

## Compendial Cancellations for USP36-NF31, First Supplement

Category	Monograph Title	Monograph Section	Scientific Liaison
New	<787> SUBVISIBLE PARTICULATE MATTER IN THERAPEUTIC PROTEIN INJECTIONS PF 38(3) Pg. ONLINE	Introduction, LIGHT OBSCURATION PARTICLE COUNT TEST, MICROSCOPIC PARTICLE COUNT TEST	<a href="#">Desmond Hunt</a>
New	<790> VISIBLE PARTICULATES IN INJECTIONS PF 38(2) Pg. ONLINE	Title, Introduction	<a href="#">Desmond Hunt</a>
Revision	ADENOSINE PF 38(1) Pg. ONLINE	IDENTIFICATION/B., IMPURITIES/Organic Impurities, SPECIFIC TESTS/Melting Range or Temperature <741>	<a href="#">Heather Joyce</a>
Revision	AMOXICILLIN CAPSULES PF 36(4) Pg. 892	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound C RS [(4S)-2-[5-(4-hydroxyphenyl)-3,6-dioxopiperazin-2-yl]-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin rearrangement product](C16H19N3O5S365.40), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl]-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C16H21N3O6S383.42), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound G RS [(2S,5R,6R)-6-[(R)-2-[(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-2-(4-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; d-hydroxyphenylglycylamoxicillin](C24H26N4O7S514.55)	<a href="#">Ahalya Wise</a>
Revision	AMOXICILLIN FOR ORAL SUSPENSION PF 36(4) Pg. 894	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D and E Mixture RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/ USP Amoxicillin Related Compound G RS (2S,5R,6R)-	<a href="#">Ahalya Wise</a>

		6-{(R)-2-[[ (R)-2-amino-2-(4-hydroxyphenyl)acetamido]-2-(4-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; d-hydroxyphenylglycylamoxicillin}(C <sub>24</sub> H <sub>26</sub> N <sub>4</sub> O <sub>7</sub> S <sub>5</sub> 14.55)	
Revision	AMOXICILLIN TABLETS PF 36(4) Pg. 896	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS [(2S,5R,6R)-6-amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid; 6-aminopenicillanic acid](C <sub>8</sub> H <sub>12</sub> N <sub>2</sub> O <sub>3</sub> S <sub>2</sub> 16.26), ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS [(4S)-2-{(R)-2-amino-2-(4-hydroxyphenyl)acetamido}(carboxy)methyl}-5,5-dimethylthiazolidine-4-carboxylic acid; amoxicillin open ring](C <sub>16</sub> H <sub>21</sub> N <sub>3</sub> O <sub>6</sub> S <sub>3</sub> 83.42)	<a href="#">Ahalya Wise</a>
Revision	AMOXICILLIN AND CLAVULANATE POTASSIUM FOR ORAL SUSPENSION PF 36(4) Pg. 899	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS	<a href="#">Ahalya Wise</a>
Revision	AMOXICILLIN AND CLAVULANATE POTASSIUM TABLETS PF 36(4) Pg. 901	IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound D RS	<a href="#">Ahalya Wise</a>
Revision	CLINDAMYCIN PHOSPHATE PF 37(5) Pg. ONLINE	IDENTIFICATION/A. Infrared Absorption <197M><197K>, IDENTIFICATION/B., ASSAY/Procedure, IMPURITIES/Organic Impurities, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Clindamycin Hydrochloride RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Lincomycin Hydrochloride RS	<a href="#">Ahalya Wise</a>
New	HYALURONATE SODIUM PF 38(1) Pg.	Title, Chemical Info/Chemical Structure, Chemical	<a href="#">Tina Morris</a>

ONLINE

Info/(C<sub>14</sub>H<sub>20</sub>NNaO<sub>11</sub>)<sub>n</sub>, Chemical Info/CAS, DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197K>, IDENTIFICATION/B. Identification Tests&mdash;General, Sodium <191>, ASSAY/Procedure, IMPURITIES/Chloride and Sulfate, Chloride <221>, IMPURITIES/Iron <241>, IMPURITIES/Heavy Metals <231>, IMPURITIES/Nucleic Acids, IMPURITIES/Protein, IMPURITIES/Sulfated Glycosaminoglycans, SPECIFIC TESTS/Intrinsic Viscosity, SPECIFIC TESTS/Appearance of the Solution, SPECIFIC TESTS/Loss on Drying <731>, SPECIFIC TESTS/pH <791>, SPECIFIC TESTS/Microbial Enumeration Test <61> and Absence of Specified Microorganisms <62>, SPECIFIC TESTS/Bacterial Endotoxins <85>, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Endotoxin RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP d-Glucuronic Acid RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Hyaluronate Sodium RS

Revision	ISOPHANE INSULIN HUMAN SUSPENSION PF 36(6) Pg. 1539	SPECIFIC TESTS/Sterility Tests <71>	<a href="#">Kevin Carrick</a>
Revision	ISOPHANE INSULIN SUSPENSION PF 36(6) Pg. 1538	SPECIFIC TESTS/Sterility Tests <71>	<a href="#">Kevin Carrick</a>
Revision	PIPERACILLIN AND TAZOBACTAM FOR INJECTION PF 37(2) Pg. ONLINE	ASSAY/Procedure, IMPURITIES/Organic Impurities, Procedure 1, IMPURITIES/Organic Impurities, Procedure 2, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Amoxicillin Related Compound A RS (2S,5R,6R)-6-Amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.C <sub>8</sub> H <sub>12</sub> N <sub>2</sub> O <sub>3</sub> S <sub>2</sub> 16.26	<a href="#">Ahalya Wise</a>
Revision	Perchloric Acid, Tenth-Normal (0.1 N) in Glacial Acetic Acid PF 38(3) Pg. ONLINE	Perchloric Acid, Tenth-Normal (0.1 N) in Glacial Acetic Acid	<a href="#">Margareth Marques</a>
New	ROPINIROLE HYDROCHLORIDE PF 36(1)	IMPURITIES/Organic Impurities /Procedure 1,	<a href="#">Ravi</a>

	Pg. 133	IMPURITIES/Organic Impurities /Procedure 2, ADDITIONAL REQUIREMENTS/Labeling	<a href="#">Ravichandran</a>
New	SCAFFOLD EQUINE PERICARDIUM COLLAGEN. PF 36(6) Pg. 1521	Title, DEFINITION/Introduction, SPECIFIC TESTS/Histological Evaluation, SPECIFIC TESTS/Protein Determination, SPECIFIC TESTS/Lipid Analysis, SPECIFIC TESTS/Moisture Determination, SPECIFIC TESTS/Ash Determination, SPECIFIC TESTS/Carbohydrates, SPECIFIC TESTS/Tensile Strength, SPECIFIC TESTS/Burst Strength, SPECIFIC TESTS/Suture Pullout Strength, SPECIFIC TESTS/Pronase Digestion Resistance, SPECIFIC TESTS/Thermal Analysis, SPECIFIC TESTS/Visual Inspection, SPECIFIC TESTS/Bacterial Endotoxin Test <85>, SPECIFIC TESTS/Sterility Tests <71>, SPECIFIC TESTS/Safety, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>	<a href="#">Fouad Atouf</a>
New	SERTRALINE HYDROCHLORIDE PF 34(5) Pg. 1189	Related compounds	<a href="#">Ravi Ravichandran</a>
New	TOPIRAMATE CAPSULES PF 36(4) Pg. 930	DEFINITION/Introduction, IDENTIFICATION/A. Infrared Absorption <197F>, IDENTIFICATION/B., ASSAY/Procedure, PERFORMANCE TESTS, PERFORMANCE TESTS/Dissolution <711>, PERFORMANCE TESTS/Uniformity of Dosage Units <905>, IMPURITIES/Organic Impurities/Procedure, SPECIFIC TESTS/Limit of Sulfamate and Sulfate, ADDITIONAL REQUIREMENTS/Packaging and Storage, ADDITIONAL REQUIREMENTS/Labeling, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topiramate RS, ADDITIONAL REQUIREMENTS/USP Reference Standards <11>/USP Topiramate Related Compound A RS 2,3:4,5-bis-O-(1-methylethylidene)-d-fructopyranose(C12H20O6260.28)	<a href="#">Ravi Ravichandran</a>
Revision	TROSPIUM CHLORIDE PF 38(1) Pg. ONLINE	IMPURITIES/Limit of Trospium Chloride Related Compound C	<a href="#">Elena Gonikberg</a>

Revision	VALERIAN PF 38(3) Pg. ONLINE	IDENTIFICATION/HPLC Identification Test, SPECIFIC TESTS/Articles of Botanical Origin, Water Content <561>	<a href="#">Maged Sharaf</a>
Revision	VALERIAN TABLETS PF 38(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, STRENGTH/Content of Valerenic Acid	<a href="#">Maged Sharaf</a>
Revision	POWDERED VALERIAN PF 38(3) Pg. ONLINE	IDENTIFICATION/HPLC Identification Test, SPECIFIC TESTS/Water, Method 1a <921>	<a href="#">Maged Sharaf</a>
Revision	POWDERED VALERIAN EXTRACT PF 38(3) Pg. ONLINE	IDENTIFICATION/A. Thin-Layer Chromatography, CONTAMINANTS/Alcohol Determination, Method II <611>	<a href="#">Maged Sharaf</a>
Revision	VALGANCICLOVIR HYDROCHLORIDE PF 36(4) Pg. 935	IMPURITIES/Organic Impurities/Procedure 3, SPECIFIC TESTS/Enantiomeric Purity of Valganciclovir	<a href="#">Leonel Santos</a>
Revision	VALPROIC ACID PF 38(3) Pg. ONLINE	IMPURITIES/Organic Impurities	<a href="#">Ravi Ravichandran</a>