

# Compendial Approvals for USP 34-NF 29, First Supplement

Monograph Title	Monograph Section	Scientific Liaison
<197> SPECTROPHOTOMETRIC IDENTIFICATION TESTS PF 36(2) Pg. 457	INFRARED ABSORPTION	<a href="#">Horacio Pappa</a>
<563> IDENTIFICATION OF ARTICLES OF BOTANICAL ORIGIN PF 36(3) Pg. 707	BOTANICAL IDENTIFICATION	<a href="#">Maged Sharaf</a>
<729> GLOBULE SIZE DISTRIBUTION IN LIPID INJECTABLE EMULSIONS PF 36(1) Pg. 223	INTRODUCTION	<a href="#">Desmond Hunt</a>
<921> WATER DETERMINATION PF 36(2) Pg. 480	METHOD I (TITRIMETRIC)	<a href="#">Antonio Hernandez-Cardoso</a>
<1010> ANALYTICAL DATA -- INTERPRETATION AND TREATMENT PF 36(2) Pg. 483	APPENDIX C: EXAMPLES OF OUTLIER TESTS FOR ANALYTICAL DATA, APPENDIX F: ADDITIONAL SOURCES OF INFORMATION	<a href="#">Horacio Pappa</a>
<1084> GLYCOPROTEIN AND GLYCAN ANALYSIS -- GENERAL CONSIDERATIONS PF 36(2) Pg. 486	OVERVIEW, PROTEIN GLYCOSYLATION, GLYCAN ANALYSIS FOR GLYCOSYLATED BIOLOGICAL DRUGS, CHOICE OF GLYCAN ANALYSIS FOR CHARACTERIZATION AND SPECIFICATION OF GLYCOSYLATED BIOLOGICAL DRUGS, CONCLUSION	<a href="#">Tina Morris</a>
<1097> BULK POWDER SAMPLING PROCEDURES PF 35(2) Pg. 367	INTRODUCTION, SAMPLING THEORY AND TERMINOLOGY, GENERAL SAMPLE COLLECTION: CONSIDERATIONS AND TOOLS, PRIMARY SAMPLE COLLECTION, PRIMARY SAMPLE SIZE REDUCTION, APPENDIX 1: SUBSAMPLING EXAMPLES, APPENDIX 2: MATERIAL CHARACTERIZATION AND SAMPLING, APPENDIX 3: RANDOM NUMBER TABLES, APPENDIX 4. ADDITIONAL SOURCES OF INFORMATION, APPENDIX 4 APPENDIX 3 ADDITIONAL SOURCES OF INFORMATION	<a href="#">Horacio Pappa</a>
<1101> MEDICINE DROPPER PF 36(2) Pg. 502	Title, Introduction	<a href="#">Desmond Hunt</a>
<1180> HUMAN PLASMA PF 35(2) Pg. 388	SCOPE, OVERVIEW, PLASMA COLLECTION AND PROCESSING, PLASMA SAFETY CONSIDERATIONS, QUALITY SYSTEMS, GLOSSARY, APPENDICES	<a href="#">Anita Szajek</a>
<1221> TEASPOON PF 36(2) Pg. 534	Title	<a href="#">Desmond Hunt</a>
<1601> PRODUCTS FOR NEBULIZATION -- CHARACTERIZATION TESTS PF 36(2) Pg. 534	DRUG SUBSTANCE DELIVERY RATE AND TOTAL DRUG SUBSTANCE DELIVERED, AERODYNAMIC ASSESSMENT OF NEBULIZED AEROSOLS	<a href="#">Kahkashan Zaidi</a>
ABACAVIR SULFATE PF 36(3) Pg. 651	Chemical Info/Chemical Structure, Chemical Info/(C <sub>14</sub> H <sub>18</sub> N <sub>6</sub> O) <sub>2</sub> ·H <sub>2</sub> SO <sub>4</sub> , Chemical Info/670.74, Chemical Info/2-Cyclopentene-1-methanol, 4-[2-amino-6-(cyclopropylamino)-9H-purin-9-yl]-, (1S-cis)-, sulfate (salt) (2:1);, Chemical Info/(1S,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1), Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests—General, Sulfate <191>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Organic Impurities/Procedure 1: Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Enantiomeric Purity, SPECIFIC TESTS/Water Determination, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Abacavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP	<a href="#">Behnam Davani</a>

ABACA VIR ORAL SOLUTION PF 36(3) Pg.652	Abacavir Stereoisomers Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Abacavir Related Compounds Mixture RS  DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Deliverable Volume <698>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS, SPECIFIC TESTS/Microbial Enumeration Tests <61> and Tests For Specified Microorganisms<62>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Abacavir Sulfate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Abacavir System Suitability Mixture RS	<a href="#">Behnam Davani</a>
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ADEMETIONINE DISULFATE TOSYLATE PF 36(2) Pg. 438	{Title} S-Adenosyl-l-methionine Disulfate Tosylate, DEFINITION/Introduction, IDENTIFICATION/B., COMPOSITION/Procedure, OTHER COMPONENTS/Content of Sulfate, SPECIFIC TESTS/Isomeric Ratio, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ademetionine Disulfate Tosylate RS USP S-Adenosyl-l-methionine Disulfate Tosylate RS	<a href="#">Huy Dinh</a>
ALPHA CYCLODEXTRIN HYDRATE PF 36(2) Pg.574	Alpha-Cyclodextrin Hydrate(Alpha-Schardinger Dextrin; Cyclohexaamylose)	<a href="#">Margareth Marques</a>
ALPRAZOLAM EXTENDED-RELEASE TABLETS PF 36(3) Pg. 655	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, IMPURITIES/Organic Impurities/Analysis, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alprazolam Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlordiazepoxide Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Nordazepam RS	<a href="#">Ravi Ravichandran</a>
AMLODIPINE BESYLATE TABLETS PF 36(2)Pg. 376	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Sujatha Ramakrishna</a>
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HYDROUS BENZOYL PEROXIDE PF 36(2) Pg.382	DEFINITION/Introduction, ASSAY/Procedure	<a href="#">Behnam Davani</a>
BIS(4-SULFOBUTYL) ETHER DISODIUM PF 36(2) Pg. 574	Bis(4-sulfobutyl) Ether Disodium,	<a href="#">Hong Wang</a>
BUPROPION HYDROCHLORIDE PF 36(2) Pg.383	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2	<a href="#">Ravi Ravichandran</a>
1,4-BUTANE SULTONE PF 36(2) Pg.574	1,4-Butane Sultone(4-Hydroxybutane-1-sulfonic acid delta-sultone),	<a href="#">Hong Wang</a>
Butyl Alcohol, Secondary PF 36(3) Pg.781	Butyl Alcohol, Secondary	<a href="#">Margareth Marques</a>
CANOLA OIL PF 36(3) Pg. 781	Canola Oil	<a href="#">Margareth Marques</a>
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36(2)Pg. 385	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Ahalya Wise</a>
CEFDINIR CAPSULES PF 36(2) Pg. 386	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Ahalya Wise</a>
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Cupric Acetate PF 36(2) Pg. 574	Cupric Acetate,	<a href="#">Margareth Marques</a>
DIETHYL SULFONE PF 36(2) Pg. 575	Diethyl Sulfone (Ethyl Sulfone),	<a href="#">Hong Wang</a>
DI(ETHYLENE GLYCOL) METHYL ETHER PF36(3) Pg. 781	Di(ethylene glycol) Methyl Ether	<a href="#">Margareth Marques</a>
DIVALPROEX SODIUM DELAYED-RELEASE CAPSULES PF 36(2) Pg. 390	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valproic Acid RS	<a href="#">Ravi Ravichandran</a>
DIVALPROEX SODIUM EXTENDED-RELEASE TABLETS PF 36(2) Pg. 391	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Valproic Acid RS	<a href="#">Ravi Ravichandran</a>
DONEPEZIL HYDROCHLORIDE TABLETS PF36(3) Pg. 658	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Related Compound ARS	<a href="#">Ravi Ravichandran</a>
DONEPEZIL HYDROCHLORIDE ORALLY DISINTEGRATING TABLETS PF 36(3) Pg. 660	DEFINITION/Introduction, IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Disintegration <701>, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Donepezil Related Compound A RS	<a href="#">Ravi Ravichandran</a>
DROSPIRENONE PF 36(2) Pg. 394	IMPURITIES/Organic Impurities/Procedure2, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Drospirenone Related Compound A RS [17-Hydroxy-6 $\beta$ ;7 $\beta$ ;15 $\beta$ ;16 $\beta$ -dimethylene-3-oxo-17 $\beta$ -pregn-4-ene-21-carboxylic acid, &gamma;-lactone](C <sub>24</sub> H <sub>30</sub> O <sub>3</sub> 366.49)  Chemical Info/Chemical Structure, Chemical Info/C <sub>14</sub> H <sub>9</sub> ClF <sub>3</sub> NO <sub>2</sub> , Chemical Info/315.67, Chemical Info/1H-Benzo[d][1,3]oxazin-2(4H)-one, 6-chloro-4-cyclopropylethynyl-4-trifluoromethyl-, Chemical Info/(S)-6-Chloro-4-(cyclopropylethynyl)-1,4-dihydro-4-(trifluoromethyl)-2H-3,1-benzoxazin-2-one, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B.	<a href="#">Domenick Vicchio</a>

EFAVIRENZ PF 36(3) Pg. 661

Ultraviolet Absorption <197U>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, SPECIFIC TESTS/Completeness of Solution <641>, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/Enantiomeric Purity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Efavirenz RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Efavirenz Related Compound BRS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Efavirenz Racemic RS

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EFAVIRENZ CAPSULES PF 36(3) Pg.664

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Ultraviolet Absorption <197U>, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Efavirenz RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Efavirenz Related Compound BRS

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ENTACAPONE PF 36(2) Pg. 396

Chemical Info/Chemical Structure, Chemical Info/C<sub>14</sub>H<sub>15</sub>N<sub>3</sub>O<sub>5</sub>, Chemical Info/305.29, Chemical Info/(E)-&alpha;-Cyano-N,N-diethyl-3,4-dihydroxy-5-nitrocinnamamide, = Chemical Info/2-Propenamamide, 2-cyano-3-(3,4-dihydroxy-5-nitrophenyl)-N,N-diethyl-, (E)-, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entacapone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entacapone Related Compound A RS [(Z)-2-Cyano-3-(3,4-dihydroxy-5-nitrophenyl)-N,N-diethylacrylamide](C<sub>14</sub>H<sub>15</sub>N<sub>3</sub>O<sub>5</sub>305.29)

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ENTACAPONE TABLETS PF 36(3) Pg.667

DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entacapone RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Entacapone Related Compound A RS

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Epiandrosterone PF 36(3) Pg. 781

Epiandrosterone

[Margareth Marques](#)

ESCITALOPRAM OXALATE PF 36(3) Pg.668

Chemical Info/Chemical Structure, Chemical Info/C<sub>20</sub>H<sub>21</sub>N<sub>2</sub>O<sub>4</sub>·C<sub>2</sub>H<sub>2</sub>O<sub>4</sub>, Chemical Info/414.43, Chemical Info/S-(+)-5-Isobenzofurancarbonitrile, 1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1,3-dihydro-, oxalate, Chemical Info/S-(+)-1-[3-(Dimethylamino)propyl]-1-(p-fluorophenyl)-5-phthalan carbonitrile oxalate, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic impurities/Residue on Ignition <281>, IMPURITIES/Inorganic impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Solution A, Solution B, Solution C, Mobile phase, System suitability solution, Standard solution, Sample solution, and Chromatographic system, IMPURITIES/Organic Impurities/System suitability, IMPURITIES/Organic Impurities/Analysis, IMPURITIES/Organic Impurities/Acceptance criteria, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Enantiomeric Purity, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL

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	<p>REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP R-Citalopram Oxalate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Citalopram Related Compound D RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Escitalopram Oxalate RS</p>	
<p>FLECAINIDE ACETATE ORAL SUSPENSION PF36(2) Pg. 401</p>	<p>DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH &lt;791&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Flecaïnide Acetate RS</p>	<p><a href="#">Rick Schnatz</a></p>
<p>FLUDARABINE PHOSPHATE INJECTION PF36(2) Pg. 402</p>	<p>IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2: Early-Eluting Impurities, IMPURITIES/Organic Impurities/Procedure 3: Late-Eluting Impurities</p>	<p><a href="#">Feiwen Mao</a></p>
<p>FORSKOHLII PF 36(3) Pg. 695</p>	<p>DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test &lt;201&gt;, IDENTIFICATION/B., COMPOSITION/Content of Forskolin, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash &lt;561&gt;, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III &lt;231&gt;, IMPURITIES/Organic Impurities/Procedure 1: Articles of Botanical Origin, Foreign Organic Matters &lt;561&gt;, IMPURITIES/Organic Impurities/Procedure 2: Articles of Botanical Origin, General Method for Pesticide Residues Analysis &lt;561&gt;, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying &lt;731&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash &lt;561&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 &lt;561&gt;, SPECIFIC TESTS/Microbial Enumeration Tests &lt;2021&gt;, SPECIFIC TESTS/Microbiological Procedures for Absence of Specified Microorganisms &lt;2022&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Test for Aflatoxins &lt;561&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Forskolin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Powdered Forskohlii Extract RS</p>	<p><a href="#">Maged Sharaf</a></p>
<p>POWDERED FORSKOHLII PF 36(3) Pg. 697</p>	<p>DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test &lt;201&gt;, IDENTIFICATION/B., COMPOSITION/Content of Forskolin, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash &lt;561&gt;, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III &lt;231&gt;, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis &lt;561&gt;, SPECIFIC TESTS/Botanic Characteristics, SPECIFIC TESTS/Loss on Drying &lt;731&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash &lt;561&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Alcohol-Soluble Extractives, Method 2 &lt;561&gt;, SPECIFIC TESTS/Microbial Enumeration Tests &lt;2021&gt;, SPECIFIC TESTS/Microbiological Procedures for Absence of Specified Microorganisms &lt;2022&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Test for Aflatoxins &lt;561&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Forskolin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards &lt;11&gt;/USP Powdered Forskohlii Extract RS</p>	<p><a href="#">Maged Sharaf</a></p>
<p>POWDERED FORSKOHLII EXTRACT PF 36(3) Pg. 698</p>	<p>DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test &lt;201&gt;, IDENTIFICATION/B., COMPOSITION/Content of Forskolin, IMPURITIES/Inorganic Impurities/Heavy Metals, Method III &lt;231&gt;, IMPURITIES/Organic Impurities/Procedure: Articles of Botanical Origin, General Method for Pesticide Residues Analysis &lt;561&gt;, SPECIFIC TESTS/Loss on Drying &lt;731&gt;, SPECIFIC TESTS/Microbial Enumeration Tests &lt;2021&gt;, SPECIFIC TESTS/Microbiological Procedures for Absence of Specified Microorganisms &lt;2022&gt;, SPECIFIC TESTS/Articles of Botanical Origin, Test for Aflatoxins &lt;561&gt;, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling,</p>	<p><a href="#">Maged Sharaf</a></p>

	ADDITIONALREQUIREMENTS/Other Requirements, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Forskolin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Powdered Forskohlii Extract RS	
HYDROCHLOROTHIAZIDE CAPSULES PF 36(2)Pg. 405	DEFINITION/Introduction,IDENTIFICATION/A., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units<905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONALREQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Chlorothiazide RS 2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide (C7H6ClN3O4S2295.72)	<a href="#">Sujatha Ramakrishna</a>
4-HYDROXYBUTANE-1-SULFONIC ACID PF36(2) Pg. 575	4-Hydroxybutane-1-sulfonic Acid (4-Hydroxy-1-butanefulfonic Acid),	<a href="#">Hong Wang</a>
INDINAVIR SULFATE PF 36(2) Pg. 406	IDENTIFICATION/C. Identification Tests&mdash;General, Sulfate <191>, ASSAY/Procedure,OTHER COMPONENTS/Procedure 1: Content of Sulfate, OTHER COMPONENTS/2, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/OpticalRotation, Specific Rotation <781S>	<a href="#">Behnam Davani</a>
IRBESARTAN AND HYDROCHLOROTHIAZIDETABLETS PF 36(2) Pg. 409	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Sujatha Ramakrishna</a>
LANTHANUM NITRATE HEXAHYDRATE PF 36(3)Pg. 782	Lanthanum Nitrate Hexahydrate,	<a href="#">Margareth Marques</a>
LEVALBUTEROL HYDROCHLORIDE PF 36(3) Pg.670	IMPURITIES/Organic Impurities/Procedure1, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USPDehydrated Alcohol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>/USP Ethyl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Heptane RS, ADDITIONAL REQUIREMENTS/USP ReferenceStandards <11>/USP Methyl Alcohol RSUSP Levalbuterol Related CompoundH RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP2-Propanol RS	<a href="#">Ravi Ravichandran</a>
LOPINAVIR PF 36(3) Pg. 671	Chemical Info/Chemical Structure,Chemical Info/C37H48N4O5, Chemical Info/628.80, Chemical Info/ [1S-[1R*(R*),3R*,4R*]]-N-[4[[2,6-Dimethylphenoxy)acetyl]amino]-3-hydroxy-5-phenyl-1-(phenylmethyl)pentyl]-tetrahydro-&alpha;-(1-methylethyl)-2-oxo-1(2H)-pyrimidineacetamide;, Chemical Info/(&alpha;S)-Tetrahydro-N-[(&alpha;S)-&alpha;-(2S,3S)-2hy= droxy-4-phenyl-3-[2-(2,6-xyllyloxy)acetamido]butyl]phenethyl]-&alpha;=- isopropyl-2-oxo-1(2H)-pyrimidineacetamide, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A.Infrared Absorption <197S>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II<231>, IMPURITIES/Organic Impurities/Procedure 1, IMPURITIES/Organic Impurities/Procedure 2, IMPURITIES/Organic Impurities/Acceptancecriteria, SPECIFIC TESTS/Water Determination, Method I <921>,ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USPReference Standards <11>/USP Lopinavir RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lopinavir System SuitabilityMixture RS	<a href="#">Behnam Davani</a>
LOSARTAN POTASSIUM TABLETS PF 36(2) Pg.411	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Sujatha Ramakrishna</a>
MEFLOQUINE HYDROCHLORIDE TABLETS PF36(3) Pg. 674	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B. Ultraviolet Absorption<197U>, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units<905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONALREQUIREMENTS/Packaging and Storage, ADDITIONAL	<a href="#">Leonel Santos</a>

MIDODRINE HYDROCHLORIDE PF 36(2) Pg.414	REQUIREMENTS/ USP Reference Standards <11>/USP Mefloquine Hydrochloride RS	Chemical Info/Chemical Structure,Chemical Info/C12H18N2O4&middledot;HCl, Chemical Info/290.74, Chemical Info/Acetamide,2-amino-N-[2-(2,5-dimethoxyphenyl)-2-hydroxyethyl]-, monohydrochloride, (&plusmn;);, Chemical Info/(&plusmn;-)-2-Amino-N-(&beta;-hydroxy-2,5-dimethoxyphenethyl)= acetamide monohydrochloride, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>,IDENTIFICATION/B., IDENTIFICATION/C. Identification Tests&mdash;General, Chloride <191>, ASSAY/Procedure, IMPURITIES/InorganicImpurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/HeavyMetals, Method II <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage,ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Midodrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Midodrine Related Compound A RS [1-(2,5 Dimethoxyphenyl)-2-aminoethanol](C10H15NO3197.23)	<a href="#">Sujatha Ramakrishna</a>
MIDODRINE HYDROCHLORIDE TABLETS PF36(2) Pg. 415	DEFINITION/Introduction,IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B.,ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>,PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging andStorage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USPMidodrine Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Midodrine Related Compound A RS [1-(2,5 Dimethoxyphenyl)-2-aminoethanol](C10H15NO3 197.23)	<a href="#">Sujatha Ramakrishna</a>	
MINOCYCLINE HYDROCHLORIDE PF 36(2) Pg.418	Chemical Info/493.95493.94,ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure	<a href="#">Ahalya Wise</a>	
MINOCYCLINE PERIODONTAL SYSTEM PF 36(2)Pg. 420	PERFORMANCE TESTS/Dissolution	<a href="#">Ahalya Wise</a>	
OLANZAPINE AND FLUOXETINE CAPSULES PF36(2) Pg. 423	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCETESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONALREQUIREMENTS/USP Reference Standards <11>/USP Fluoxetine Hydrochloride RS [Benzenepropanamine, N-methyl-gamma-[4-(trifluoromethyl)phenoxy]-, hydrochloride,&plusmn;](C17H18F3NO&middledot;HC1345.79),ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP FluoxetineRelated Compound B RS [N-Methyl-3-phenylpropylamine](C10H15N149.23),ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Olanzapine RS [10H-Thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-(4-methyl-1-piperaziny)](C17H20N4S312.43), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP OlanzapineRelated Compound B RS [2-Methyl-10H-thieno-[2,3-b][1,5]benzodiazepin-4[5H]-one](C12H10N2OS230.2= 9)	<a href="#">Ravi Ravichandran</a>	
PENTOBARBITAL ORAL SOLUTION PF 36(2)Pg. 425	Title, DEFINITION/Introduction, IDENTIFICATION/Thin-Layer Chromatography, ASSAY/Procedure, OTHER COMPONENTS/Alcohol Determination, Method I <611>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USPReference Standards <11>/USP Pentobarbital RS	<a href="#">Ravi Ravichandran</a>	
PENTOBARBITAL SODIUM CAPSULES PF 36(2)Pg. 426	Title, DEFINITION/Introduction, IDENTIFICATION/Ultraviolet Absorption <197U>,ASSAY/Barbiturate Assay <361>, PERFORMANCE TESTS/Dissolution <711>,PERFORMANCE TESTS/Uniformity of dosage units <905>, ADDITIONAL REQUIREMENTS/Packaging and Storage,	<a href="#">Ravi Ravichandran</a>	

ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP  
Pentobarbital RS

ALCOHOLIC POTASSIUM HYDROXIDE  
TS2 PF36(3) Pg. 782

Potassium Hydroxide TS 2,Alcoholic

[Margareth  
Marques](#)

Chemical Info/Chemical Structure,Chemical  
Info/C10H17N3S&middledot;2HCl&middledot;H2O, ChemicalInfo/302.26,  
Chemical Info/Benzothiazole-2,6-diamine,4,5,6,7-tetrahydro-N6-propyl-,  
dihydrochloride, monohydrate, (S)-,; Chemical Info/(S)-2-Amino-4,5,6,7-  
tetrahydro-6-(propylamino)benzothiazole dihydrochloride monohydrate,  
Chemical Info/CAS,DEFINITION/Introduction, IDENTIFICATION/A.  
Infrared Absorption <197A> or<197M>, IDENTIFICATION/B.,  
IDENTIFICATION/C. Identification Tests&mdash;General, Chloride <191>,  
ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition  
<281>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method I<231>,  
IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/ Water  
Determination, Method I <921>, SPECIFIC TESTS/EnantiomericPurity,  
SPECIFIC TESTS/Limit of Palladium,  
ADDITIONALREQUIREMENTS/Packaging and Storage, ADDITIONAL  
REQUIREMENTS/USP Reference Standards<11>/USP Pramipexole  
Dihydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference  
Standards <11>/USP Pramipexole Related Compound A RS,ADDITIONAL  
REQUIREMENTS/USP Reference Standards <11>/ USP  
PramipexoleRelated Compound D RS

PRAMIPEXOLE DIHYDROCHLORIDE PF  
36(3)Pg. 676

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Ravichandran](#)

Potassium Pyroantimonate TS PF 36(3)Pg. 783

Potassium Pyroantimonate TS

[Margareth  
Marques](#)

RALOXIFENE HYDROCHLORIDE  
TABLETS PF36(2) Pg. 427

PERFORMANCE TESTS/Dissolution<711>

[Mary  
Waddell](#)

REPAGLINIDE PF 36(2) Pg. 428

SPECIFIC TESTS/Loss on drying<731>

[Elena  
Gonikberg](#)

Chemical Info/Chemical Structure,Chemical Info/C22H25N5O2, Chemical  
Info/391.47, Chemical Info/1H-Indole-3-ethanamine, N,N-dimethyl-5-(1H-  
1,2,4-triazol-1-ylmethyl)-, monobenzoate,;Chemical Info/3-[2-  
(Dimethylamino)ethyl]-5-(1H-1,2,4-triazol-1-ylmethyl)indole monobenzoate,  
Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A.  
Infrared Absorption <197K>,IDENTIFICATION/B., ASSAY/Procedure,  
IMPURITIES/Inorganic Impurities/Residue on Ignition <281>,  
IMPURITIES/Inorganic Impurities/Heavy Metals<231>,  
IMPURITIES/Inorganic Impurities/Sample solution,IMPURITIES/Inorganic  
Impurities/Reference solution, IMPURITIES/InorganicImpurities/Blank  
solution, IMPURITIES/Inorganic Impurities/Analysis,IMPURITIES/Organic  
Impurities/Procedure, SPECIFIC TESTS/Water Determination, MethodIa  
<921>, ADDITIONAL REQUIREMENTS/Packaging and  
Storage,ADDITIONAL REQUIREMENTS/USP Reference Standards  
<11>/USP RizatriptanBenzoate RS, ADDITIONAL REQUIREMENTS/USP  
Reference Standards <11>/USP Rizatriptan Benzoate System Suitability  
Mixture RS. Mixture of rizatriptan benzoate and at least 0.1% of rizatriptan  
impurity C. Rizatriptanimpurity C is 2-{5-[(1H-1,2,4-triazol-1-yl)methyl]-  
1H-indol-2-yl}-N,N-dimethylethanamin= e. (C15H19N5 269.34)

RIZATRIPTAN BENZOATE PF 36(1) Pg.132

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ROPINIROLE TABLETS PF 36(3) Pg.678

DEFINITION/Introduction, IDENTIFICATION/Introduction,  
ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE  
TESTS/Dissolution <711>, PERFORMANCETESTS/Uniformity of Dosage  
Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL  
REQUIREMENTS/Packaging and Storage, ADDITIONAL  
REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP  
ReferenceStandards <11>/USP Ropinirole Hydrochloride RS,  
ADDITIONALREQUIREMENTS/USP Reference Standards <11>/USP  
Ropinirole Related Compound BRS

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{Title} Scaffold Human Dermis, DEFINITION/Introduction, SPECIFIC  
TESTS/Histological Evaluation,SPECIFIC TESTS/Biochemical Analysis,  
SPECIFIC TESTS/Microbial EnumerationTests <61> and Tests for Specified



SCAFFOLD HUMAN DERMIS PF 36(3) Pg.680	Microorganisms <62>,SPECIFIC TESTS/Particle Size Analysis, ADDITIONAL REQUIREMENTS/Labeling,ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Authentic Visual References <11>	<a href="#">Fouad Atouf</a>
SECOBARBITAL ORAL SOLUTION PF 36(2) Pg.430	Title, DEFINITION/Introduction, IDENTIFICATION/Infrared Absorption <197M>, ASSAY/Barbiturate Assay <361>, OTHER COMPONENTS/Alcohol Determination <611>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONALREQUIREMENTS/USP Reference Standards <11>	<a href="#">Ravi Ravichandran</a>
SODIUM ACETATE PF 36(2) Pg. 430	IDENTIFICATION/B. Identification Tests&mdash;General, Acetate <191>, IMPURITIES/Inorganic Impurities/Aluminum <206>	<a href="#">Mary Waddell</a>
BACTERIOSTATIC SODIUM CHLORIDE INJECTION PF 36(2) Pg. 431	IDENTIFICATION/Identification Tests&mdash;General, Sodium <191> and Chloride<191>, SPECIFIC TESTS/Other Requirements	<a href="#">Domenick Vicchio</a>
Sodium Bisulfite PF 36(3) Pg. 782	Sodium Bisulfite,	<a href="#">Margareth Marques</a>
SUCCINIC ACID PF 36(2) Pg. 453	IDENTIFICATION/Procedure,IDENTIFICATION/Infrared Absorption <197K>, ADDITIONAL REQUIREMENTS/USP ReferenceStandards <11>	<a href="#">Robert Lafaver</a>
SUNFLOWER OIL PF 36(3) Pg. 782	Sunflower Oil	<a href="#">Margareth Marques</a>
TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS PF 36(3) Pg. 683	DEFINITION/Introduction,IDENTIFICATION/A. Ultraviolet Absorption <197U>, IDENTIFICATION/B.,ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>,PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging andStorage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Benzothiadiazine Related Compound A RS, ADDITIONALREQUIREMENTS/USP Reference Standards <11>/USP Hydrochlorothiazide RS,ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP TelmisartanRS	<a href="#">Sujatha Ramakrishna</a>
TERAZOSIN CAPSULES PF 35(4) Pg.872	PERFORMANCE TESTS/Dissolution<711>, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Margareth Marques</a>
TERAZOSIN TABLETS PF 35(4) Pg. 874	PERFORMANCE TESTS/Dissolution<711>	<a href="#">Margareth Marques</a>
0.4 M AQUEOUS TETRABUTYLAMMONIUMHYDROXIDE PF 36(2) Pg. 575	0.4 M Aqueous TetrabutylammoniumHydroxide,	<a href="#">Margareth Marques</a>
THEOPHYLLINE ORAL SUSPENSION PF 36(2)Pg. 432	DEFINITION/Introduction,ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packagingand Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Theophylline RS, ADDITIONALREQUIREMENTS/USP Reference Standards <11>/USP Caffeine RS	<a href="#">Rick Schnatz</a>
TOPIRAMATE PF 36(2) Pg. 433	IMPURITIES/Inorganic Impurities/Limit of Sulfamate and Sulfate, SPECIFIC TESTS/Limit of Sulfamate and Sulfate	<a href="#">Ravi Ravichandran</a>
VALACYCLOVIR TABLETS PF 35(4) Pg.878	DEFINITION/Introduction,IDENTIFICATION/A., IDENTIFICATION/B. Identification Tests-General, Chloride<191>, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units<905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONALREQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards<11>	<a href="#">Leonel Santos</a>
	DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCETESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL	

ZONISAMIDE CAPSULES PF 36(2) Pg.436

REQUIREMENTS/Packaging and Storage,  
ADDITIONALREQUIREMENTS/USP Reference Standards <11>/USP  
Zonisamide RS, ADDITIONAL REQUIREMENTS/USP Reference  
Standards <11>/USP ZonisamideRelated Compound C RS [N'-  
(Benzisoxazol-3-ylmethylsulfonyl)-N,N-  
dimethylformimidamide](C<sub>11</sub>H<sub>13</sub>N<sub>3</sub>O<sub>3</sub>S267.30)

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[Ravichandran](#)

DESCRIPTION AND SOLUBILITY PF 36(3)  
Pg.786

Abacavir Sulfate, DonepezilHydrochloride, Cefdinir, Enrofloxacin,  
Efavirenz, Entacapone, EscitalopramOxalate, Rizatriptan Benzoate,  
Lopinavir, Indinavir Sulfate, Pramipexole Dihydrochloride, Midodrine  
Hydrochloride, MoxifloxacinHydrochloride, Valsartan

[Behnam](#)  
[Davani](#)