

Revisions to USP33-NF28 2S

Published June 2010

General Chapters

Monographs:

Monograph Title	Monograph Section	Scientific Liaison
<1> INJECTIONS PF 35(5) Pg. 1214	PACKAGING	Desmond Hunt
<11> USP REFERENCE STANDARDS PF 35(5) Pg. 1217	USP Andrographolide RS, USP Powdered Andrographis Extract RS, USP 3-Acetyl-11-keto-beta-Boswellic Acid RS, USP Boswellia Serrata Extract RS, USP Clenbuterol Hydrochloride RS, USP Clenbuterol Related Compound B RS, USP Cyclophosphamide Related Compound A RS, USP Cyclophosphamide Related Compound B RS, USP Cyclophosphamide Related Compound C RS, USP Cyclophosphamide Related Compound D RS, USP Powdered Ashwagandha Extract RS, USP Balsalazide Disodium RS, USP Docetaxel RS, USP Balsalazide Related Compound A RS, USP Docetaxel Identification RS, USP Balsalazide Related Compound B RS, USP Dofetilide RS, USP Benzethonium Chloride RS, USP Dofetilide Related Compound A RS, USP Ensulizole RS, USP L-Glutamic Acid, Hydrochloride RS, USP Orlistat RS., USP Hydromorphone Related Compound A RS, USP rHuman Interleukin 4 RS, USP Orlistat Related Compound D RS, USP Lactobionic Acid RS, USP Levetiracetam RS, USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS, USP Levetiracetam Related Compound A RS, USP Methacrylic Acid and Methyl Methacrylate Copolymer (1:1) RS, USP Levetiracetam Related Compound B RS, USP Methacrylic Acid and Methyl Methacrylate Copolymer (1:2) RS, USP Levetiracetam Racemic Mixture RS, USP Methylbenzethonium Chloride RS, USP Phenylbenzimidazole Sulfonic Acid RS, USP Risperidone Related Compounds	Barbara Jones

Mixture RS, USP Methylpyrrolidone RS,
USP Withanolide A RS, USP Morphine
Related Compound B RS, USP
Withanoside IV RS, USP Orlistat Related
Compound A RS, USP Zolpidem
Impurities Mixture RS, USP Orlistat
Related Compound B RS, USP Orlistat
Related Compound C RS, USP Orlistat
Related Compound E RS, USP
Polydextrose RS, USP Propranolamine
RS, USP Ractopamine Hydrochloride
RS, USP Raspberry Ketone RS, USP
Raspberry Alcohol RS, USP Riluzole RS,
USP Riluzole Related Compound A RS,
USP Tartaric Acid RS, USP Tramadol
Related Compound B RS

<92> GROWTH FACTORS AND
CYTOKINES USED IN CELL
THERAPY MANUFACTURING
PF 35(4) Pg. 915

Title, DEFINITION/Introduction,
IDENTIFICATION/A.,
IDENTIFICATION/B./Phosphate
buffered saline,
IDENTIFICATION/B./Laemmli sample
buffer, reducing,
IDENTIFICATION/B./Laemmli sample
buffer, nonreducing,
IDENTIFICATION/B./Standard stock
solution, IDENTIFICATION/B./Standard
solution, IDENTIFICATION/B./Standard
solution, reducing,
IDENTIFICATION/B./Standard solution,
nonreducing,
IDENTIFICATION/B./Sample stock
solution, IDENTIFICATION/B./Sample
solution, IDENTIFICATION/B./Sample
solution, reducing,
IDENTIFICATION/B./Sample solution,
nonreducing,
IDENTIFICATION/B./Analysis/Samples,
IDENTIFICATION/B./Western blotting,
IDENTIFICATION/B./Acceptance
criteria, ASSAY/Purity:/Molecular
weight marker,
ASSAY/Purity:/Phosphate buffered
saline, ASSAY/Purity:/Laemmli sample
buffer, nonreducing,
ASSAY/Purity:/Laemmli sample buffer,
reducing, ASSAY/Purity:/Sample stock
solution, ASSAY/Purity:/Sample solution
1, ASSAY/Purity:/Sample solution 2,
ASSAY/Purity:/Control A stock solution,
ASSAY/Purity:/Control A solution 1,
ASSAY/Purity:/Control A solution 2,
ASSAY/Purity:/Control B stock solution,
ASSAY/Purity:/Control B solution 1,

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ASSAY/Purity:/Control B solution 2,
ASSAY/Purity:/Electrophoretic
conditions/Mode,
ASSAY/Purity:/Electrophoretic
conditions/Stacking gel,
ASSAY/Purity:/Electrophoretic
conditions/Resolving gel,
ASSAY/Purity:/Electrophoretic
conditions/Run conditions,
ASSAY/Purity:/Electrophoretic
conditions/Protein detection,
ASSAY/Purity:/Analysis/Samples,
ASSAY/Purity:/Acceptance criteria,
ASSAY/Protein Content:/Sample
solution, ASSAY/Protein Content:/Blank,
ASSAY/Protein Content:/Spectroscopic
conditions/Mode, ASSAY/Protein
Content:/Spectroscopic
conditions/Pathlength, ASSAY/Protein
Content:/Spectroscopic
conditions/Analytical wavelength,
ASSAY/Protein
Content:/Analysis/Samples, SPECIFIC
TESTS/Bioidentity:/RPMI 1640 medium
with L-glutamine, SPECIFIC
TESTS/Bioidentity:/Growth medium,
SPECIFIC TESTS/Bioidentity:/Assay
medium, SPECIFIC
TESTS/Bioidentity:/Phosphate buffered
saline, SPECIFIC
TESTS/Bioidentity:/Resazurin solution,
SPECIFIC TESTS/Bioidentity:/Standard
stock solution, SPECIFIC
TESTS/Bioidentity:/Standard solutions,
SPECIFIC TESTS/Bioidentity:/Sample
stock solution, SPECIFIC
TESTS/Bioidentity:/Sample solutions,
SPECIFIC TESTS/Bioidentity:/Control
solution, SPECIFIC
TESTS/Bioidentity:/Cell culture
preparation, SPECIFIC
TESTS/Bioidentity:/Analysis/Samples,
SPECIFIC
TESTS/Bioidentity:/Acceptance criteria,
SPECIFIC TESTS/Sterility Tests <71>,
SPECIFIC TESTS/Bacterial Endotoxins
Test <85>, ADDITIONAL
REQUIREMENTS/Packaging and
Storage, ADDITIONAL
REQUIREMENTS/Labeling,
ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>

DIOXANE PF 35(4) Pg. 917

<331> AMPHETAMINE ASSAY
PF 35(4) Pg. 920

Title, USP REFERENCE STANDARDS
<11>, STANDARD PREPARATION,
ASSAY PREPARATION,
PREPARATION OF
CHROMATOGRAPHIC COLUMN,
PROCEDURE

[Ravi Ravichandran](#)

<381> ELASTOMERIC
CLOSURES FOR INJECTIONS PF
35(5) Pg. 1225

INTRODUCTION

[Desmond Hunt](#)

<645> WATER CONDUCTIVITY
PF 35(5) Pg. 1226

Introduction, INSTRUMENT
SPECIFICATIONS AND OPERATING
PARAMETERS, BULK WATER,
PACKAGED STERILE WATER

[Antonio Hernandez-Cardoso](#)

<670> CONTAINERS --
AUXILIARY COMPONENTS PF
34(6) Pg. 1533

Title, Introduction,
PHARMACEUTICAL COIL

[Desmond Hunt](#)

<741> MELTING RANGE OR
TEMPERATURE PF 35(4) Pg. 925

Introduction, PROCEDURE FOR
CLASS I, APPARATUS II,
PROCEDURE FOR CLASS IA,
APPARATUS II, PROCEDURE FOR
CLASS IB, APPARATUS II

[Antonio Hernandez-Cardoso](#)

<1059> EXCIPIENT
PERFORMANCE PF 35(5) Pg.
1228

Title, INTRODUCTION, TABLETS
AND CAPSULES, ORAL LIQUIDS,
SEMISOLIDS, TOPICALS, AND
SUPPOSITORIES, PARENTERALS,
AEROSOLS

[Robert Lafaver](#)

<1072> DISINFECTANTS AND
ANTISEPTICS PF 35(5) Pg. 1250

CLASSIFICATION OF
DISINFECTANTS, SELECTION OF A
DISINFECTANT FOR USE IN A
PHARMACEUTICAL
MANUFACTURING ENVIRONMENT,
THEORETICAL DISCUSSION OF
DISINFECTANT ACTIVITY,
MECHANISM OF DISINFECTANT
ACTIVITY, MICROBIAL
RESISTANCE TO DISINFECTANTS,
DISINFECTANT CHALLENGE
TESTING, DISINFECTANTS IN A
CLEANING AND SANITIZATION
PROGRAM

[Radhakrishna Tirumalai](#)

<1075> GOOD COMPOUNDING
PRACTICES PF 35(4) Pg. 942

Title, Introduction, APPLICABLE
DEFINITIONS, RESPONSIBILITIES
OF THE COMPOUNDER, TRAINING,
PROCEDURES AND
DOCUMENTATION, DRUG
COMPOUNDING FACILITIES, DRUG
COMPOUNDING EQUIPMENT,

[Rick Schnatz](#)

COMPONENT SELECTION
REQUIREMENTS, PACKAGING AND
DRUG PREPARATION CONTAINERS,
COMPOUNDING CONTROLS,
LABELING, RECORDS AND
REPORTS, COMPOUNDING FOR A
PRESCRIBER'S OFFICE USE,
COMPOUNDING VETERINARIAN
PRODUCTS

<1086> IMPURITIES IN
OFFICIAL ARTICLES PF 35(5)
Pg. 1254

Title, INTRODUCTION, INITIAL IND
FILING, DRUG SUBSTANCE, NDA
FILING, DRUG PRODUCT, POST
NDA APPROVAL, ANDA FILING,
DEFINITIONS

[Antonio Hernandez-Cardoso](#)

<1117> MICROBIOLOGICAL
BEST LABORATORY
PRACTICES PF 35(4) Pg. 945

INTRODUCTION, MEDIA
PREPARATION AND QUALITY
CONTROL, MAINTENANCE OF
MICROBIOLOGICAL CULTURES,
MAINTENANCE OF LABORATORY
EQUIPMENT, LABORATORY
LAYOUT AND OPERATIONS,
SAMPLE HANDLING,
MICROBIOLOGICAL MEDIA
INCUBATION TIMES, TRAINING OF
PERSONNEL, LABORATORY
RESOURCES, DOCUMENTATION,
MAINTENANCE OF LABORATORY
RECORDS, INTERPRETATION OF
ASSAY RESULTS

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<1211> STERILIZATION AND
STERILITY ASSURANCE OF
COMPENDIAL ARTICLES PF
35(4) Pg. 952

Introduction, METHODS OF
STERILIZATION, STERILITY
TESTING OF LOTS, PERFORMANCE,
OBSERVATION, AND
INTERPRETATION

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<1231> WATER FOR
PHARMACEUTICAL PURPOSES
PF 35(5) Pg. 1310

INTRODUCTION, TYPES OF WATER,
CHEMICAL CONSIDERATIONS

[Antonio Hernandez-Cardoso](#)

<1235> VACCINES FOR HUMAN
USE -- GENERAL
CONSIDERATIONS PF 35(4) Pg.
960

Title, INTRODUCTION, OVERALL
MANUFACTURING PLAN, SEED LOT
SYSTEMS, FERMENTATION AND
CELL CULTURE MEDIA,
PROPAGATION AND HARVEST,
PURIFICATION, INTERMEDIATES,
FINAL BULK, FINAL CONTAINER,
EVALUATING THE STABILITY OF
VACCINES, NOMENCLATURE,
LABELING, LOT RELEASE TESTING,
APPENDIX 1. TYPES OF VACCINES
CURRENTLY LICENSED IN THE U.S.
(EXAMPLES), APPENDIX 2.

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SELECTED REGULATORY
DOCUMENTS, GLOSSARY

<2040> DISINTEGRATION AND
DISSOLUTION OF DIETARY
SUPPLEMENTS PF 35(4) Pg. 984

DISINTEGRATION, DISSOLUTION

[Natalia Davydova](#)

<2750> MANUFACTURING
PRACTICES FOR DIETARY
SUPPLEMENTS PF 35(5) Pg. 1319

Introduction, GENERAL PROVISIONS,
ORGANIZATION AND PERSONNEL,
GROUNDS, BUILDINGS, AND
FACILITIES, EQUIPMENT AND
UTENSILS, RAW MATERIALS,
PRODUCT CONTAINERS, AND
CLOSURES, PRODUCTION AND
PROCESS CONTROLS, LABELING
AND PACKAGING, QUALITY
CONTROL OPERATIONS, RECORDS
AND REPORTS, RETURNED AND
SALVAGED PRODUCTS, GLOSSARY

[Yoshiyuki Tokiwa](#)

General Chapters
Monographs: