

# Revisions to USP33-NF28 2S

Published June 2010

## [General Chapters](#)

## Monographs:

Monograph Title	Monograph Section	Scientific Liaison
1,3-DICAFFEYOYLQUINIC ACID PF 35(4) Pg. 990	1,3-Dicaffeoylquinic Acid (Cynarin; (1R,3R,4S,5R)-1,3-Bis[[3-(3,4-dihydroxyphenyl)propenoyl]oxy]-4,5-dihydroxycyclohexanecarboxylic Acid)	<a href="#">Margareth Marques</a>
DICLOFENAC SODIUM DELAYED-RELEASE TABLETS PF 35(5) Pg. 1129	PERFORMANCE TESTS/Dissolution <711>	<a href="#">Margareth Marques</a>
DICLOFENAC SODIUM EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1130	ASSAY/Procedure, IMPURITIES/Organic Impurities	<a href="#">Clydewyn Anthony</a>
DINOPROSTONE PF 35(5) Pg. 1132	IMPURITIES/Organic Impurities/Procedure	<a href="#">Domenick Vicchio</a>
DISULFIRAM PF 35(4) Pg. 848	ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Selenium <291>	<a href="#">Ravi Ravichandran</a>
DOCETAXEL PF 35(5) Pg. 1133	Title, Chemical Info/Chemical Structure, Chemical Info/C43H53NO14·3H2O, Chemical Info/861.93, Chemical Info/Benzenepropanoic acid, &beta;-[[(1,1-dimethylethoxy)carbonyl]amino]-&alpha;-hydroxy-, 12b-(acetyloxy)-12-(benzoyloxy)-2a,3,4,4a,5,6,9,10,11,12,12a,12b-dodecahydro-4,6,11-trihydroxy-4a,8,13,13-tetramethyl-5-oxo-7,11-methano-1H-cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester trihydrate, [2aR-[2a&alpha;,4&beta;,4a&beta;,6&beta;,9&alpha;(&alpha;R*,&beta;S*),11&alpha;,12&alpha;,12a&alpha;,12b&alpha;]]-(2R,3S)-N-Carboxy-3-phenylisoserine, N-tert-butyl ester, 13-ester with 5&beta;,20-epoxy-1,2&alpha;,4,7&beta;,10&beta;,13&alpha;-hexahydroxytax-11-en-9-one 4-acetate 2-benzoate, trihydrate, Chemical Info/CAS, DEFINITION/Introduction, DEFINITION/Paragraph Text, IDENTIFICATION/A. Infrared Absorption <197S>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Residue on Ignition <281>, IMPURITIES/Inorganic Impurities/Heavy Metals Method I <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Microbial Enumeration Tests <61>, SPECIFIC TESTS/Bacterial Endotoxins Test <85>, SPECIFIC TESTS/Water Determination, Method Ic <921>, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Feiwen Mao</a>
DOFETILIDE PF 35(5) Pg. 1135	Title, Chemical Info/Chemical Structure, Chemical Info/C19H27N3O5S2, Chemical Info/441.56, Chemical Info/Methanesulfonamide, N-[4-[2-[methyl[2-[4-[(methylsulfonyl)amino]phenoxy]ethyl]amino]ethyl]phenyl]-, Chemical Info/&beta;-[(p-Methanesulfonamidophenethyl)methylamino]methanesulfono-p-phenetidine, 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>, Method II, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Water Determination, Method I <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Sujatha Ramakrishna</a>
ENSULIZOLE PF 35(4) Pg. 849	ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Behnam Davani</a>
ESTRADIOL AND NORETHINDRONE ACETATE TABLETS PF 35(5) Pg. 1139	PERFORMANCE TESTS/Dissolution <711>	<a href="#">Margareth Marques</a>
CONJUGATED ESTROGENS PF 35(5) Pg. 1142	ASSAY/Procedure	<a href="#">Domenick Vicchio</a>
FENTANYL PF 34(3) Pg. 602	Related compounds, Assay, Title, Chemical formula, Molecular weight, Chemical names, CAS number, Definition, Packaging and storage, USP Reference standards, Identification A, B, Loss on drying, Residue on ignition, Heavy metals, Residual solvents	<a href="#">Clydewyn Anthony</a>
FOSINOPRIL SODIUM PF 35(5) Pg. 1144	IMPURITIES/Organic Impurities/Procedure 1	<a href="#">Sujatha Ramakrishna</a>
GALANTAMINE TABLETS PF 35(5) Pg. 1145	IMPURITIES/Organic Impurities/Procedure	<a href="#">Ravi Ravichandran</a>
HYDROXYPROPYL CELLULOSE OCULAR SYSTEM PF 35(4) Pg. 852	ASSAY/Procedure	<a href="#">Feiwen Mao</a>

LACTOBIONIC ACID PF 35(4) Pg. 904	Title, Chemical Info/C12H22O12 (acid form), Chemical Info/358.3, Chemical Info/CAS, Chemical Info/Chemical Structure, Chemical Info/C12H20O11 (&delta;-lactone), Chemical Info/340.3, Chemical Info/4-O-&beta;-galactopyranosyl-d-gluconic acid., DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Thin-Layer Chromatography <621>, ASSAY/Procedure, IMPURITIES/Inorganic Impurities/Heavy Metals <231>, SPECIFIC TESTS/Water Determination, Method Ia <921>, SPECIFIC TESTS/Appearance of Solution, SPECIFIC TESTS/Optical Rotation <781S>, SPECIFIC TESTS/Reducing Sugars, SPECIFIC TESTS/Articles of Botanical Origin, Total Ash <561>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Robert Lafaver</a>
LEFLUNOMIDE PF 35(5) Pg. 1158	IMPURITIES/Organic Impurities/Procedure 1: Limit of Leflunomide Related Compound A, SPECIFIC TESTS/Loss on Drying <731>	<a href="#">Clydewyn Anthony</a>
LEFLUNOMIDE TABLETS PF 35(5) Pg. 1159	SPECIFIC TESTS/Water Determination, Method Ic <921>	<a href="#">Clydewyn Anthony</a>
Lead Subacetate TS PF 35(5) Pg. 1339	Lead Subacetate TS	<a href="#">Margareth Marques</a>
MEFLOQUINE HYDROCHLORIDE PF 35(5) Pg. 1160	ASSAY/Procedure	<a href="#">Behnam Davani</a>
METHACRYLIC ACID COPOLYMER PF 35(4) Pg. 905	Chemical Info, DEFINITION/Introduction, IDENTIFICATION/B. Procedure, ASSAY/Procedure, IMPURITIES/Organic Impurities/Procedure: Limit of Monomers, SPECIFIC TESTS/Viscosity <911>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Hong Wang</a>
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER PF 35(4) Pg. 907	Title, Chemical Info/Chemical Structure, Chemical Info/Poly(methacrylic acid, ethyl acrylate);, Chemical Info/Methacrylic acid-ethyl acrylate copolymer, 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: Limit of Methacrylic Acid and Ethyl Acrylate, SPECIFIC TESTS/Viscosity <911>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Hong Wang</a>
METHACRYLIC ACID AND METHYL METHACRYLATE COPOLYMER PF 35(4) Pg. 909	Title, Chemical Info/Chemical Structure, Chemical Info/(Ratio of H to CH3 is either 1:1 or 1:2), Chemical Info/Poly(methacrylic acid, methyl methacrylate);, Chemical Info/Methacrylic acid-methyl methacrylate copolymer, 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/Limit of Methacrylic Acid and Methyl Methacrylate, SPECIFIC TESTS/Viscosity <911>, SPECIFIC TESTS/Loss on Drying <731>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Hong Wang</a>
METHYLBENZETHONIUM CHLORIDE PF 35(4) Pg. 853	IDENTIFICATION/B. Procedure, IDENTIFICATION/C. Procedure, IDENTIFICATION/D. Procedure, IDENTIFICATION/B. Infrared Absorption <197K>, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Behnam Davani</a>
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE TABLETS PF 35(5) Pg. 1162	IDENTIFICATION/B., IMPURITIES/Organic Impurities	<a href="#">Ravi Ravichandran</a>
METHYLPYRROLIDONE PF 35(5) Pg. 1205	Title, Chemical Info/C5H9NO, Chemical Info/99.1, Chemical Info/Chemical Structure, Chemical Info/1-Methyl-2-pyrrolidinone;, Chemical Info/N-Methyl-2-pyrrolidone;, Chemical Info/N-Methylpyrrolidone;, Chemical Info/1-Methyl-2-Pyrrolidone;, Chemical Info/Pyrrolidin, 1-methyl-2-one-;, Chemical Info/1-Methylpyrrolidin-2-one;, Chemical Info/N-Methyl-&gamma;-butyrolactam;, Chemical Info/N-Methyl tetrahydropyrrolone;, Chemical Info/1-Methyl-2-oxopyrrolidine;, Chemical Info/N-Methyl-1-oxotetramethyleneamine;, Chemical Info/2-Methyl-2-azacyclopentanone, Chemical Info/CAS, IDENTIFICATION/Infrared Absorption <197F>, IMPURITIES/Inorganic Impurities/Heavy Metals <231>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Alkalinity, SPECIFIC TESTS/Clarity of Solution, SPECIFIC TESTS/Color of Solution, SPECIFIC TESTS/Water, Method Ic <921>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Robert Lafaver</a>
Methyl Red PF 35(4) Pg. 990	Methyl Red	<a href="#">Margareth Marques</a>
MYCOPHENOLATE MOFETIL CAPSULES PF 35(4) Pg. 854	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 1: Limit of Degradation Products, IMPURITIES/Organic Impurities/Procedure 2: Limit of Z-Mycophenolate Mofetil, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Feiwen Mao</a>
MYCOPHENOLATE MOFETIL TABLETS PF 35(4) Pg. 856	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 1: Limit of Degradation Products, IMPURITIES/Organic Impurities/Procedure 2: Limit of Z-Mycophenolate Mofetil, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Feiwen Mao</a>
NEVIRAPINE ORAL	IMPURITIES/Organic Impurities/Procedure	<a href="#">Behnam</a>

SUSPENSION PF 35(4) Pg.  
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NOREPINEPHRINE  
BITARTRATE PF 35(5) Pg.  
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IMPURITIES/Inorganic Impurities/Residue on Ignition <281>

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**Monographs:**