidelines on GMP for Traditional  
Medicines / Health Supplements - 2015  
Chapter 3 Premises and Equipment 20 •

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Premises shall be designed, constructed and maintained to protect against access and harboring of vermin, rodents, birds, insects or other animals. • Protection can be done by implementing a pest control program

### **ASEAN Guidelines on GMP for Traditional Medicines / Health ...**

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ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements - 2015  
Chapter 9 - Complaints and Product Recalls  
5 PRINCIPLE All complaints and other information concerning potentially defective products must be kept and reviewed according to written procedures. In order to provide for all contingencies, a system shall

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## **ASEAN Guidelines on GMP for Traditional Medicines & Health ...**

The GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive. As this document is particularly intended for cosmetic

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products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

## **GOOD MANUFACTURING PRACTICE (GMP) FOR COSMETICS**

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## **Ministry Of Public Health**

ASEAN Guideline on Good Manufacturing Practice for Traditional Medicines 10  
Version 1 Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that: 1.3.1. all manufacturing processes are clearly defined, systematically

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## **Association of South East Asian Nations (ASEAN)**

October 17, 2012 - Contract

Manufacturing & Analysis

Documentation Equipment Internal

Quality Audit Personnel Premises

Product Complaint Production Quality

Control Qualit

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## **ASEAN Cosmetic Good Manufacturing Practice (GMP ...**

ASEAN Guidelines on GMP for Traditional  
Medicines / Health Supplements - 2015  
Appendix 2 Verification

DOCUMENTATION • Every aspect of the  
verification process must be evaluated  
and then documented in a systematic

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way to ensure that all the relevant data is retained in an appropriate manner.

## **APPENDIX 2 VERIFICATION - ASEAN MINISTRY OF HEALTH . TURKISH MEDICINES AND MEDICAL DEVICES AGENCY. GOOD MANUFACTURING PRACTICES (GMP) GUIDE FOR MANUFACTURING PLANTS OF HUMAN**

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MEDICINAL PRODUCTS . Version:  
2018/02 . Effective Date: 01/08/2018  
(Compatible with PIC/S GMP Guide  
version: PE 009-14)

## **GOOD MANUFACTURING PRACTICES (GMP) GUIDE FOR MANUFACTURING**

...

The primary purpose of the Guidelines is

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to promote investment in food, agriculture - including fisheries and forestry in the ASEAN region that contributes to regional economic development, food and nutrition security, food safety and equitable benefits, as well as the sustainable use of natural resources.

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## **The ASEAN Guidelines**

17. The manufacturer must comply with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for cosmetics. 4 Guidelines for Notification of Cosmetics Products in Brunei Darussalam - 3rd Edition, 2015  
Guidelines for Notification of Cosmetics Products in Brunei Darussalam - 3rd



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## **guidelines - Ministry of Health**

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products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

## **ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE**

...

GMP Modules. 13 ASEAN GMP TRAINING  
MODULES Note: the following modules

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can be downloaded in ppt format (Microsoft Powerpoint). QUALITY MANAGEMENT SYSTEM Understand the key concepts of quality management, quality assurance, GMP, quality control, the level of quality documentation and the specific requirements on quality manual.

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## **GMP Modules | ASEAN Cosmetics Association**

MINISTRY OF HEALTH, MALAYSIA 1st  
Revision ... Annex I, part 10: Guideline  
for Cosmetic Good Manufacturing  
Practice (GMP) Annex I, part 11: List of  
Equivalent Cosmetic GMP Guidelines ...  
The content of this guideline is adapted  
from the ASEAN Cosmetic Directive

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## **GUIDELINES FOR CONTROL OF COSMETIC PRODUCTS IN MALAYSIA**

The Federal Food, Drug and Cosmetic Act prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301).. A

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cosmetic may ...

## **Good Manufacturing Practice (GMP) Guidelines/Inspection ...**

An ASEAN GMP inspectorate that intends to be an ASEAN LIS can submit an official application to the JSC. Future developments: Scope may be extended to include APIs and biologicals. ASEAN is

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collaborating with PIC/S, ISPE, and other stakeholders to improve its inspectorates and inspectors' competency.

### **Lapses in Global GMP Compliance & Enforcement Impact on ...**

Adaptations ensure a high level of quality for ATMPs and patient protection.

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The European Commission has published a set of guidelines on good manufacturing practice (GMP) specific to advanced therapy medicinal products (ATMPs).. ATMPs are medicines for human use that are based on genes or cells. These therapies offer ground-breaking new opportunities for the treatment of diseases and injuries.



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## **New guidelines on good manufacturing practices for ...**

Good Manufacturing Practice Standard

Good Manufacturing Practice Standard .

Good Manufacturing Practice (GMP) is a vital component of Quality Assurance to help ensure that therapeutic products and Chinese Proprietary Medicines (CPM)

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are consistently produced with the quality standards appropriate for their intended use.

## **HSA | Good Manufacturing Practice and Good Distribution ...**

GMP MRA TF 9ACTD implemented 9ACTR  
& technical guidelines established  
(maintenance and enhancement of

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common interpretation ongoing) 9Post-  
Market Alert System established GMP  
Inspection MRA finalized Training  
identified Pan-ASEAN registration 9ACTD  
development 9ACTR & technical  
guidelines development 9Regulatory  
capacity building 9Post-Market ...

## **COPING WITH INCREASING NEEDS**

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### **FOR INSPECTIONS: ASEAN ...**

Lastly, the ASEAN Consultative Committee for Standards and Quality (ACCSQ) agreed to recognize ISO 22716 as equivalent to the ASEAN Cosmetic GMP guideline. Each of these regions has its regulations that must be followed for any cosmetic products being brought to the market. Guidelines are generated

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from these regulations.

## **Requirements of the ISO 22716 Good Manufacturing Practices**

Guidelines Edit Title Bar Properties >  
ORGANISATION CHART > ACTS &  
REGULATIONS - Poisons Act - Misuse of  
Drugs Act - Medicines Order 2007 -  
Medicines (Cosmetic Products)

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Regulation 2007 - ASEAN Cosmetic  
Directives (ACD) > BANNED MEDICINES  
> FORMS > USEFUL LINKS > PATIENT  
INFORMATION > CAREER IN PHARMACY  
> REGISTERED MEDICAL PRODUCTS >  
ACCEPTED ...

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