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TYPE OF ESTABLISHMENT INSPECTED

Active Pharmaceutical Ingredient Manufacturer

DATE(S) OF INSPECTION

01/05-11/2014

FED NUMBER

3002807972

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OBSERVATION 1

Raw materials, intermediates, and finished API analytical results found to be failing specifications or otherwise suspect (e.g. OOT) are retested until acceptable results are obtained. These failing or otherwise suspect results are not reported.

Specifically,

A) Our review of your firm's Chemstore archived database and system audit trail on GC # 06 identified the practice of over-writing electronic raw data files (samples and standards) for ongoing sample sequences until acceptable results are achieved.

Based on this practice, Out-Of-Specification (OOS) investigations are not initiated as required per SOP OP003684, "Handling of Out of Specification (OOS)", and/or Deviation investigations are not initiated as required per SOP OP003440, "Handling of Deviations". We identified numerous such examples during our review of archived data drawn from approximately 5 months of data. The number of such examples of over-writing raw data files until acceptable results are achieved could not be quantified during our inspection due to the large amount of data.

For example:

i) Raw material [REDACTED] batch # [REDACTED] was analyzed for Chromatographic Purity via GC as follows:

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Printer Type)

Peter E. Baker, Investigator
Dipesh Shah, Investigator

DATE ISSUED

01/11/2014

483

A. Peter Brown



483:

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Disciplinary Hearing and Related Materials United States. Congress. House. Committee on Standards of Official Conduct, 1988 **Special Publications** ,1918 **Water-supply Paper** ,1925 **Magnetograms and Hourly Values, Tucson, Arizona** U.S. Coast and Geodetic Survey. Magnetic Observatory (Tucson, Ariz.), 1955 **Harper's New Monthly Magazine** ,1888 Harper's Magazine made its debut in June 1850 the brainchild of the prominent New York book publishing firm Harper Brothers Harper's Magazine the oldest general interest monthly in America explores the issues that drive our national conversation through long form narrative journalism and essays and such celebrated features as the iconic Harper's Index With its emphasis on fine writing and original thought Harper's provides readers with a unique perspective on politics society the environment and culture **Nuclear Science Abstracts** ,1959 NSA is a comprehensive collection of international nuclear science and technology literature for the period 1948 through 1976 pre dating the prestigious INIS database which began in 1970 NSA existed as a printed product Volumes 1-33 initially created by DOE's predecessor the U.S. Atomic Energy Commission AEC NSA includes citations to scientific and technical reports from the AEC the U.S. Energy Research and Development Administration and its contractors plus other agencies and international organizations universities and industrial and research organizations References to books conference proceedings papers patents dissertations engineering drawings and journal articles from worldwide sources are also included Abstracts and full text are provided if available **United Nations Convention on the Law of the Sea 1982, Volume VII** Myron Nordquist, Satya N. Nandan, 2011-07-31 This is the seventh and final volume of the most authoritative reference on the Third United Nations Convention on the Law of the Sea UNCLOS III 1973 1982 The volume provides the original text of the 1982 convention as fully integrated with the provisions of the 1994 Agreement on the Implementation of XI in addition to an extensive subject index to Volumes I through VI of the series **Merchant Vessels of the United States** ,1976 From 1894-95 1935-36 pt 6 of each volume is issued separately with titles 1894-95 1902-03 Code list of merchant vessels of the United States 1903-04 1935-36 Seagoing vessels of the United States **Annual Report of the Director of the United States Geological Survey to the Secretary of the Interior** Geological Survey (U.S.), 1900 *Geological Survey Professional Paper* ,1957

Food Process Engineering F. Xavier Malcata, 2020-12-13 Food Process Engineering Safety Assurance and Complements pursues a logical sequence of coverage of industrial processing of food and raw material where safety and complementary issues are germane Measures to guarantee food safety are addressed at start and the most relevant intrinsic and extrinsic factors are reviewed followed by description of unit operations that control microbial activity via the supply of heat supply or the removal of heat Operations prior and posterior are presented as is the case of handling cleaning

disinfection and rinsing and effluent treatment and packaging complemented by a brief introduction to industrial utilities normally present in a food plant Key Features Overviews the technological issues encompassing properties of food products Provides comprehensive mathematical simulation of food processes Analyzes the engineering of foods at large and safety and complementary operations in particular with systematic derivation of all relevant formulae Discusses equipment features required by the underlying processes

United Nations Convention on the Law of the Sea 1982, Volume VI Myron H. Nordquist, 2021-08-04 Volume VI is the sixth substantive volume to be published in the series It deals with the work of the First Committee at the Third UN Conference on the Law of the Sea namely the international seabed area The volume thus embraces the deep seabed mining regime set out in Part XI of the 1982 Convention on the Law of the Sea together with the 1994 Agreement on its implementation Completion of this commentary was delayed first by the consultations and negotiations that commenced in 1990 and led to the 1994 Agreement and the entry into force of the Convention It was further delayed until the Assembly of the International Seabed Authority approved the detailed mining regulations in 2000 Additional supplementary material can be found at UNCLOS 1982 Commentary Supplementary Documents

Manage Software Testing Peter Farrell-Vinay, 2008-03-07 Whether you are inheriting a test team or starting one up Manage Software Testing is a must have resource that covers all aspects of test management It guides you through the business and organizational issues that you are confronted with on a daily basis explaining what you need to focus on strategically tactically and operationally Using a

The Symphonic Repertoire, Volume IV A. Peter Brown, 2003-08-07 This volume contains the symphonies of Brahms Bruckner Dvor k and Mahler covering the period from roughly 1860 to 1930 Other contemporaries are discussed including Goldmark Zemlinsky and Berg

Digital Forensics Processing and Procedures David Lilburn Watson, Andrew Jones, 2013-08-30 This is the first digital forensics book that covers the complete lifecycle of digital evidence and the chain of custody This comprehensive handbook includes international procedures best practices compliance and a companion web site with downloadable forms Written by world renowned digital forensics experts this book is a must for any digital forensics lab It provides anyone who handles digital evidence with a guide to proper procedure throughout the chain of custody from incident response through analysis in the lab A step by step guide to designing building and using a digital forensics lab A comprehensive guide for all roles in a digital forensics laboratory Based on international standards and certifications

Diplomatic List United States. Department of State, 1989 Directory of foreign diplomatic officers in Washington

Title List of Documents Made Publicly Available , 1985

Synthetic Organic Chemicals United States Tariff Commission, 1931

The Symphonic Repertoire, Volume IV A. Peter Brown, 2003-08-07 This volume contains the symphonies of Brahms Bruckner Dvor k and Mahler covering the period from roughly 1860 to 1930 Other contemporaries are discussed including Goldmark Zemlinsky and Berg

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