Chart 1. Noncomplex Active Drug Substances

Universal Tests

Description

- <659> Packaging and Storage Requirements

Identification

- <181> Identification---Organic Nitrogenous Bases
- <191> Identification Tests---General
- <193> Identification---Tetracyclines
- <197> Spectrophotometric Identification Tests
- <201> Thin-Layer Chromatographic Identification Test
- <401> Fats and Fixed Oils
- <541> Titrimetry
- <621> Chromatography
- <731> Loss on Drying
- <736> Mass Spectrometry
- <761> Nuclear Magnetic Resonance
- <781> Optical Rotation
- <851> Spectrophotometry and Light-Scattering
- <941> Characterization of Crystalline and Partially Crystalline Solids By X-Ray Powder Diffraction (XRPD)
- <1119> Near-Infrared Spectrophotometry
- <1120> Raman Spectroscopy

Assay

- <11> USP Reference Standards
- <81> Antibiotics---Microbial Assays
- <351> Assay for Steroids
- <361> Barbiturate Assay
- <391> Epinephrine Assay
- <425> Iodometric Assay---Antibiotics
- <451> Nitrite Titration
- <511> Single-Steroid Assay
- <541> Titrimetry
- <621> Chromatography
- <736> Mass Spectrometry
- <801> Polarography
- <851> Spectrophotometry and Light-Scattering
- <1120> Raman Spectroscopy

Impurities

Organic

- <223> Dimethylaniline
- <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

- <467> Residual Solvents
- <621> Chromatography
- <731> Loss on Drying

Specific Tests

Physicochemical Characterization

- <301> Acid-Neutralizing Capacity
- <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> Refractive 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 (XRPD)
- <1119> Near-Infrared Spectrophotometry
- <1120> Raman Spectroscopy
- <1171> Phase-Solubility Analysis

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

Water Content

- <541> Titrimetry
- <731> Loss on Drying
- <891> Thermal Analysis
- <921> Water Determination