Chart 3. Excipients

Universal Tests

Description

- <1091> Labeling of Inactive Ingredients

Identification

- <181> Identification---Organic Nitrogenous Bases
- <191> Identification Tests---General
- <197> Spectrophotometric Identification Tests
- <201> Thin-Layer Chromatographic Identification Test
- <401> Fats and Fixed Oils
- <621> Chromatography
- <731> Loss on Drying
- <736> Mass Spectrometry
- <781> Optical Rotation
- <851> Spectrophotometry and Light-Scattering
- <941> Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction
- <1119> Near-Infrared Spectrophotometry

Assay

- <311> Alginates Assay
- <345> Assay for Citric Acid/ Citrate and Phosphate
- <425> Iodometric Assay---Antibiotics
- <431> Methoxy Determination
- <541> Titrimetry
- <621> Chromatography
- <801> Polarography
- <851> Spectrophotometry and Light-Scattering

Impurities

Organic

- <226> 4-Epianhydrotetracycline
- <461> Nitrogen Determination
- <466> Ordinary Impurities
- <621> Chromatography
- <781> Optical Rotation
- <801> Polarography
- <851> Spectrophotometry and Light-Scattering
- <1086> Impurities in Drug Substances and Drug Products

Inorganic

- <206> Aluminum
- <211> Arsenic
- <221> Chloride and Sulfate
- <231> Heavy Metals
- <232> Elemental Impurities---Limits
- <233> Elemental Impurities---Procedures
- <241> Iron
- <251> Lead
- <261> Mercury
- <281> Residue on Ignition
- <291> Selenium
- <471> Oxygen Flask Combustion
- <730> Plasma Spectrochemistry
- <733> Loss on Ignition

Residual Solvents

- <228> Ethylene Oxide and Dioxane
- <467> Residual Solvents
- <621> Chromatography
- <731> Loss on Drying

Specific Tests

Physicochemical Characterization

- <429> Light Diffraction Measurement of Particle Size
- <616> Bulk Density and Tapped Density
- <631> Color and Achromicity
- <641> Completeness of Solution
- <651> Congealing Temperature
- <695> Crystallinity
- <699> Density of Solids
- <721> Distilling Range
- <731> Loss on Drying
- <741> Melting Range or Temperature
- <761> Nuclear Magnetic Resonance
- <776> Optical Microscopy
- <781> Optical Rotation
- <785> Osmolality and Osmolarity
- <786> Particle Size Distribution Estimation by Analytical Sieving
- <791> pH
- <811> Powder Fineness
- <821> Radioactivity
- <831> Refractve Index
- <841> Specific Gravity
- <846> Specific Surface Area
- <881> Tensile Strength
- <911> Viscosity---Capillary Viscometer Methods
- <912> Rotational Rheometer Methods
- <913> Rolling Ball Viscometer Method
- <941> Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction
- <1045> Biotechnology-Derived Articles
- <1119> Near-Infrared Spectrophotometry
- <1174> Powder Flow

Equipment

- <16> Automated Methods of Analysis
- <21> Thermometers
- <31> Volumetric Apparatus
- <41> Weights and Balances
- <1051> Cleaning Glass Apparatus
- <1251> Weighing on an Analytical Balance

Pharmaceutical Water

- <541> Titrimetry
- <643> Total Organic Carbon
- <645> Water Conductivity
- <791> pH
- <891> Thermal Analysis
- <921> Water Determination
- <1230> Water for Health Applications
- <1231> Water for Pharmaceutical Purposes See *Microbiology (Chart 10)*
- <1644> Theory and Practice of Electrical Conductivity Measurements of Solutions

Functionality/Safety/GMPs

- <301> Acid-Neutralizing Capacity
- <1059> Excipient Performance
- <1074> Excipient Biological Safety Evaluation Guidelines
- <1078> GMPs for Bulk Pharmaceutical Excipients
- <1080> Bulk Pharmaceutical Excipients---Certificate of Analysis
- <1081> Gel Strength of Gelatin
- <1097> Bulk Powder Sampling Procedures
- <1174> Powder Flow
- <1195> Significant Change Guide for Bulk Pharmaceutical Excipients