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ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements - 2015 Chapter 3 Premises and Equipment 20 • 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 ...

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

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

GOOD MANUFACTURING PRACTICE (GMP) FOR COSMETICS

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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

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

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 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 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 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.

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 Edition, 2015 5

guidelines - Ministry of Health

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ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE ...

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

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 (ACD). This

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 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 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. 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.

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