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Kakhkashan Zaidi

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Natalia Davydova

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Heather Joyce

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Domenick Vicchio

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Hong Wang

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Rick Schnatz

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Ahalya Wise

Revision

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Ahalya Wise

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Ahalya Wise

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Rick Schnatz

New

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Rick Schnatz
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Chemical Info/Chemical Structure, Chemical Info/CH3CH2OOC(CH2)8COOCH2CH3, Chemical Info/C14H26O4, Chemical Info/258.35, Chemical Info/Decanedioic acid, 1,10-diethyl ester;, Chemical Info/Diethyl 1,10-decanedioate, Chemical Info/CAS,


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ASSAY/Procedure

**POTASSIUM IODIDE**

ASSAY/Procedure

**Revision**

**Hong Wang**

**Hariram Ramanathan**
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Hariram Ramanathan

Rick Schnatz
**New TACROLIMUS ORAL SUSPENSION PF 37(1) Pg. ONLINE**

**Rick Schnatz**

Hydrochlorothiazide RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus RS

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus RS

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tacrolimus RS

**New TADALAFIL PF 38(1) Pg. ONLINE**

**Mary Waddell**

Chemical Info/Chemical Structure, Chemical Info/C22H19N3O4, Chemical Info/389.40, Chemical Info/Pyrazino[1′,2′:1,6]pyrido[3,4-b]indole-1,4-dione, 6-(1,3-benzodioxol-5-yl)-2,3,6,7,12,12a-hexahydro-2-methyl-, (6R-12aR)-; Chemical Info/(6R,12aR)-2,3,6,7,12,12a-Hexahydro-2-methyl-6-[(3,4-(methylenedioxy)phenyl]pyrazino[1′prime;:2′prime;;1,6]pyrido[3,4-b]indole-1,4-dione, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Residue on Ignition <281>, IMPURITIES/Organic Impurities, IMPURITIES/Enantiomeric and Diastereomeric Purity, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tadalafil RS

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

**New TADALAFIL TABLETS PF 38(1) Pg. ONLINE**

**Mary Waddell**

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tadalafil RS

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tadalafil RS

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tadalafil RS

**New TRAMADOL HYDROCHLORIDE ORAL SUSPENSION PF 37(1) Pg. ONLINE**

**Rick Schnatz**

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Hydrochloride RS

**New TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN ORAL SUSPENSION PF 37(1) Pg. ONLINE**

**Rick Schnatz**

DEFINITION/Introduction, ASSAY/Procedure for Tramadol Hydrochloride, ASSAY/Procedure for Acetaminophen, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Tramadol Hydrochloride RS

DEFINITION/Introduction, ASSAY/Procedure, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage,

New URSODIOL ORAL SUSPENSION PF 37(1) Pg. ONLINE

DEFINITION/Introduction, ASSAY/Procedure, SPECIFIC TESTS/pH <791>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Beyond-Use Date, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ursodiol RS

Revision USP AND NF EXCIPIENTS, LISTED BY CATEGORY PF 35(5) Pg. 1197

{Flavors and Perfumes} Diethyl Sebacate, {Emulsifying and/or Solubilizing Agent} Caprylic Acid, {Emulsifying and/or Solubilizing Agent} Glyceril Tristearate, {Tablet and/or Capsule Lubricant} Glyceril Tristearate

New VALACYCLOVIR ORAL SUSPENSION PF 37(1) Pg. ONLINE

ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS

Revision VITAMIN E CAPSULES PF 38(1) Pg. ONLINE

ASSAY/Alpha Tocopherol, ASSAY/Alpha Tocopheryl Acetate, ASSAY/Alpha Tocopheryl Acid Succinate, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/Alpha Tocopheryl Acid Succinate RS

Revision VITAMIN E PREPARATION PF 38(1) Pg. ONLINE

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, OTHER COMPONENTS/Alcohol Determination, Method I <611> (if present), CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/Alpha Tocopheryl Acid Succinate RS

New OIL–SOLUBLE VITAMINS ORAL SOLUTION PF 37(6) Pg. ONLINE

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, OTHER COMPONENTS/Alcohol Determination, Method I <611> (if present), CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Labeling/1 &nbsp;USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass

Rick Schnatz

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Rick Schnatz

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is as follows. One USP Vitamin A Unit = 0.3 µg of all-trans-retinol (vitamin A alcohol) or 0.344 µg of all-trans-retinyl acetate (vitamin A acetate) or 0.55 µg of all-trans-retinyl palmitate (vitamin A palmitate), and 1 µg of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 µg of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 µg of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former U, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergocalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phytonadione RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinol Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Calcium, Method 1, STRENGTH/Chromium, Method 1, STRENGTH/Copper, Method 1, STRENGTH/Fluoride, Method 1, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, Method 1, STRENGTH/Magnesium, Method 1, STRENGTH/Manganese, Method 1, STRENGTH/Molybdenum, Method 1, STRENGTH/Molybdenum, Method 2, STRENGTH/Phosphorus, Method 1, STRENGTH/Potassium, STRENGTH/Selenium, Method 1, STRENGTH/Selenium, Method 2, STRENGTH/Zinc, Method 1; Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Phosphorus, and Zinc, Method 2; Molybdenum and Selenium, Method 3, PERFORMANCE TESTS/Disintegration and Dissolution <2040>, PERFORMANCE TESTS/Weight Variation <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling1: 1 &thinsp;USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 &micro;g of all-trans-retinol (vitamin A alcohol) or 0.344 &micro;g of all-trans-retinyl acetate (vitamin A acetate) or 0.55
&micro;g of all-trans-retinyl palmitate (vitamin A palmitate), and 1 &micro;g of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 &micro;g of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 &micro;g of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Beta Carotene System Suitability RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Cholecalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Ergocalciferol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Phytonadione RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Retinyl Palmitate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Fluoride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Vitamin A RS

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Chromium, STRENGTH/Fluoride, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, STRENGTH/Magnesium, STRENGTH/Manganese, STRENGTH/Molybdenum, STRENGTH/Zinc, OTHER COMPONENTS/Alcohol Determination, Method I <611> (if present), CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling: 1 USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued. However, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 &micro;g of all-trans-retinol (vitamin A alcohol) or 0.344 &micro;g of all-trans-retinyl acetate (vitamin A acetate) or 0.55 &micro;g of all-trans-retinyl palmitate (vitamin A palmitate), and 1 &micro;g of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 &micro;g of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 &micro;g of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former. ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP

DEFINITION/Introduction, STRENGTH/Vitamin A, STRENGTH/Vitamin D, STRENGTH/Vitamin E, STRENGTH/Phytonadione (Vitamin K1), STRENGTH/Beta Carotene, STRENGTH/Calcium, Method 1, STRENGTH/Chromium, Method 1, STRENGTH/Copper, Method 1, STRENGTH/Fluoride, Method 1, STRENGTH/Fluoride, Method 2, STRENGTH/Iodide, Method 1, STRENGTH/Iodide, Method 2, STRENGTH/Iron, Method 1, STRENGTH/Magnesium, Method 1, STRENGTH/Manganese, Method 1, STRENGTH/Molybdenum, Method 1, STRENGTH/Molybdenum, Method 2, STRENGTH/Phosphorus, Method 1, STRENGTH/Potassium, STRENGTH/Selenium, Method 1, STRENGTH/Selenium, Method 2, STRENGTH/Zinc, Method 1, STRENGTH/Boron, Nickel, Tin, and Vanadium, Method 1; Calcium, Chromium, Copper, Iron, Magnesium, Manganese, Phosphorus, and Zinc, Method 2; Molybdenum and Selenium, Method 3, PERFORMANCE TESTS/Disintegration and Dissolution of Dietary Supplements <2040>, Dissolution, PERFORMANCE TESTS/Weight Variation of Dietary Supplements <2091>, CONTAMINANTS/Microbial Enumeration Tests <2021>, CONTAMINANTS/Absence of Specified Microorganisms <2022>, ADDITIONAL REQUIREMENTS/Shipping and Storage, ADDITIONAL REQUIREMENTS/Labeling: 1

USP Units of activity for vitamins, where such exist or formerly existed, are equivalent to the corresponding international units, where such formerly existed. The USP Unit for Vitamin E has been discontinued. International units (IU) for vitamins also have been discontinued; however, the use of IU on the labels of vitamin products continues. Where articles are labeled in terms of Units in addition to the required labeling, the relationship of the USP Units or IU to mass is as follows. One USP Vitamin A Unit = 0.3 &micro;g of all-trans-retinol (vitamin A alcohol) or 0.344 &micro;g of all-trans-retinyl acetate (vitamin A acetate) or 0.55 &micro;g of all-trans-retinyl palmitate (vitamin A palmitate), and 1 &micro;g of retinol (3.3 USP Vitamin A Units) = 1 retinol equivalent (RE); 1 IU of beta carotene = 0.6 &micro;g of all-trans-beta carotene; 1 USP Vitamin D Unit = 0.025 &micro;g of ergocalciferol or cholecalciferol; and 1 mg of dl-alpha tocopherol = 1.1 former, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopherol RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acetate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Alpha Tocopheryl Acid Succinate RS, ADDITIONAL

Natalia Davydoa