

A gloved hand in a blue nitrile glove is using a purple pipette tip to transfer liquid into a multi-well plate. The background is a blurred laboratory setting with various glassware and equipment.

# **MEDICAL DEVICE CHEMICAL CHARACTERISATION**

## **ISO 10993-18**

### **Extractables & Leachables Studies**

# Extractables And Leachables Services Intertek

**Sarfaraz K. Niazi, Justin L. Brown**



## **Extractables And Leachables Services Intertek:**

Leachables and Extractables Handbook Douglas J. Ball, Daniel L. Norwood, Cheryl L. M. Stults, Lee M. Nagao, 2012-02-08

A practical and science based approach for addressing toxicological concerns related to leachables and extractables associated with inhalation drug products Packaging and device components of Orally Inhaled and Nasal Drug Products OINDP such as metered dose inhalers dry powder inhalers and nasal sprays pose potential safety risks from leachables and extractables chemicals that can be released or migrate from these components into the drug product Addressing the concepts background historical use and development of safety thresholds and their utility for qualifying leachables and extractables in OINDP the Leachables and Extractables Handbook takes a practical approach to familiarize readers with the recent recommendations for safety and risk assessment established through a joint effort of scientists from the FDA academia and industry Coverage includes best practices for the chemical evaluation and management of leachables and extractables throughout the pharmaceutical product life cycle as well as Guidance for pharmaceutical professionals to qualify and risk assess container closure system leachables and extractables in drug products Principles for defining toxicological safety thresholds that are applicable to OINDP and potentially applicable to other drug products Regulatory perspectives along with an appendix of key terms and definitions case studies and sample protocols Analytical chemists packaging and device engineers formulation development scientists component suppliers regulatory affairs specialists and toxicologists will all benefit from the wealth of information offered in this important text

**Disposable Bioprocessing Systems** Sarfaraz K. Niazi, 2016-04-19 Written by a researcher with experience designing establishing and validating biological manufacturing facilities worldwide this is the first comprehensive introduction to disposable systems for biological drug manufacturing It reviews the current state of the industry tackles questions about safety costs regulations and waste disposal and guides readers to choose disposable components that meet their needs This practical manual covers disposable containers mixing systems bioreactors connectors and transfers controls and sensors downstream processing systems filling and finishing systems and filters The author also shares his predictions for the future calling disposable bioprocessing technology a game changer

Fundamentals of Modern Bioprocessing Sarfaraz K. Niazi, Justin L. Brown, 2017-07-27 Biological drug and vaccine manufacturing has quickly become one of the highest value fields of bioprocess engineering and many bioprocess engineers are now finding job opportunities that have traditionally gone to chemical engineers Fundamentals of Modern Bioprocessing addresses this growing demand Written by experts well established in the field this book connects the principles and applications of bioprocessing engineering to healthcare product manufacturing and expands on areas of opportunity for qualified bioprocess engineers and students The book is divided into two sections the first half centers on the engineering fundamentals of bioprocessing while the second half serves as a handbook offering advice and practical applications Focused on the fundamental principles at the core of this discipline this work outlines every facet of design

component selection and regulatory concerns It discusses the purpose of bioprocessing to produce products suitable for human use describes the manufacturing technologies related to bioprocessing and explores the rapid expansion of bioprocess engineering applications relevant to health care product manufacturing It also considers the future of bioprocessing the use of disposable components which is the fastest growing area in the field of bioprocessing to replace traditional stainless steel In addition this text Discusses the many types of genetically modified organisms Outlines laboratory techniques Includes the most recent developments Serves as a reference and contains an extensive bibliography Emphasizes biological manufacturing using recombinant processing which begins with creating a genetically modified organism using recombinant techniques Fundamentals of Modern Bioprocessing outlines both the principles and applications of bioprocessing engineering related to healthcare product manufacturing It lays out the basic concepts definitions methods and applications of bioprocessing A single volume comprehensive reference developed to meet the needs of students with a bioprocessing background it can also be used as a source for professionals in the field

**Essential Chemistry for Formulators of Semisolid and Liquid Dosages** Vitthal S. Kulkarni, Charles Shaw, 2015-10-15 A needed resource for pharmaceutical scientists and cosmetic chemists Essential Chemistry for Formulators of Semisolid and Liquid Dosages provides insight into the basic chemistry of mixing different phases and test methods for the stability study of nonsolid formulations The book covers foundational surface colloid chemistry which forms the necessary background for making emulsions suspensions solutions and nano drug delivery systems and the chemistry of mixing which is critical for further formulation of drug delivery systems into semisolid gels creams lotions and ointments or liquid final dosages Expanding on these foundational principles this useful guide explores stability testing methods such as particle size rheological viscosity microscopy and chemical and closes with a valuable discussion of regulatory issues Essential Chemistry for Formulators of Semisolid and Liquid Dosages offers scientists and students the foundation and practical guidance to make and analyze semisolid and liquid formulations Unique coverage of the underlying chemistry that makes possible stable dosages Quality content written by experienced experts from the drug development industry Valuable information for academic and industrial scientists

developing topical and liquid dosage formulations for pharmaceutical as well as skin care and cosmetic products **Update on Undertaking Extractable and Leachable Testing** Andrew Feilden, 2011 The assessment of all materials and especially elastomeric and plastic components for the presence of leachable and extractable components forms an important part of the submission for approval of a new drug system or medical device This Update gives a detailed state of the art review of the selection of techniques available to the analyst to perform a controlled extraction study for leachables and extractables with an overview of the factors to consider when selecting the extraction technique This book will be of interest to Chemists and R D managers

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