Asean Guideline On Stability Study Of Drug Product Version

A new edition of one of Zola's lesser-known novels from the Rougon-Macquart Cycle Finding the young Angélique on their doorstep one Christmas Eve, the pious Hubert couple decide to bring her up as their own. As the girl grows up in the vicinity of the town's towering cathedral and learns her parents' trade of embroidery, she becomes increasingly fascinated by the lives of the saints, a passion fueled by her reading of the Golden Legend and other mystical Christian writings. One day love, in the shape of Félicien Hautecoeur, enters the dream world she has constructed around herself, bringing about upheaval and distress. Although it provides a detailed portrait of provincial 19th-century life and it adheres to a naturalist approach, The Dream eschews many of the characteristics of Zola's other novels of the Rougon-Macquart cycle—such as a pronounced polemical agenda or a gritty subject matter—offering instead a timeless, lyrical tale of love and innocence.

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a

scientific understanding of regulations and balances methodologies and best practices.

Business and human rights has emerged as a distinct field within the corporate governance movement. The endorsement by the United Nations Human Rights Council of a new set of Guiding Principles for Business and Human Rights in 2011 reinforces the State's duty to protect against human rights abuses by third parties, including business; the corporate responsibility to respect human rights; and greater access by victims to effective remedy, both judicial and non-judicial. This book draws on the UN Guiding Principles and recent national plans of action, to provide an overview of relevant developments within the ASEAN region. Bridging theory and practice, the editors have positioned this book at the intersection of human rights risk and its regulation. Chapter authors discuss the implications of key case-studies undertaken across the region and various sectors, with a particular focus on extractive industries, the environment, and infrastructure projects. Topics covered include: due diligence and the role of audits; businesses' responsibilities to women and children; and the mitigation of human rights risks in the region's emerging markets. The book sheds light on how stakeholders currently approach business and human rights, and explores how the role of ASEAN States, and that of the institution itself, may be

strengthened. In doing so, the book identifies critical challenges and opportunities that lie ahead for the region in relation to business and human rights. This book will be of excellent use and interest to scholars, practitioners and students of human rights, business and company law, international law, and corporate governance.

WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/I>. The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on

quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).

This book examines successful firms operating within the ASEAN Economic Community, their reasons for success, and their role in regional integration.

This report discusses the monographs on antiretrovirals proposed for inclusion in The International Pharmacopoeia and specifications for radiopharmaceuticals, quality specifications for antituberculosis drugs and the revision of the monograph on artemisinin derivatives, as well as quality control of reference materials, good manufacturing practices, inspection, distribution and trade, and other aspects of quality assurance of pharmaceuticals, and regulatory issues. Several annexes include an amendment togood manufacturing practices: main principles regarding the requirement for the sampling of starting materials, guidelines on good manufacturing practices regarding water for pharmaceutical use, guidelines on the sampling of pharmaceutical products, and draft guidelines for registration of fixed-dose combination medicinal products.

A collection of recommended procedures for analysis and specifications for the

determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state. Explore this comprehensive discussion of the application of physiologically- and physicochemical-based models to guide drug delivery edited by leading experts in the field Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics delivers a thorough discussion of drug delivery options to achieve target profiles and approaches as defined by physical and pharmacokinetic models. The book offers an overview of drug absorption and physiological models, chapters on oral delivery routes with a focus on both PBPK and multiple dosage form options. It also provides an explanation of the pharmacokinetics of the formulation of drugs delivered by systemic transdermal routes. The distinguished editors have included practical and accessible resources that address the biological and delivery approaches to pulmonary and mucosal delivery of drugs. Emergency care settings are also described, with explorations of the relationship between parenteral infusion profiles and PK/PD. The future of drug delivery is addressed via discussions of virtual experiments to elucidate mechanisms and approaches to drug delivery and personalized medicine. Readers will also benefit from the inclusion of: A thorough introduction to the utility of mathematical models in drug development and delivery An

exploration of the techniques and applications of physiologically based models to drug delivery Discussions of oral delivery and pharmacokinetic models and oral site-directed delivery A review of integrated transdermal delivery and pharmacokinetics in development An examination of virtual experiment methods for integrating pharmacokinetic, pharmacodynamic, and drug delivery mechanisms Alternative endpoints to pharmacokinetics for topical delivery Perfect for researchers, industrial scientists, graduate students, and postdoctoral students in the area of pharmaceutical science and engineering, Drug Delivery Approaches: Perspectives from Pharmacokinetics and Pharmacodynamics will also earn a place in the libraries of formulators, pharmacokineticists, and clinical pharmacologists.

Project economic analysis is a tool used by the Asian Development Bank (ADB) to ensure that ADB operations comply with its Charter. The guidelines in this publication are a revised version of the 1997 edition. The revision responds to the changing development context and ADB operational priorities, and aims to address the recommendations of the ADB Quality-at-Entry Assessments for more methodological work on project economic analysis. The revised guidelines provide general principles for the conduct of project economic analysis, and should be read together with handbooks, technical reports, and other reference materials published by ADB dealing

with sector-specific project economic analysis in detail.
Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)
Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the

science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

A Brookings Institution Press and the National University of Singapore Press publication This is the story of the Singapore healthcare system: how it works, how it is financed, its history, where it is going, and what lessons it may hold for national health systems around the world. Singapore ranks sixth in the world in healthcare outcomes, yet spends proportionally less on healthcare than any other high-income country. This is the first book to set out a comprehensive system-level description of healthcare in Singapore, with a view to understanding what can be learned from its unique system design and development path. The lessons from Singapore will be of interest to those

currently planning the future of healthcare in emerging economies, as well as those engaged in the urgent debates on healthcare in the wealthier countries faced with serious long-term challenges in healthcare financing. Policymakers, legislators, public health officials responsible for healthcare systems planning, finance and operations, as well as those working on healthcare issues in universities and think tanks should understand how the Singapore system works to achieve affordable excellence.

In Resilience: The Science of Adaptation to Climate Change leading experts analyze and question ongoing adaptation interventions. Contributions span different disciplinary perspectives, from law to engineering, and cover different regions from Africa to the Pacific. Chapters assess the need for adaptation, highlighting climate change impacts such as sea level rise, increases in temperature, changing hydrological variability, and threats to food security. The book then discusses the state of global legislation and means of tracking progress. It reviews ways to build resilience in a range of contexts—from the Arctic, to small island states, to urban areas, across food and energy systems. Critical tools for adaptation planning are highlighted - from social capital and ethics, to decision support systems, to innovative finance and risk transfer mechanisms. Controversies related to geoengineering and migration are also discussed. This book is an indispensable resource for scientists, practitioners, and policy makers working in climate change adaptation, sustainable development, ecosystem management, and urban planning. Provides a summary of tools and methods used in adaptation including

recent innovations Includes chapters from a diverse range of authors from academic institutions, humanitarian organizations, and the United Nations Evaluates adaptation options, highlighting gaps in knowledge where further research or new tools are needed Unity in Diversity and the Standardisation of Clinical Pharmacy Services represents the proceedings of the 17th Asian Conference on Clinical Pharmacy (ACCP 2017), held 28—30 July 2017 in Yogyakarta, Indonesia. The primary aim of ACCP 2017 was to bring together experts from all fields of clinical pharmacy to facilitate the discussion and exchange of research ideas and results. The conference provided a forum for the dissemination of knowledge and exchange of experiences. As such, it brought together clinical pharmacy scholars, pharmacy practitioners, policy makers and stakeholders from all areas of pharmacy society and all regions of the world to share their research, knowledge, experiences, concepts, examples of good practice, and critical analysis with their international peers. This year also marks the celebration of 20 years of ACCP. Central themes of the conference and contributed papers were Clinical Pharmacy, Social and Administrative Pharmacy, Pharmacy Education, Pharmacoeconomics, Pharmacoepidemiology, Complementary and Alternative Medicine (CAM) and a number of related topics in the field of Pharmacy.

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical

kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.
This detailed volume collects numerous methods and protocols related to different aspects of stability programs that are followed in pharmaceutical development laboratories. Implementation of a successful stability program, vital in preventing product failures and recalls, requires critical and logical thinking that goes beyond the regular documented protocols and methods, so the experiences of the book's internationally-based expert contributors fill the chapters with practical guidance. As a volume in the Methods in Pharmacology and Toxicology series, this book presents the kind of real-world advice that is essential for advancing laboratory research. Authoritative and thorough, Methods for Stability Testing of Pharmaceuticals serves as a valuable addition to the existing armamentarium of resources available to stability testing personnel in research and industry.
Botanicals, which have been part of human food and medicine for thousands of years, are

perceived as being safer than synthetic pharmaceuticals. The global botanical drug market was expected to reach $26.6 billion by 2017. In terms of FDA regulations, botanical drugs are no different from non-botanical products, having to meet the safety and effectiveness standards of a new drug in accordance. This book comprises a complete start-to-end process from drug-idea conception, to drug development process.

Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS) Presents the scientific basis of different APS models Includes the applications and utilities of APS that are demonstrated through numerous case studies Covers up-to-date regulatory experience

Pharmaceutical Stability Testing to Support Global MarketsSpringer Science & Business Media

This handbook serves as a guide to deploying battery energy storage technologies, specifically for distributed energy resources and flexibility resources. Battery energy storage technology is

the most promising, rapidly developed technology as it provides higher efficiency and ease of control. With energy transition through decarbonization and decentralization, energy storage plays a significant role to enhance grid efficiency by alleviating volatility from demand and supply. Energy storage also contributes to the grid integration of renewable energy and promotion of microgrid.

Long acting veterinary formulations play a significant role in animal health, production and reproduction within the animal health industry. Such technologies offer beneficial advantages to the veterinarian, farmer and pet owner. These advantages have resulted in them growing in popularity in recent years. The pharmaceutical scientist is faced with many challenges when innovating new products in this demanding field of controlled release. This book provides the reader with a comprehensive guide on the theories, applications, and challenges associated with the design and development of long acting veterinary formulations. The authoritative chapters of the book are written by some of the leading experts in the field. The book covers a wide scope of areas including the market influences, preformulation, biopharmaceutics, in vitro drug release testing and specification setting to name but a few. It also provides a detailed overview of the major technological advances made in this area. As a result this book covers everything a formulation scientist in industry or academia, or a student needs to know about this unique drug delivery field to advance health, production and reproduction treatment options and benefits for animals worldwide.

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical

manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

This book looks at the evidence and assesses the impact of competition among governments to attract FDI. It finds little evidence directly to support fears of a "global race to the bottom" in labour and environmental standards.

Addressing concerns for patient welfare while protecting producer reputation, and providing a database for formulation of other products, this multiauthored reference blends fundamental theory and practical advice on drug product stability in scientific, technical, and regulatory environments, covering development of indicating assays, computer use, clinical trial materials, strategic planning, and packaging. Describing the documentation required to minimize the changes of regulatory citations, the book lists manufacturers of photostability testing chambers, stability system software, and laboratory information management systems for pharmaceutical applications.

Pharmacogenomics: Challenges and Opportunities in Therapeutic Implementation includes discussions and viewpoints from the academic, regulatory, pharmaceutical, clinical, socio-ethical and economic perspectives. Each chapter presents an overview of the potential or opportunity within the areas discussed and also outlines foreseeable challenges and limitations in moving pharmacogenomics into drug development and direct therapeutic applications. This edited book contains review questions for a more in-

depth analysis of the implications of pharmacogenomics and discussion points to generate ideas on best to move the field forward. Clinical pearls and case studies are used to illustrate real-life experiences and both successful and unsuccessful applications. Tables, figures, and annotations are included throughout the book to facilitate understanding and further reference. Multi-contributed book and chapters are written by contributors who are experts in their field Provides perspectives from those involved in all aspects of pharmacogenomics-including academic, regulatory, economic, industry and medical-to illustrate how all of the pieces fit together and where the challenges may be Includes case studies of both successful and unsuccessful applications so readers can consider the potential and challenges in moving the science into drug development and direct therapeutic applications Chapters contain discussion questions and clinical pearls and enable readers to reflect on how to move pharmacogenomics forward and apply these observations and useful tips to their own work and research

Pharmaceutical Technology – Concepts and Applications articulates on the various pharmaco-technological concepts associated with industrial pharmacy. The book not only focuses on providing comprehensive information on formulation development and affiliated areas but also emphasizes on their industrial applications. With a plethora of examples that illustrate important concepts, the book equips students of pharmacy to rise to the requirements of the industry.

Deep trade agreements (DTAs) cover not just trade but additional policy areas, such as international flows of investment and labor and the protection of intellectual property rights and the environment. Their goal is integration beyond trade or deep integration. These agreements matter for economic development. Their rules influence how countries (and hence, the people and firms that live and operate within them) transact, invest, work, and ultimately, develop. Trade and investment regimes determine the extent of economic integration, competition rules affect economic efficiency, intellectual property rights matter for innovation, and environmental and labor rules contribute to environmental and social outcomes. This Handbook provides the tools and data needed to analyze these new dimensions of integration and to assess the content and consequences of DTAs. The Handbook and the accompanying database are the result of collaboration between experts in different policy areas from academia and other international organizations, including the International Trade Centre (ITC), Organisation for Economic Co-operation and Development (OECD), United Nations Conference on Trade and Development (UNCTAD), and World Trade Organization (WTO).

As the costs and resources of delivering health services have increased over the years, the importance of evaluating health services and interventions has become essential. An evaluation provides a systematic process of assessing the efficacy and efficiency of health services, including an assessment of their impact on beneficiaries, whether it be individuals or communities. Evaluation in the health sector includes the evaluation of

burden disease where human and economic costs resulting from poor health are measured.In this book, various evaluation studies are detailed, providing an excellent resource for both evaluation practitioners and academics alike. The geographical range and variety of case studies showcase how evaluation has become integral for health service planning and assessment and to assist public health policy makers decide how to use limited resources to minimize burden and inequity. This book will act as a ready resource for both workers experienced in health service evaluation and those intending to learn about burden of disease of evaluation.

Due to a worldwide need for lower cost drug therapy, use of generic and multi-source drug products have been increasing. To meet international patent and trade agreements, the development and sale of these products must conform to national and international laws, and generic products must prove that they are of the same quality and are therapeutically equivalent to the brand name alternative. However, many countries have limited resources to inspect and verify the quality of all drug products for sale in their country. This title discusses the worldwide legislative and regulatory requirements for the registration of generic and multi-source drug products.

Entrepreneurship is a key means through which women can both empower themselves and contribute to inclusive and sustainable development. A vital part of this agenda includes the 61.3 million women who own and operate businesses within the ten member States of ASEAN. It is the particular challenges and opportunities that the

recently introduced ASEAN Economic Community (AEC) will bring to women entrepreneurs which provide the impetus and focus for this report. The measures set out in the AEC Blueprint 2025 are expected to affect the prospects for SME growth in various ways. This publication proposes critical actions that can be taken by ASEAN governments to address the particular constraints facing women entrepreneurs — in association with the finance sector, entrepreneur associations, international agencies, civil society and other key actors — towards the realization of both the 2030 Agenda for Sustainable Development and the AEC Blueprint 2025.

The International Conference of Harmonization (ICH) has worked on har- nizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices.

Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions. Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

This handbook features contributions from a team of expert authors representing

the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

This report is structured in five parts: national framework for traditional and complementary medicine (T&CM); product regulation; practices and practitioners; the challenges faced by countries; and, finally, the country profiles. Apart from the section on practices and practitioners, the report is consistent with the format of the report of the first global survey in order to provide a useful comparison. The section on practices and practitioners, which covers providers, education and health insurance, is a new section incorporated to reflect the emerging trends in T&CM and to gather new information regarding these topics at a national level. All new information received has been incorporated into individual country profiles and data graphs. The report captures the three phases of progress made by Member States; that is, before and after the first WHO Traditional Medicine Strategy (1999-2005), from the first global survey to the second global survey (2005-2012) and from the second survey to the most recent

timeline (2012-2018).

Since they were issued in 1999, the OECD Principles of Corporate Governance have gained worldwide recognition as an international benchmark for good corporate governance.

The main purpose of this research was to develop orodispersible tablets containing Phikud Navakot Extract (NVK-E) with consistent quality and convenience. Phikud Navakot is a traditional Thai herbal medicine that has been used in Thailand for more than 100 years. Preformulation studies of NVK-E and excipients were carried out. High performance liquid chromatography (HPLC) method was validated according to AOAC Guidelines for Dietary Supplements and Botanicals to determine existing three analytical markers, i.e. gallic acid, vanillic acid and ferulic acid. The viscous NVK-E was transformed to more processable powder by adsorption on the selected excipient. Orodispersible tablets containing NVK-E were developed by direct compression method using three superdisintegrants, i.e. Polyplasdone® XL-10, Explotab® and Ac-Di-Sol® at different percentages of 2%, 6% and 10% in formulations. Quality control of tablets were performed. The stability study of the chosen formulation was evaluated in the intended package for commercialization according to ASEAN Guideline on Stability Study of Drug Product under accelerated and long term

storage conditions. At 3 months under accelerated storage condition, more than 5% deviated from initial values which failed to meet the requirement. However, at 3 and 6 months under long term storage condition, analytical markers still retained values of not more than 5% from initial values. Thus, their values must be monitored real-time up to 12 months under long term storage condition for the conclusion on shelf-life of the finished product.