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This is the English version of the 15th edition of the Japanese Pharmacopoeia setting out the official Japanese standards for the description and quality of drug substances and products. It contains over 1,400 articles regarding: general rules for preparations; general tests, processes and apparatus; monographs on drugs; infrared reference spectra and ultraviolet-visible reference spectra.

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.

The Japanese Pharmacopoeia 17th edition (JP XVII) English translation is fully endorsed by the society of the Japanese Pharmacopoeia. It defines the specifications, criteria and standard test methods necessary to properly ensure the quality of medicines in Japan. The Japanese language edition was effective from 1st April 2016. Key features: -General Notices, General Rules for Crude Drugs, General Rules for Preparations: revised and expanded. -Official monographs: 76 new monographs and 473 revised monographs. -General tests, processes and apparatus: 23 new standards and 10 revised standards. -Infrared reference spectra: 21 new spectra and 2 revised spectra. -Ultraviolet-visible reference spectra: 14 new spectra and 2 revised spectra This title supersedes the Japanese Pharmacopoeia 16th edition (ISBN 9784840812023), as well as JP 16th edition Supplement I (ISBN 9784840812382) and JP 16th edition Supplement II (ISBN 9784840812832). The JP aims to: 1.Include all drugs which are important from the viewpoint of health care and medical treatment. 2.Make qualitative improvement by introducing the latest science and technology. 3.Promote internationalization. Make prompt partial revision as necessary and facilitating smooth administrative operation. Ensure transparency regarding the revision, and disseminating the JP to

the public.

Plants and plant-derived compounds and drugs are becoming moreand more popular with increasing numbers of scientists researchingplant analysis. The quality control of herbal drugs is alsobecoming essential to avoid severe health problems, and in thefuture many more new drugs will be developed from plantsources. This three-volume Handbook, featuring 47 detailed review articles,is unique as it deals with chemical and biological methodologiesfor plant analysis. It presents the most important and mostaccurate methods which are available for plant analysis. This comprehensive work is divided into six sections asfollows: Sample preparation and identification – discussingplant selection and collection, followed by extraction and samplepreparation methodologies. Extraction and sample preparation methodologies Instrumentation for chemical analysis - severalinstrumentations for chemical plant analysis are presented with anemphasis on hyphenated techniques, e.g. the coupling between HPLCand mass spectroscometry, and HPLC with NMR. Strategies for selective classes of compounds –coverage of the most interesting classes of compounds such aspolysaccharides, saponins, cardiotonic glycosides, alkaloids,terpenoids, lipids, volatile compounds and polyphenols (flavonoids, xanthones, coumarins, naphthoquinones, anthraquinones,proanthocyanidins, etc.). Biological Analysis - includes phenotyping, DNA barcodingtechniques, transcriptome analysis , microarray, metabolomics andproteomics. Drugs from Plants – covers the

screening of plantextracts and strategies for the quick discovery of novelbioactive natural products. Safety assessment of herbal drugs ishighly dependent on outstanding chromatographic and spectroscopicmethods which are also featured here. This Handbook introduces to scientists involved in plant studiesthe current knowledge of methodologies in various fields ofchemically- and biochemically-related topics in plantresearch. The content from this Handbook will publish online within theEncyclopedia of Analytical Chemistry via Wiley Online Library: ahref="http://www.wileyonlinelibrary.com/ref/eac"http://www.wileyonlinelibrary.com/ref/eac/a Benefit from the introductory offer, valid until 30 November2014! Introductory price: £425.00 / $695.00 /€550.00 List price thereafter: £495.00 / $795.00 / €640.00

Encyclopedia of Dietary Supplements presents peer-reviewed, objective entries that rigorously examine the most significant scientific research on basic chemical, preclinical, and clinical data. Designed for healthcare professionals, researchers, and health-conscious consumers, it presents evidence-based information on the major vitamin and mineral micronutrients, herbs, botanicals, phytochemicals, and other bioactive preparations. Supplements covered include: Vitamins, beta-carotene, niacin, and folate Omega-3 and omega-6 fatty acids, isoflavones, and quercetin Calcium, copper, iron, and phosphorus 5-hydroxytryptophan, glutamine, and L-arginine St. John's Wort, ginkgo biloba, green tea, kava, and noni Androstenedione, DHEA, and melatonin Coenzyme Q10 and S-adenosylmethionine

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The authoritative and comprehensive modern textbook on western herbal medicine - now in its second edition This long-awaited second edition of Principles and Practice of Phytotherapy covers all major aspects of herbal medicine from fundamental concepts, traditional use and scientific research through to safety, effective dosage and clinical applications. Written by herbal practitioners with active experience in clinical practice, education, manufacturing and research, the textbook is both practical and evidence based. The focus, always, is on the importance of tailoring the treatment to the individual case. New insights are given into the herbal management of approxiately 100 modern ailments, including some of the most challenging medical conditions, such as asthma, inflammatory bowel

disease and other complex autoimmune and inflammatory conditions, and there is vibrant discussion around the contribution of phytotherapy in general to modern health issues, including health ageing. Fully referenced throughout, with more than 10, 000 citations, the book is a core resource for students and practitioners of phytotherapy and naturopathy and will be of value to all healthcare professionals - pharmacists, doctors, nurses - with an interest in herbal therapeutics. 50 evidence-based monographs, including 7 new herbs Rational guidance to phytotherapeutic strategies in the consulting room New appendices provide useful information on topics such as herbal actions, dosage in children and reading and interpreting herbal clinical trials Comprehensive revision of vital safety data, including an extensive herb-drug interaction chart. 50 evidence-based monographs, including 7 new herbs Rational guidance to phytotherapeutic strategies in the consulting room New appendices provide useful information on topics such as herbal actions, dosage in children and reading and interpreting herbal clinical trials Comprehensive revision of vital safety data, including an extensive herb-drug interaction chart.

This manual, to be published in two volumes, provides a condensed overview of the analytical investigation of 80 Chinese Herbal Drugs which are most frequently in use. Thin layer chromatographic-, high pressure liquid chromatographic- and gas

chromatographic-fingerprint analytical techniques allow the detection of all main low-molecular constituents of a plant drug and even single constituents can be visualized. Analytical results thereof are shown in numerous color figures. The quality proof of the investigation meets the standard of the European Drug Regulatory Authority. Furthermore, this volume gives a detailed description of the analytical methods used for several drugs. Bioactive constituents, pharmacological and biological activities of several single herbal drugs as well as their therapeutic applications are discussed.

This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical

knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.

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.