

Compendial Cancellations for USP36–NF31

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<7> LABELING PF 38(1) Pg. ONLINE	Title, DEFINITION, LABELS AND LABELING	Donna Bohannon
New	<17> PRESCRIPTION CONTAINER LABELING PF 37(1) Pg. ONLINE	REFERENCES	Donna Bohannon
Revision	<1121> NOMENCLATURE PF 38(1) Pg. ONLINE	Title, Introduction, “SEC. 299.4 ESTABLISHED NAMES OF DRUGS.”;, GENERAL NOMENCLATURE FORMS, MONOGRAPH NAMING POLICY FOR SALT DRUG SUBSTANCES IN DRUG PRODUCTS AND COMPOUNDED PREPARATIONS, POLICY FOR POSTPONEMENT SCHEDULES, ROLE IN LAW OF ARTICLES RECOGNIZED IN USP–NF	Andrzej Wilk
Revision	AMOXAPINE PF 37(5) Pg. ONLINE	IMPURITIES/Organic Impurities	Ravi Ravichandran
New	ARTEMETHER PF 36(2) Pg. 377	Title, Chemical Info/Chemical Structure, Chemical Info/C16H26O5, Chemical Info/298.37, Chemical Info/(3R,5aS,6R,8aS,9R,10S,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4.3-j]-1,2-benzodioxepin, 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 1: Analysis of Cyclohexanone Propanal Derivative and Furoisochromen Derivative by TLC, IMPURITIES/Organic Impurities/Procedure 2: Analysis of Artemether Related Compound A, Artemether Related Compound B, and Any Other Individual Impurity by HPLC, SPECIFIC TESTS/Optical Rotation, Specific Rotation <781S>, SPECIFIC TESTS/Color of solution, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C15H24O5284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-	Behnam Davani

		benzodioxepin](C16H26O5298.37)	
New	ARTEMETHER AND LUMEFANTRINE TABLETS PF 36(2) Pg. 379	Title, DEFINITION/Introduction, IDENTIFICATION/A. Thin Layer Chromatography, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure 1: Impurities of Artemether, IMPURITIES/Organic Impurities/Procedure 2: Impurities of Lumefantrine, IMPURITIES/Organic Impurities/Acceptance criteria, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound A RS [(3R,5aS,6R,8aS,9R,12R,12aR)-Decahydro-10-hydroxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C15H24O5284.35), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Artemether Related Compound B RS [(3R,5aS,6R,8aS,9R,10R,12R,12aR)-Decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzodioxepin](C16H26O5298.37), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene)-9H-fluoren-4-yl)ethanol](C30H32Cl3NO528.94)	Behnam Davani
Revision	DESCRIPTION AND SOLUBILITY PF 36(2) Pg. 578	Artemether, Fosfomycin Tromethamine, Lumefantrine	Behnam Davani
New	LUMEFANTRINE PF 36(2) Pg. 413	Title, Chemical Info/Chemical Structure, Chemical Info/C30H32Cl3NO, Chemical Info/528.94, Chemical Info/(±)-2,7-Dichloro-9-[(Z)-p-chlorobenzylidene]-α[(dibutylamino)methyl]-fluorene-4-methanol, Chemical Info/CAS, DEFINITION/Paragraph Text, 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, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound A RS [(RS, Z)-2-(Dibutylamino)-2-(2,7-dichloro-9-(4-chlorobenzylidene)-9H-	Behnam Davani

		<p>fluoren-4-yl)ethanol](C30H32Cl3NO528.94), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lumefantrine Related Compound B RS Lumefantrine related compound B is a mixture of isomers A and B. [Isomer A is (1S,3R,5R)-1,3-bis[(EZ)-2,7- Dichloro-9-(4-chlorobenzylidene)-9H-fluoren- 4-yl]-2,6-dioxabicyclo[3.1.0]hexane.] [Isomer B is 2-((EZ)-2,7-Dichloro-9-(4- chlorobenzylidene)-9H-fluoren-4-yl)-3'-((EZ)- 2,7-dichloro-9-(4-chlorobenzylidene)-9H- fluoren-4-yl)-2,2'- bioxirane.](C44H24Cl6O2797.4)</p>	
Revision	MESORIDAZINE BESYLATE PF 38(1) Pg. ONLINE	<p>ASSAY/Procedure, IMPURITIES/Procedure: Ordinary Impurities <466>, IMPURITIES/Organic Impurities</p>	<p>Hariram Ramanathan</p>
New	SCAFFOLD HUMAN PERIPHERAL NERVE PF 36(5) Pg. 1205	<p>Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/ChABCCase Residual Testing, SPECIFIC TESTS/Visual, SPECIFIC TESTS/Safety, SPECIFIC TESTS/Suture Pullout, SPECIFIC TESTS/Sterility Tests <71>, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging, Sterilization, and Storage, ADDITIONAL REQUIREMENTS/USP Authentic Visual References <11></p>	<p>Fouad Atouf</p>
New	SODIUM PHENYLBUTYRATE ORAL SUSPENSION PF 37(1) Pg. ONLINE	<p>ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Sodium Phenylbutyrate RS</p>	<p>Rick Schnatz</p>