

Revisions to USP33-NF28 2S

Published June 2010

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Monographs:

Monograph Title	Monograph Section	Scientific Liaison
OMEGA-3 ACIDS ETHYL ESTERS PF 35(5) Pg. 1190	Title, DEFINITION/Introduction, IDENTIFICATION/Introduction, ASSAY/Content of EPAee, DHAee, and Total Omega-3 Acids Ethyl Esters, IMPURITIES/Inorganic Impurities/Fats and Fixed Oils <401>, IMPURITIES/Organic Impurities/Procedure 1: Cholesterol, IMPURITIES/Organic Impurities/Procedure 2: Oligomers, IMPURITIES/Organic Impurities/Procedure 3: Limit of Dioxins, Furans, and Polychlorinated Biphenyls (PCBs), IMPURITIES/Organic Impurities/Procedure 5: Limit of Total Unidentified Fatty Acids Ethyl Esters, SPECIFIC TESTS/Fats and Fixed Oils <401>, Acid Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Anisidine Value, SPECIFIC TESTS/Fats and Fixed Oils <401>, Peroxide Value, SPECIFIC TESTS/Absorbance, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Curtis Phinney
OXAZEPAM CAPSULES PF 35(5) Pg. 1170	ASSAY/Procedure, IMPURITIES/Organic Impurities	Ravi Ravichandran
PANTOPRAZOLE ORAL SUSPENSION PF 35(4) Pg. 863	Title, DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/ pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL	Rick Schnatz

REQUIREMENTS/Beyond-Use
Date, ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>

PENTOBARBITAL PF 35(4) Pg. 864	IDENTIFICATION/B. Ultraviolet Absorption <197U>, IDENTIFICATION/C., ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Melting Range or Temperature, Class I <741>	Ravi Ravichandran
POLYDEXTROSE PF 35(5) Pg. 1206	ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure 2: Limit of Monomers, IMPURITIES/Inorganic Impurities/Limit of Lead, SPECIFIC TESTS/Molecular Weight Limit, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>, SPECIFIC TESTS/Water Determination <921>	Hong Wang
HYDROGENATED POLYDEXTROSE PF 35(5) Pg. 1210	Title, DEFINITION/Introduction, IDENTIFICATION/A., IDENTIFICATION/B., IDENTIFICATION/C., IDENTIFICATION/D., IDENTIFICATION/E., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Limit of Lead, IMPURITIES/Inorganic Impurities/Limit of Nickel, IMPURITIES/Organic Impurities/Procedure 1: Limit of 5- Hydroxymethylfurfural and Related Compounds, IMPURITIES/Organic Impurities/Procedure 2: Limit of Monomers, SPECIFIC TESTS/Molecular Weight Limit, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	Hong Wang
POWDERED ASHWAGANDHA	Title, DEFINITION/Introduction,	Maged Sharaf

IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Withanolides, IMPURITIES/Inorganic Impurities/Articles of Botanical Origin, Acid-Insoluble Ash <561>, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <231>, IMPURITIES/Organic Impurities/Procedure: 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 <2021>, SPECIFIC TESTS/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Articles of Botanical Origin, Aflatoxins <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin-Layer Chromatographic Identification Test <201>, IDENTIFICATION/B., COMPOSITION/Content of Withanolides, IMPURITIES/Inorganic Impurities/Heavy Metals, Method II <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/Absence of Specified Microorganisms <2022>, SPECIFIC TESTS/Articles

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of Botanical Origin, Aflatoxins <561>, SPECIFIC TESTS/Other Requirements, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

PROPOXYPHENE
HYDROCHLORIDE PF 35(4) Pg.
865

DEFINITION/Introduction,
ASSAY/Procedure,
IMPURITIES/Organic
Impurities/Procedure, SPECIFIC
TESTS/Melting Range or
Temperature <741>

[Clydewyn Anthony](#)

RACTOPAMINE
HYDROCHLORIDE SUSPENSION
PF 35(5) Pg. 1171

Title, Chemical Info/Chemical
Structure, Chemical
Info/C18H23NO3·HCl,
Chemical Info/337.84, Chemical
Info/Benzenemethanol, 4-hydroxy-
α-[[[3-(4-hydroxyphenyl)-1-
methylpropyl]amino]methyl]-,
hydrochloride;, Chemical
Info/(±-)-all-rac-p-Hydroxy-
α-[[[3-(p-hydroxyphenyl)-1-
methylpropyl]amino]methyl]benzyl
alcohol, hydrochloride, Chemical
Info/CAS,
DEFINITION/Introduction,
IDENTIFICATION/Infrared
Absorption <197K>,
ASSAY/Procedure,
IMPURITIES/Organic
Impurities/Procedure, SPECIFIC
TESTS/Diastereomer Ratio,
ADDITIONAL
REQUIREMENTS/Packaging and
Storage, ADDITIONAL
REQUIREMENTS/Labeling,
ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>

[Elena Gonikberg](#)

RAMIPRIL CAPSULES PF 35(4) Pg.
867

Title, DEFINITION/Introduction,
IDENTIFICATION/A. Ultraviolet
Absorption <197U>,
IDENTIFICATION/B.,
ASSAY/Procedure,
PERFORMANCE TESTS,
PERFORMANCE
TESTS/Dissolution <711>,
PERFORMANCE
TESTS/Uniformity of Dosage Units

[Sujatha Ramakrishna](#)

<905>, IMPURITIES/Organic Impurities/Procedure, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

RILUZOLE PF 35(5) Pg. 1173

Title, Chemical Info/Chemical Structure, Chemical Info/C8H5F3N2OS, Chemical Info/234.20, Chemical Info/2-Benzothiazolamine, 6-(trifluoromethoxy)-, Chemical Info/2-Amino-6-(trifluoromethoxy)benzothiazole, 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/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>

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RILUZOLE TABLETS PF 35(5) Pg. 1174

Title, 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>

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RISPERIDONE ORAL SOLUTION PF 35(4) Pg. 870

Title, DEFINITION/Introduction, IDENTIFICATION/Introduction,

[Ravi Ravichandran](#)

ASSAY/Procedure,
PERFORMANCE
TESTS/Deliverable Volume <698>,
IMPURITIES/Organic
Impurities/Procedure, SPECIFIC
TESTS/pH <791>, ADDITIONAL
REQUIREMENTS/Packaging and
Storage, ADDITIONAL
REQUIREMENTS/USP Reference
Standards <11>

SUMATRIPTAN TABLETS PF 35(4)
Pg. 871

Title, 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
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Starch TS PF 35(5) Pg. 1340

Starch TS

[Margareth Marques](#)

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