

Revisions to USP 30–NF 25, First Supplement

Published February 2007

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Upcoming Revisions to USP 30–NF 25, First Supplement

Scientific Liaison

THIABENDAZOLE TABLETS

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USP 27, p. 1821

PF29(6) p. 1991

Current Title (not to change until February 1, 2007)

PF29(6) p. 1991

New Title: Thiabendazole Chewable Tablets (to become official February 1, 2007)

Definition

Packaging and storage

Labeling

USP Reference standards

Identification A, B

Uniformity of dosage units

Assay

TOMATO EXTRACT CONTAINING LYCOPENE

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USP 28 2S, p. 3554

PF 30(2), p. 578

Limit of aflatoxins

TOMATO EXTRACT CONTAINING LYCOPENE

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USP 28 2S, p. 3554

PF 30(2), p. 578

Microbial limits

TOPIRAMATE (new)

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PF 30(4), p. 1307

Title

Chemical structure

Chemical formula

Molecular weight

Chemical name

CAS number

Definition

Packaging and storage

USP Reference standards

Identification A, B

Specific rotation

Water

Residue on ignition

Related compounds

Limit of sulfamate and sulfate

Limit of residual solvents

Assay	
TRIBASIC SODIUM PHOSPHATE	(0)
USP 29–NF 24 p. 3425	
PF 32(2) p. 402	
Loss on ignition <733>	
TRICLOSAN	(0)
USP 29–NF 24 1S p. 3585	
PF 32(2) p. 377	
Assay (Standard preparation, Assay preparation, Procedure)	
CRYSTALLIZED TRYPSIN	(0)
USP 29–NF 24 p. 2223	
PF 32(3) p. 779	
Definition	
VALERIAN	(0)
USP 29–NF 24 p. 2384	
PF 32(2) p. 394	
Microbial enumeration <2021>	
VALERIAN	(0)
USP 29–NF 24 p. 2384	
PF 32(2) p. 394	
Packaging and storage	
Extractable matter	
POWDERED VALERIAN	(0)
USP 29–NF 24 p. 2385	
PF 32(2) p. 395	
Packaging and storage	
Labeling	
Botanic characteristics	
VALERIAN TABLETS	(0)
USP 29–NF 24 p. 2386	
PF 32(2) p. 395	
Packaging and storage	
USP Reference standards <11>	
VALPROIC ACID INJECTION (new)	(0)
PF 32(2) p. 387	
Title Change (Title for this new monograph--to become official October 1, 2008)	
Definition	
Packaging and storage	
Labeling	
USP Reference standards <11>	
Identification A, B	
pH <791>	
Particulate matter <788>	
Other requirements	
Assay	
VALPROIC ACID INJECTION	(0)
PF 32(2) p. 387	
Bacterial endotoxins <85>	

Sterility <71>

VASOPRESSIN

USP28 p. 2016

PF 31(4) p. 1127

Identification B

()

VERAPAMIL HYDROCHLORIDE INJECTION

USP 29–NF 24 Pg. 2245

PF 32(1) Pg. 154

USP Reference standards (USP Verapamil Related Compound E RS, USP Verapamil Related Compound F RS)

Related compounds (Standard solution, Procedure)

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VERAPAMIL HYDROCHLORIDE TABLETS

USP 29–NF 24 Pg. 2246

PF 32(1) Pg. 158

USP Reference standards (USP Verapamil Related Compound E RS, USP Verapamil Related Compound F RS)

Related compounds (Standard solution, Procedure)

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STERILE PURIFIED WATER

USP28, p. 2035

USP28 1S, p. 3282

PF 31(3), p. 804

pH (delete)

Ammonia (delete)

Calcium (delete)

Carbon dioxide (delete)

Chloride (delete)

Sulfate (delete)

Conductivity (add)

()

STERILE WATER FOR INHALATION

USP28, p. 2034

USP28 1S, p. 3282

PF 31(3), p. 802

pH (delete)

Ammonia (delete)

Calcium (delete)

Carbon dioxide (delete)

Chloride (delete)

Sulfate (delete)

Conductivity (add)

()

STERILE WATER FOR IRRIGATION

USP28, p. 2035

PF 31(3), p. 804

pH (delete)

Ammonia (delete)

Calcium (delete)

Carbon dioxide (delete)

Chloride (delete)

Sulfate (delete)

Conductivity (add)

()

<1> INJECTIONS	()
USP 29–NF 24 1S p. 3590	
PF 32(2) p. 402	
LABELS AND LABELING (Labeling; Aluminum in Large Volume Injections (LVIs), Small Volume Injections (SVIs), and Pharmacy Bulk Packages (PBPs) Used in Total Parenteral Nutrition (TPN) Therapy)	
<1> INJECTIONS	()
USP 29–NF 24 1S p. 3590	
PF 32(2) p. 402	
PACKAGING (Printing on Ferrules and Cap Overseals, Packaging and Storage)	
<11> USP REFERENCE STANDARDS	()
USP 29–NF 24 1S Pg. 3591	
PF 32(2) Pg. 407	
Introduction	
Authentic Visual Reference	
Other Reference Substances	
Current Lots	
Authority for Establishment and Release	
History	
Nomenclature	
Diversity and Implications	
Uses of USP Reference Standards	
Steps in Establishing a USP Reference Standard	
Collaborative Study for the Evaluation of a USP RS Candidate Material	
Biological Reference Standards	
Suitability for Use and Purity Assignment	
Label Text	
USP Reference Standards Expert Committee	
Packaging	
Impurity Reference Standards	
Continued Suitability for Use Program	
Proper Use	
Storage	
Relationships with Other Standards-setting Organizations	
USP Reference Standards Specified in USP and NF Monographs and General Chapters	
<311> ALGINATES ASSAY	()
USP 29–NF 24 p. 2562	()
PF 32(2) p. 516	
System suitability	
<611> ALCOHOL DETERMINATION	()
USP 29–NF 24 p. 2637	()
PF 32(3) p. 830	
Method II—Gas-Liquid Chromatographic Method	
<730> PLASMA SPECTROCHEMISTRY	()
USP 29–NF 24 p. 2700	()
PF 32(3) p. 836	
Introduction	
Sample Preparation	
Sample Introduction	
Standard Preparation	

ICP
ICP–AES
ICP–MS
Glossary

<785> OSMOLALITY AND OSMOLARITY

()

USP 29–NF 24 p. 2718

()

PF 32(3) p. 850

Osmolarity

Measurement of Osmolality

<921> Water Determination

()

USP 28, p. 2510

()

PF 31(2), p. 517

Method I (Titrimetric)

Method Ia (Direct Titration)

<1047> BIOTECHNOLOGY-DERIVED ARTICLES--TESTS

()

USP 29 p.2858

PF 32(2) p.516

Title (delete)

Introduction (delete)

Amino Acid Analysis (delete)

Capillary Electrophoresis (delete)

Isoelectric Focusing (delete)

Peptide Mapping (delete)

Polyacrylamide Gel Electrophoresis (delete)

TOTAL PROTEIN ASSAY (delete)

<1052> BIOTECHNOLOGY-DERIVED ARTICLES -- AMINO ACID ANALYSIS (new)

()

PF 32(2) p. 542

Title

Introduction

Introduction

Apparatus

General Precautions

Reference Standard Material

Calibration of Instrumentation

Repeatability

Sample Preparation

Internal Standards

Protein Hydrolysis

Methodologies of Amino Acid Analysis

Data Calculation and Analysis

<1053> BIOTECHNOLOGY-DERIVED ARTICLES -- CAPILLARY ELECTROPHORESIS (new)

()

PF 32(2) p. 559

Title

Introduction

Introduction

General Principle

Apparatus

Free Solution Capillary Electrophoresis

Capillary Gel Electrophoresis

Capillary Isoelectric Focusing

Micellar Electrokinetic Chromatography (MEKC)
Capillary Electrophoresis System Suitability

- <1054> BIOTECHNOLOGY-DERIVED ARTICLES -- ISOELECTRIC FOCUSING (new) ()
PF 32(2) p. 568
Title
Introduction
Introduction
General Principles
Apparatus
Procedure
Specified Variations to the General Method
- <1055> BIOTECHNOLOGY-DERIVED ARTICLES -- PEPTIDE MAPPING (new) ()
PF 32(2) p. 571
Title
Introduction
Introduction
- <1056> BIOTECHNOLOGY-DERIVED ARTICLES -- POLYACRYLAMIDE GEL ELECTROPHORESIS (new) ()
PF 32(2) p. 580
Title
Introduction
Introduction
General Principle of Electrophoresis
Characteristics of Polyacrylamide Gels for Protein Electrophoresis
- <1057> BIOTECHNOLOGY-DERIVED ARTICLES -- TOTAL PROTEIN ASSAY (new) ()
PF 32(2) p. 589
Title
Introduction
Introduction
- <1065> ION CHROMATOGRAPHY ()
USP 29–NF 24 p. 2898 ()
PF 32(3) p. 899
Apparatus
- <1070> EMERGENCY MEDICAL SERVICES VEHICLES AND AMBULANCES -- STORAGE OF PREPARATIONS (new) ()
PF 32(2) p. 605
Title
Introduction
Pharmaceutical Storage Cabinet Monitoring; Location of Parked Vehicles
Stock Rotation
Portable Carrying Case Storage and Monitoring
Additional Requirements for Some Articles
Storage and Handling of Sensitive Preparations
Use of Time–Temperature Indicators
Composite Inventory of Typical Ambulance Service Medications (delete)
- <1080> BULK PHARMACEUTICAL EXCIPIENTS--CERTIFICATE OF ANALYSIS (new) () ()
PF 31(4) p. 1167
Title
Background

General Guidance
Design and Suggested Elements of a Certificate of Analysis
Certificate of Analysis Template
Compendial Designation
Dates on a Certificate of Analysis
Testing Frequency
Use of Electronic Signatures
Distributor Information
Appendix 1-- Definitions
Appendix 2-- State of Statistical Control: Process Capability Parameters For Determining Levels of Control

<1118> MONITORING DEVICES--TIME, TEMPERATURE, AND HUMIDITY (0)
USP 29--NF 24 p. 2976
PF 32(3) p. 900
Electronic Time--Temperature History Recorders

<1184> SENSITIZATION TESTING (new) (0)
PF 30(1) p. 289
Title
Introduction
Magnusson & Kligman guinea pig maximization test
Standard Buehler tests
Other sensitization test procedures

<1208> STERILITY TESTING--VALIDATION OF ISOLATOR SYSTEMS (0)
USP 28, p. 2735
PF 30(6), p. 2162
Introduction
Isolator Design and Construction
Validation of the Isolator System
Package Integrity Verification
Maintenance of Asepsis Within the Isolator Environment
Interpretation of Sterility Test Results
Training and Safety

<1217> TABLET BREAKING FORCE (new) (0)
PF 31(6) p. 1695
Title
Introduction
Tablet breaking force determinations
Tensile strength
References

<1222> TERMINALLY STERILIZED PHARMACEUTICAL PRODUCTS-PARAMETRIC RELEASE (0)
USP 28, p. 2746
PF 30(5), p. 1741
Introduction
General review
Modes of sterilization
Summary

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