

Revisions to FCC Sixth Edition, Second Supplement

Published August 2009

Monograph Title	Monograph Section	Scientific Liaison
<p>AMMONIUM CITRATE, TRIBASIC</p>	<p>Title, Chemical Info/Chemical Name, Chemical Info/Chemical Formula, Chemical Info/Molecular Weight, Chemical Info/INS, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and Storage, IDENTIFICATION/A. Ammonium, Appendix IIIA/Sample solution, IDENTIFICATION/A. Ammonium, Appendix IIIA/Acceptance criteria, IDENTIFICATION/B. Citrate, Appendix IIIA/Sample solution, IDENTIFICATION/B. Citrate, Appendix IIIA/Acceptance criteria, ASSAY/Procedure/Phenolphthalein solution, ASSAY/Procedure/Sample, ASSAY/Procedure/Analysis, ASSAY/Procedure/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Acceptance criteria, SPECIFIC TESTS/Oxalate/Sample, SPECIFIC TESTS/Oxalate/Analysis, SPECIFIC TESTS/Oxalate/Acceptance criteria</p>	<p>Kristie Bowman</p>
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ALPHA-CYCLODEXTRIN	<p>Title, Chemical Info/Chemical Name, Chemical Info/Chemical Structure, Chemical Info/Chemical Formula, Chemical Info/Molecular Weight, Chemical Info/INS, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and storage, IDENTIFICATION/Procedure/Acceptance criteria, ASSAY/Procedure/Mobile phase, ASSAY/Procedure/Standard solution, ASSAY/Procedure/Sample solution, ASSAY/Procedure/Chromatographic system, Appendix IIA/Mode, ASSAY/Procedure/Chromatographic system, Appendix IIA/Detector, ASSAY/Procedure/Chromatographic system, Appendix IIA/Column, ASSAY/Procedure/Chromatographic system, Appendix IIA/Column temperature, ASSAY/Procedure/Chromatographic system, Appendix IIA/Flow rate, ASSAY/Procedure/Chromatographic system, Appendix IIA/Injection volume, ASSAY/Procedure/Analysis, ASSAY/Procedure/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I, Appendix IIIB/Acceptance criteria, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Reagent solution, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Standard stock solution, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Standard solutions, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Sample solutions, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Calibration curve, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Analysis, IMPURITIES/Organic Impurities/Reducing Substances (as Dextrose) /Acceptance criteria, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Tris buffer solution, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Internal standard solution, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Standard stock solution, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Standard solution, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Sample solution, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Chromatographic</p>	<p>Jeffrey Moore</p>
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	<p>system, Appendix IIA, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Analysis, IMPURITIES/Organic Impurities/Residual Complexant (1-Decanol)/Acceptance criteria, SPECIFIC TESTS/Melting Range or Temperature, Appendix IIB/Acceptance criteria, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Sample, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Acceptance criteria, SPECIFIC TESTS/Optical (Specific) Rotation, Appendix IIB/Sample solution, SPECIFIC TESTS/Optical (Specific) Rotation, Appendix IIB/Acceptance criteria, SPECIFIC TESTS/Water, Water Determination, Method I, Appendix IIB/Acceptance criteria</p>	
CALCIUM PROPIONATE	<p>DESCRIPTION/Introduction, SPECIFIC TESTS/Acid- Insoluble Substances/Sample, SPECIFIC TESTS/Acid- Insoluble Substances/Analysis</p>	Jeffrey Moore
SYNTHETIC IRON OXIDE	<p>Title, Chemical Info/Chemical Name, Chemical Info/Chemical Formula, Chemical Info/Molecular Weight, Chemical Info/INS, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and Storage, ASSAY/Assay for Iron (III)/Sample, ASSAY/Assay for Iron (III)/Analysis, ASSAY/Assay for Iron (III)/Acceptance criteria, IMPURITIES/Inorganic Impurities/Arsenic/Solution A, IMPURITIES/Inorganic Impurities/Arsenic/Solution B, IMPURITIES/Inorganic Impurities/Arsenic/Mercuric bromide paper, IMPURITIES/Inorganic Impurities/Arsenic/Lead acetate cotton, IMPURITIES/Inorganic Impurities/Arsenic/Standard stock solution, IMPURITIES/Inorganic Impurities/Arsenic/Standard solution, IMPURITIES/Inorganic Impurities/Arsenic/Sample solution, IMPURITIES/Inorganic Impurities/Arsenic/Apparatus, IMPURITIES/Inorganic Impurities/Arsenic/Analysis, IMPURITIES/Inorganic Impurities/Arsenic/Acceptance criteria, IMPURITIES/Inorganic Impurities/Cadmium, Cadmium Limit Test, Appendix IIIB/Sample solution, IMPURITIES/Inorganic Impurities/Cadmium, Cadmium Limit Test, Appendix IIIB/Test solutions, IMPURITIES/Inorganic Impurities/Cadmium, Cadmium</p>	Kristie Bowman

	Limit Test, Appendix IIIB/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead/Standard stock solution, IMPURITIES/Inorganic Impurities/Lead/Standard solution, IMPURITIES/Inorganic Impurities/Lead/Sample solution, IMPURITIES/Inorganic Impurities/Lead/Analysis, IMPURITIES/Inorganic Impurities/Lead/Acceptance criteria, IMPURITIES/Inorganic Impurities/Mercury, Mercury Limit Test, Method I, Appendix IIIB/Sample solution, IMPURITIES/Inorganic Impurities/Mercury, Mercury Limit Test, Method I, Appendix IIIB/Acceptance criteria, SPECIFIC TESTS/Loss on Drying, Appendix IIC (105Å° for 4h)/Acceptance criteria/Red iron oxide, SPECIFIC TESTS/Water-Soluble Matter/Sample, SPECIFIC TESTS/Water-Soluble Matter/Analysis, SPECIFIC TESTS/Water-Soluble Matter/Acceptance criteria	
MAGNESIUM PHOSPHATE, TRIBASIC	IMPURITIES/Inorganic Impurities/Fluoride, Fluoride Limit Test, Method III, Appendix IIIB/Acceptance criteria	Kristie Bowman
NICKEL	ASSAY/Supported Nickel Catalyst/Acceptance criteria	Kristie Bowman
POLYVINYL ACETATE	(C4H6O2) _n , IMPURITIES/Organic Impurities/Free Vinyl Acetate	Jeffrey Moore
POTASSIUM METABISULFITE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Acceptance criteria	Kristie Bowman
POTASSIUM SULFATE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method II, Appendix IIIB/Acceptance criteria	Kristie Bowman
POTASSIUM SULFITE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Acceptance criteria	Kristie Bowman

REBAUDIOSIDE A	<p>Title, Chemical Info/Chemical Name, Chemical Info/Chemical Structure, Chemical Info/Chemical Formula, Chemical Info/Molecular Weight, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and storage, IDENTIFICATION/A. Infrared Absorption, Spectrophotometric Identification Tests, Appendix IIIC/Reference standard, IDENTIFICATION/A. Infrared Absorption, Spectrophotometric Identification Tests, Appendix IIIC/Sample and standard preparation, IDENTIFICATION/A. Infrared Absorption, Spectrophotometric Identification Tests, Appendix IIIC/Acceptance criteria, IDENTIFICATION/B. Procedure/Acceptance criteria, ASSAY/Procedure/Acetate buffer, ASSAY/Procedure/Mobile phase, ASSAY/Procedure/Diluent, ASSAY/Procedure/Rebaudioside A standard solutions, ASSAY/Procedure/Stevioside standard stock solution, ASSAY/Procedure/Stevioside standard solutions, ASSAY/Procedure /Sample solution, ASSAY/Procedure/Chromatographic system, Appendix IIA/Mode, ASSAY/Procedure/Chromatographic system, Appendix IIA/Detector, ASSAY/Procedure/Chromatographic system, Appendix IIA/Column, ASSAY/Procedure/Chromatographic system, Appendix IIA/Column temperature, ASSAY/Procedure /Chromatographic system, Appendix IIA/Flow rate, ASSAY/Procedure/Chromatographic system, Appendix IIA/Injection size, ASSAY/Procedure/Chromatographic system, Appendix IIA/System suitability, ASSAY/Procedure/Analysis, ASSAY/Procedure/Acceptance criteria, IMPURITIES/Inorganic Impurities/Arsenic/Dilute nitric acid, IMPURITIES/Inorganic Impurities/Arsenic/Yttrium internal standard solution, IMPURITIES/Inorganic Impurities/Arsenic/Standard stock solution, IMPURITIES/Inorganic Impurities/Arsenic/Standard solution, IMPURITIES/Inorganic Impurities/Arsenic/Standard blank solution, IMPURITIES/Inorganic Impurities/Arsenic/Sample solution, IMPURITIES/Inorganic Impurities/Arsenic/Spectrophotometric system, Plasma Spectrochemistry, Appendix IIC, IMPURITIES/Inorganic Impurities/Arsenic/Analysis, IMPURITIES/Inorganic Impurities/Arsenic/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead/Dilute nitric acid,</p>	<p>Jeffrey Moore</p>
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	<p>IMPURITIES/Inorganic Impurities/Lead/Thallium internal standard solution, IMPURITIES/Inorganic Impurities/Lead/Standard stock solution, IMPURITIES/Inorganic Impurities/Lead/Standard solution, IMPURITIES/Inorganic Impurities/Lead/Standard blank solution, IMPURITIES/Inorganic Impurities/Lead/Sample solution, IMPURITIES/Inorganic Impurities/Lead/Spectrophotometric system, Plasma Spectrochemistry, Appendix IIC, IMPURITIES/Inorganic Impurities/Lead/Analysis, IMPURITIES/Inorganic Impurities/Lead /Acceptance criteria, IMPURITIES/Organic Impurities/Ethanol and Methanol/Internal standard solution, IMPURITIES/Organic Impurities/Ethanol and Methanol/Standard stock solution, IMPURITIES/Organic Impurities/Ethanol and Methanol/Standard solutions, IMPURITIES/Organic Impurities/Ethanol and Methanol/Sample, IMPURITIES/Organic Impurities/Ethanol and Methanol/Sample solution, IMPURITIES/Organic Impurities/Ethanol and Methanol/Blank, IMPURITIES/Organic Impurities/Ethanol and Methanol/Chromatographic system, Appendix IIA, IMPURITIES/Organic Impurities/Ethanol and Methanol/System suitability, IMPURITIES/Organic Impurities/Ethanol and Methanol/Analysis, IMPURITIES/Organic Impurities/Ethanol and Methanol/Acceptance criteria, IMPURITIES/Organic Impurities/Related Steviol Glycosides/Acetate buffer, Mobile phase, Diluent, Rebaudioside A standard solutions, Stevioside standard stock solution, Stevioside standard solutions, Sample solution, Chromatographic system, and System suitability, IMPURITIES/Organic Impurities/Related Steviol Glycosides/Analysis, IMPURITIES/Organic Impurities/Related Steviol Glycosides/Acceptance criteria, SPECIFIC TESTS/Loss on Drying, Appendix IIC/Sample, SPECIFIC TESTS/Loss on Drying, Appendix IIC/Acceptance criteria, SPECIFIC TESTS/Optical (Specific) Rotation, Appendix IIB/Sample solution, SPECIFIC TESTS/Optical (Specific) Rotation, Appendix IIB/Acceptance criteria</p>	
SODIUM FUMARATE	<p>Title, Chemical Info/Chemical Name, Chemical Info/Chemical Structure, Chemical Info/Chemical Formula, Chemical Info/Molecular Weight, Chemical Info/INS, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function,</p>	<p>Kristie Bowman</p>

	<p>DESCRIPTION/Packaging and Storage, IDENTIFICATION/A. Procedure/Sample, IDENTIFICATION/A. Procedure/Analysis, IDENTIFICATION/A. Procedure/Acceptance criteria, IDENTIFICATION/B. Procedure/Sample, IDENTIFICATION/B. Procedure/Analysis, IDENTIFICATION/B. Procedure/Acceptance criteria, IDENTIFICATION/C. pH, pH Determination, Appendix II/Sample solution, IDENTIFICATION/C. pH, pH Determination, Appendix II/Analysis, IDENTIFICATION/C. pH, pH Determination, Appendix II/Acceptance criteria, IDENTIFICATION/D. Sodium, Appendix IIIA/Acceptance criteria, ASSAY/Procedure /Phenolphthalein solution, ASSAY/Procedure/Sample, ASSAY/Procedure/Analysis, ASSAY/Procedure/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Acceptance criteria, IMPURITIES/Inorganic Impurities/Sulfate/Sample, IMPURITIES/Inorganic Impurities/Sulfate /Analysis, IMPURITIES/Inorganic Impurities/Sulfate/Acceptance criteria, IMPURITIES/Organic Impurities/Maleic Acid/Mobile phase, IMPURITIES/Organic Impurities/Maleic Acid/Standard solution, IMPURITIES/Organic Impurities/Maleic Acid/Sample solution, IMPURITIES/Organic Impurities/Maleic Acid/Resolution solution, IMPURITIES/Organic Impurities/Maleic Acid/Chromatographic system, Appendix IIA, IMPURITIES/Organic Impurities/Maleic Acid/Analysis, IMPURITIES/Organic Impurities/Maleic Acid/Acceptance criteria, SPECIFIC TESTS/Loss on Drying, Appendix IIC/Acceptance criteria</p>	
<p>SORBITAN MONOOLEATE</p>	<p>Title, Chemical Info/INS, Chemical Info/CAS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and Storage, IDENTIFICATION/Iodine Value, Appendix VII/Sample, IDENTIFICATION/Iodine Value, Appendix VII/Acceptance criteria, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Sample solution, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Standard solution, IDENTIFICATION/Thin-Layer</p>	<p>Kristie Bowman</p>

	<p>Chromatography, Appendix IIA/Adsorbent, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Application volume, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Developing solvent system, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Spray reagent, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Analysis, IDENTIFICATION/Thin-Layer Chromatography, Appendix IIA/Acceptance criteria, ASSAY/Procedure/Sample, ASSAY/Procedure/Analysis, ASSAY/Procedure/Acceptance criteria/Fatty acids, ASSAY/Procedure/Acceptance criteria/Polyols (as sorbitol, 1,4-sorbitan and isosorbide), IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Acceptance criteria, SPECIFIC TESTS/Acid Value, Method II, Appendix VII/Acceptance criteria, SPECIFIC TESTS/Hydroxyl Value, Method II, Appendix VII/Acceptance criteria, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Sample, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Acceptance criteria, SPECIFIC TESTS/Saponification value, Appendix VII/Sample, SPECIFIC TESTS/Saponification value, Appendix VII/Acceptance criteria, SPECIFIC TESTS/Water, Water Determination, Appendix IIB/Acceptance criteria</p>	
<p>STEARYL CITRATE</p>	<p>Title, Chemical Info/Chemical Structure, Chemical Info/INS, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and Storage, IDENTIFICATION/Test for Stearyl Alcohol/Sample, IDENTIFICATION/Test for Stearyl Alcohol/Acceptance criteria, IDENTIFICATION/Test for Citrate/Sample, IDENTIFICATION/Test for Citrate/Analysis 1, IDENTIFICATION/Test for Citrate/Acceptance criteria 1, IDENTIFICATION/Test for Citrate/Analysis 2, IDENTIFICATION/Test for Citrate/Acceptance criteria 2, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix</p>	<p>Kristie Bowman</p>

	IIIB/Sample, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Acceptance criteria, SPECIFIC TESTS/Chloroform-Insoluble Matter/Sample, SPECIFIC TESTS/Chloroform-Insoluble Matter/Analysis, SPECIFIC TESTS/Chloroform-Insoluble Matter/Acceptance criteria	
SODIUM BISULFATE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method II, Appendix IIIB/Acceptance criteria	Kristie Bowman
SODIUM BISULFITE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Acceptance criteria	Kristie Bowman
SODIUM METABISULFITE	IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Selenium, Selenium Limit Test, Method I, Appendix IIIB/Acceptance criteria	Kristie Bowman
SUCRALOSE	ASSAY/Procedure/Standard solution, SPECIFIC TESTS/Related Substances, Thin-Layer Chromatography, Appendix IIA/Standard solution, SPECIFIC TESTS/Related Substances, Thin-Layer Chromatography, Appendix IIA/Dilute standard solution	Jeffrey Moore
THAUMATIN	Title, Chemical Info/Chemical Name, Chemical Info/Molecular Weight, Chemical Info/INS, Chemical Info/CAS, Chemical Info/FEMA, DESCRIPTION/Introduction, DESCRIPTION/Function, DESCRIPTION/Packaging and Storage, IDENTIFICATION/Ninhydrin Test/Solution A, IDENTIFICATION/Ninhydrin Test/Sample solution, IDENTIFICATION/Ninhydrin Test/Analysis, IDENTIFICATION/Ninhydrin Test/Acceptance criteria, IDENTIFICATION/Infrared Spectra, Spectrophotometric Identification Tests, Appendix IIIC/Sample preparation, IDENTIFICATION/Infrared Spectra, Spectrophotometric Identification Tests, Appendix IIIC/Acceptance criteria, ASSAY/Protein, Nitrogen Determination, Method II, Appendix	Kristie Bowman

IIIC/Analysis, ASSAY/Protein, Nitrogen Determination, Method II, Appendix IIIC/Acceptance criteria, IMPURITIES/Inorganic Impurities/Aluminum, Aluminum Limit Test, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Aluminum, Aluminum Limit Test, Appendix IIIB/Acceptance criteria, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Sample, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Analysis, IMPURITIES/Inorganic Impurities/Lead, Lead Limit Test, Flame Atomic Absorption Spectrophotometric Method, Appendix IIIB/Acceptance criteria, IMPURITIES/Organic Impurities/Carbohydrates/Solution A, IMPURITIES/Organic Impurities/Carbohydrates/Sample solution, IMPURITIES/Organic Impurities/Carbohydrates/Standard solutions, IMPURITIES/Organic Impurities/Carbohydrates/Analysis, IMPURITIES/Organic Impurities/Carbohydrates/Acceptance criteria, SPECIFIC TESTS/Loss on Drying, Appendix IIC (105Â° to constant weight) /Acceptance criteria, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Sample, SPECIFIC TESTS/Residue on Ignition (Sulfated Ash), Appendix IIC/Acceptance criteria, SPECIFIC TESTS/Specific Absorption/Sample solution, SPECIFIC TESTS/Specific Absorption/Analysis, SPECIFIC TESTS/Specific Absorption/Acceptance criteria