

Compendial Approvals for USP 34-NF 29, Second Supplement

Monograph Title	Monograph Section	Scientific Liaison
<413> IMPURITIES TESTING IN MEDICAL GASES PF 35(4) Pg. 920	INTRODUCTION, CONTINUOUS FLOW SYSTEM, HAND PUMP-FIXED VOLUME	Kahkashan Zaidi
<415> MEDICAL GASES ASSAY PF 35(4) Pg. 921	INTRODUCTION, METHODS, QUALIFICATION, VALIDATION, PROCEDURE, SAMPLING, CERTIFIED STANDARDS FOR MEDICAL GAS ANALYSIS	Kahkashan Zaidi
<711> DISSOLUTION USP34-NF29 1S Pg.4654	APPARATUS 1, 2, 3 AND 4/ PROCEDURE/INTERPRETATION/DELAYED-RELEASE DOSAGE FORMS	William Brown
<905> UNIFORMITY OF DOSAGE UNITS USP34-NF29 1S Pg.403	CONTENT UNIFORMITY/WEIGHT VARIATION/CRITERIA	William Brown
<1027> FLOW CYTOMETRY PF 36(5) Pg. 1267	INTRODUCTION, PRINCIPLES OF OPERATION, METHODS, QUALITY, AND STANDARDIZATION, FLOW CYTOMETRY APPLICATIONS FOR CELLULAR SAMPLES AND CELL THERAPY PRODUCTS, FLOW CYTOMETRY ASSAY TROUBLESHOOTING, REFERENCES	Fouad Atouf
<1046> CELL AND GENE THERAPY PRODUCTS PF 36(5) Pg. 1289	INTRODUCTION, MANUFACTURING OVERVIEW, MANUFACTURING OF CELL THERAPY PRODUCTS, MANUFACTURING OF GENE THERAPY PRODUCTS, ON-SITE PREPARATION AND ADMINISTRATION, ANALYTICAL METHODOLOGIES, STABILITY, STORAGE AND SHIPPING, LABELING, REGULATIONS, STANDARDS, AND NEW METHODOLOGIES, DEFINITION OF TERMS, ABBREVIATIONS, COMPONENTS USED IN CELL AND TISSUE-BASED PRODUCT MANUFACTURING, MANUFACTURING OF CELL OR TISSUE-BASED PRODUCTS, ANALYTICAL METHODS, QUALITY SYSTEMS, FACILITY DESIGN AND OPERATION CONSIDERATIONS, CONSIDERATIONS FOR VALIDATION AND QUALIFICATION, CLINICAL SITE PREPARATION AND ADMINISTRATION, CONSIDERATIONS FOR TECHNOLOGY TRANSFER, REGULATIONS AND STANDARDS, APPENDIX, GLOSSARY AND DEFINITION OF TERMS	Fouad Atouf
<1047> GENE THERAPY PRODUCTS PF 36(5) Pg. 1337	INTRODUCTION, CHAPTER PURPOSE AND ORGANIZATION, MANUFACTURING OVERVIEW, MANUFACTURING OF GENE THERAPY PRODUCTS, ON-SITE PREPARATION AND ADMINISTRATION, ANALYTICAL METHODS, STABILITY, STORAGE AND SHIPPING, LABELING, REGULATIONS AND STANDARDS, APPENDIX, GLOSSARY OF TERMS	Fouad Atouf
<2040> DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS PF 36(2) Pg. 567	DISSOLUTION	Natalia Davydova
2-Dimethylaminoethyl	2-Dimethylaminoethyl Methacrylate	Margareth Marques

methacrylate PF 36(5) Pg. 1392		
ALCLOMETASONE DIPROPIONATE PF 36(5) Pg. 1156	IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alclometasone Dipropionate Related Compound A RS 11β;17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate.C28H38O7486.60	Domenick Vicchio
AMMONIUM CARBONATE TS2 PF 36(3) Pg. 782	Ammonium Carbonate TS 2	Antonio Hernandez-Cardoso
AMMONIUM MOLYBDATE PF 36(5) Pg. 1159	ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Arsenate, Phosphate, and Silicate	Elena Gonikberg
AMOXICILLIN CAPSULES PF 36(4) Pg. 892	IDENTIFICATION/Thin-Layer Chromatographic Identification Test, IDENTIFICATION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Microbial enumeration tests <61> and Tests for specified microorganisms <62>	Ahalya Wise
AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894	IDENTIFICATION/Thin-Layer Chromatographic Identification Test, IDENTIFICATION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>	Ahalya Wise
AMOXICILLIN TABLETS PF 36(4) Pg. 896	IDENTIFICATION/Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>	Ahalya Wise
AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION PF 36(4) Pg. 899	ASSAY/Procedure, SPECIFIC TESTS/Microbial enumeration tests <61> and Tests for specified microorganisms <62>	Ahalya Wise
AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS PF 36(4) Pg. 901	ASSAY/Procedure, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests for Specified Microorganisms <62>	Ahalya Wise
ANTIHEMOPHILIC FACTOR PF 36(5) Pg. 1163	Title, DEFINITION/Introduction, SPECIFIC TESTS/Expiration Date, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
CROSPVIDONE USP34-NF29 Pg. 1506	DEFINITION/IDENTIFICATION/ASSAY/IMPURITIES/SPECIFIC TESTS/ADDITIONAL REQUIREMENTS/LABELING	Kevin Moore
CRYOPRECIPITATED ANTIHEMOPHILIC FACTOR PF 36(5) Pg. 1164	Title, DEFINITION/Introduction, SPECIFIC TESTS/Expiration Date, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
ANTIVENIN (CROTALIDAE) POLYVALENT PF 36(5) Pg. 1164	Title, DEFINITION/Introduction, SPECIFIC TESTS/Safety, ADDITIONAL	Maura Kibbey

	REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Expiration Date	
ANTIVENIN (LATRODECTUS MACTANS) PF 36(5) Pg. 1165	Title, DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Expiration Date	Maura Kibbey
ANTIVENIN (MICRURUS FULVIUS) PF 36(5) Pg. 1165	Title, DEFINITION/Introduction, SPECIFIC TESTS/Safety, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Expiration Date	Maura Kibbey
BACOPA PF 36(3) Pg. 691	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure 1: Articles of Botanical Origin, Foreign Organic Matters <561>, IMPURITIES/Organic Impurities/Procedure 2: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS	Maged Sharaf
POVIDONE USP34-NF29 Pg. 3981	DEFINITION/IDENTIFICATION/ASSAY IMPURITIES/SPECIFIC TESTS/ADDITIONAL REQUIREMENTS/LABELING	Kevin Moore
POWDERED BACOPA PF 36(3) Pg. 692	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of	Maged Sharaf

Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 <561>, SPECIFIC TESTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS

POWDERED BACOPA EXTRACT PF 36(3) Pg. 694

Maged Sharaf

DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Glycosides, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III <231>, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Microbial Enumeration Tests <2021>, SPECIFIC TESTS/Microbiological Procedures for Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bacoside A3 RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Bacopa Extract RS

BICALUTAMIDE PF 36(5) Pg. 1165

Feiwen Mao

ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Bicalutamide Related Compound A RS

WHOLE BLOOD PF 36(5) Pg. 1170

Maura Kibbey

Title, Chemical Info/ACD Whole Blood;, Chemical Info/CPD Whole Blood;, Chemical Info/CPDA-1 Whole Blood;, Chemical Info/Heparin Whole Blood., DEFINITION/Introduction, IDENTIFICATION/A. ABO Blood Group, IDENTIFICATION/B. Rh Type, SPECIFIC TESTS/Visual Inspection, SPECIFIC TESTS/Hemoglobin Content, SPECIFIC TESTS/Leukocyte Count (for units labeled as Whole Blood, Leukocytes Reduced), ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP

	Hemoglobin RS	
ANTI-A BLOOD GROUPING SERUM PF 36(5) Pg. 1169	Title, DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
ANTI-B BLOOD GROUPING SERUM PF 36(5) Pg. 1170	Title, DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
BLOOD GROUPING SERUMS PF 36(5) Pg. 1168	Title, DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
BLOOD GROUPING SERUMS ANTI- D, ANTI-C, ANTI-E, ANTI-c, ANTI-e PF 36(5) Pg. 1168	Title, Chemical Info/Anti-Rh Blood Grouping Serums., DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
BOTULISM ANTITOXIN PF 36(5) Pg. 1172	Title, DEFINITION/Introduction, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Expiration Date, ADDITIONAL REQUIREMENTS/Labeling	Maura Kibbey
BROMOCRIPTINE MESYLATE PF 36(5) Pg. 1173	IMPURITIES/Organic Impurities/Procedure 2	Domenick Vicchio
BUPROPION HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 36(4) Pg. 906	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure	Ravi Ravichandran
CENTELLA ASIATICA PF 36(4) Pg. 941	DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Triterpene Derivatives, CONTAMINANTS/Heavy Metals, Method III <231>, CONTAMINANTS/Articles of Botanical Origin, General Method for Pesticide Residues Analysis <561>, CONTAMINANTS/Microbial Enumeration Tests—Nutritional and Dietary Supplements <2021>, CONTAMINANTS/Absence of Specified Microorganisms—Nutritional and Dietary Supplements <2022>, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Acid-Insoluble Ash <561>, SPECIFIC TESTS/Articles of Botanical Origin, Foreign Organic Matter <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Asiaticoside RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Centella asiatica Extract RS	Maged Sharaf

CENTELLA ASIATICA TRITERPENES
PF 36(4) Pg. 946

DEFINITION/Introduction,
IDENTIFICATION/A. Thin-Layer
Chromatographic Identification Test
<201>, IDENTIFICATION/B.,
COMPOSITION/Content of Triterpene
Derivatives, CONTAMINANTS/Heavy
Metals, Method III <231>,
CONTAMINANTS/Articles of Botanical
Origin, General Method for Pesticide
Residues Analysis <561>,
CONTAMINANTS/Microbial Enumeration
Tests—Nutritional and Dietary
Supplements <2021>,
CONTAMINANTS/Absence of Specified
Microorganisms—Nutritional and
Dietary Supplements <2022>, SPECIFIC
TESTS/Water Determination, Method I
<921>, ADDITIONAL
REQUIREMENTS/Packaging and Storage,
ADDITIONAL REQUIREMENTS/Labeling,
ADDITIONAL REQUIREMENTS/Other
Requirements, ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>/USP Asiaticoside RS,
ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP
Powdered Centella asiatica Extract RS

Maged Sharaf

POWDERED CENTELLA ASIATICA
PF 36(4) Pg. 943

DEFINITION/Introduction,
IDENTIFICATION/A. Thin-Layer
Chromatographic Identification Test
<201>, IDENTIFICATION/B.,
COMPOSITION/Content of Triterpene
Derivatives, CONTAMINANTS/Heavy
Metals, Method III <231>,
CONTAMINANTS/Articles of Botanical
Origin, General Method for Pesticide
Residues Analysis <561>,
CONTAMINANTS/Microbial Enumeration
Tests—Nutritional and Dietary
Supplements <2021>,
CONTAMINANTS/Absence of Specified
Microorganisms—Nutritional and
Dietary Supplements <2022>, SPECIFIC
TESTS/Botanic Characteristics, SPECIFIC
TESTS/Loss on Drying <731>, SPECIFIC
TESTS/Articles of Botanical Origin, Total
Ash <561>, SPECIFIC TESTS/Articles of
Botanical Origin, Acid-Insoluble Ash
<561>, ADDITIONAL
REQUIREMENTS/Packaging and Storage,
ADDITIONAL REQUIREMENTS/Labeling,
ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP
Asiaticoside RS, ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>/USP Powdered Centella
asiatica Extract RS

Maged Sharaf

POWDERED CENTELLA ASIATICA
EXTRACT PF 36(4) Pg. 944

DEFINITION/Introduction,
IDENTIFICATION/A. Thin-Layer
Chromatographic Identification Test
<201>, IDENTIFICATION/B.,
COMPOSITION/Content of Triterpene
Derivatives, CONTAMINANTS/Heavy
Metals, Method III <231>,
CONTAMINANTS/Articles of Botanical
Origin, General Method for Pesticide
Residues Analysis <561>,
CONTAMINANTS/Microbial Enumeration
Tests—Nutritional and Dietary
Supplements <2021>,
CONTAMINANTS/Absence of Specified

Maged Sharaf

Microorganisms—Nutritional and
Dietary Supplements <2022>, SPECIFIC
TESTS/Loss on Drying <731>,
ADDITIONAL REQUIREMENTS/Packaging
and Storage, ADDITIONAL
REQUIREMENTS/Labeling, ADDITIONAL
REQUIREMENTS/Other Requirements,
ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>, ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>/USP Asiaticoside RS,
ADDITIONAL REQUIREMENTS/USP
Reference Standards <11>/USP
Powdered Centella asiatica Extract RS