Chart 4. Noncomplex Active Drug Products

Universal Tests

Description
- <1121> Nomenclature

Identification
- <191> Identification Tests---General
- <197> Spectrophotometric Identification Tests
- <201> Thin-Layer Chromatographic Identification Test
- <501> Salts of Organic Nitrogenous Bases
- <621> Chromatography
- <736> Mass Spectrometry
- <851> Spectrophotometry and Light-Scattering

Assay
- <81> Antibiotics---Microbial Assays
- <341> Antimicrobial Agents---Content
- <351> Assay for Steroids
- <361> Barbiturate Assay
- <391> Epinephrine Assay
- <415> Medical Gases Assay
- <451> Nitrite Titration
- <501> Salts of Organic Nitrogenous Bases
- <541> Titrimetry
- <611> Alcohol Determination
- <621> Chromatography
- <801> Polarography
- <851> Spectrophotometry and Light-Scattering
- <1065> Ion Chromatography

Impurities

Organic
- <413> Impurities Testing in Medical Gases
- <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
- <281> Residue on Ignition
- <232> Elemental Impurities---Limits
- <233> Elemental Impurities---Procedures
- <730> Plasma Spectrochemistry
- <733> Loss on Ignition

Residual Solvents
- <467> Residual Solvents
- <621> Chromatography

Specific Tests

Equipment
- <16> Automated Methods of Anaylsis
- <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

Performance Test

Mucosal

Ophthalmic
- <751> Metal Particles in Ophthalmic Ointments
- <771> Ophthalmic Ointments
- <785> Osmolality and Osmolarity
- <789> Particulate Matter in Ophthalmic Solutions
- <791> pH
- See *Microbiology (Chart 10)*

Otic

Nasal
- <601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers
- <791> pH

Urethral

Vaginal

Rectal

Parenteral
- <1> Injections
- <71> Sterility Tests
- <85> Bacterial Endotoxins Test
- <87> Biological Reactivity Tests, In Vitro
- <88> Biological Reactivity Tests, In Vivo
- <151> Pyrogen Test
- <381> Elastomeric Closures for Injections
- <729> Globule Size Distribution in Lipid Injectable Emulsions
- <788> Particulate Matter in Injections
- <791> pH
- <1113> Microbial Identification, Characterization, and Strain Typing
- <1788> Particulate Matter Determination in Parenteral and Ophthalmic Products

Topical
- <3> Topical and Transdermal Drug Products---Product Quality Tests
- <724> Drug Release
- <791> pH

Inhalational
- <601> Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers
- <791> pH
- <1601> Products for Nebulization---Characterization Tests

Oral
- <301> Acid-Neutralizing Capacity
- <701> Disintegration
- <711> Dissolution
- <724> Drug Release
- <905> Uniformity of Dosage Units
- <1005> Acoustic Emission
- <1087> Apparent Intrinsic Dissolution---Dissolution Testing Procedures for Rotating Disk and Stationary Disk
- <1088> In Vitro and In Vivo Evaluation of Dosage Forms
- <1090> Assessment of Drug Product Performance---Bioavailability, Bioequivalence, and Dissolution
- <1092> The Dissolution Procedure: Development and Validation
- <1216> Tablet Friability
- <1217> Tablet Breaking Force

Oropharyngeal