Test and Equipment List

cGMP Drug Development Support Services (CMC)

Focus on the things you can change and let go of the things you can’t.
USP/NF General Chapters

Microbiological Tests
- 〈51〉 Antimicrobial Effectiveness Testing
- 〈55〉 Biological Indicators-Resistance Performance Tests
- 〈61〉 Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests
- 〈62〉 Microbiological Examination of Non-Sterile Products: Tests For Specified Microorganisms
- 〈71〉 Sterility Tests

Biological Tests And Assays
- 〈81〉 Antibiotics-Microbial Assays
- 〈85〉 Bacterial Endotoxins Test
- 〈111〉 Design and Analysis of Biological Assays

Identification Tests
- 〈191〉 Identification Tests-General
- 〈197〉 Spectrophotometric Identification Tests
- 〈201〉 Thin-Layer Chromatographic Identification Test

Other Tests And Assays
- 〈467〉 Residual Solvents
- 〈541〉 Titrimetry

Physical Tests And Determinations
- 〈601〉 Aerosols, Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers
- 〈611〉 Alcohol Determination
- 〈621〉 Chromatography
- 〈631〉 Color and Achromicity
- 〈641〉 Completeness of Solution
- 〈701〉 Disintegration
- 〈711〉 Dissolution
- 〈726〉 Electrophoresis
- 〈731〉 Loss on Drying
- 〈733〉 Loss on Ignition
- 〈736〉 Mass Spectrometry
- 〈741〉 Melting Range or Temperature
- 〈781〉 Optical Rotation
- 〈785〉 Osmolality and Osmolarity
- 〈788〉 Particulate Matter in Injections
- 〈789〉 Particulate Matter in Ophthalmic Solutions
- 〈791〉 Ph
- 〈831〉 Refractive Index
- 〈841〉 Specific Gravity
- 〈851〉 Spectrophotometry And Light-Scattering
- 〈905〉 Uniformity of Dosage Units
- 〈911〉 Viscosity-Capillary Viscometer Methods
- 〈921〉 Water Determination
Appendix II
A. Infrared Spectrophotometry
B. Ultraviolet and Visible Absorption Spectrophotometry
G. Mass Spectrometry

Appendix III
Chromatographic Separation Techniques
A. Thin-layer Chromatography
B. Gas Chromatography
C. Size-exclusion Chromatography
D. Liquid Chromatography
F. Electrophoresis
J. Isoelectric Focusing

Appendix IV
A. Clarity of Solution
B. Colour of Solution

Appendix V
A. Determination of Melting Point
B. Determination of Freezing Point
C. Determination of Distillation Range
D. Determination of Boiling Point
E. Determination of Refractive Index
F. Determination of Optical Rotation and Specific Optical Rotation
G. Determination of Weight per Millilitre, Density, Relative Density and Apparent Density
H. Viscosity
L. Determination of pH Values
N. Osmolality
O. Conductivity

Appendix VII
Limit Tests

Appendix VIII
A. Non-aqueous Titration
B. Potentiometric Titrations
D. Complexometric Titrations
E. Potentiometric Determination of Ionic Concentration Using Ion-selective Electrode
F. Determination of Ethanol
G. Determination of Methanol and 2-Propanol
H. Determination of Nitrogen
K. Ethylene Glycol and Diethylene Glycol in Ethoxylated Substances
L. Residual Solvents
M. Residual Ethylene Oxide and Dioxan
BP General Chapters (Cont.)

Appendix IX

A. Determination of Sulfated Ash
B. Determination of Sulfur Dioxide
C. Determination of Water
D. Determination of Loss on Drying

Appendix X

A. Acetyl Value
B. Acid Value
C. Ester Value
D. Hydroxyl Value
E. Iodine Value
F. Peroxide Value
G. Saponification Value
H. Unsaponifiable matter
L. Oxidising Substances

Appendix XI

J. Ash
P. Dry Residue of Extracts
Q. Loss on Drying of Extracts

Appendix XII

A. Disintegration
   1. Disintegration Test for Tablets and Capsules
   2. Disintegration Test for Suppositories and Pessaries
B. Dissolution
   1. Dissolution Test for Tablets and Capsules (Dissolution Test for Solid Dosage Forms)
C. Consistency of Formulated Preparations
   1. Uniformity of Weight (Mass)
   2. Uniformity of Weight (Mass) of Delivered Doses from Multi-dose Containers
   3. Uniformity of Content
   4. Uniformity of Dosage Units
   5. Extractable Volume of Parenteral Preparations

Appendix XIII

A. Particulate Contamination: Sub-visible Particles
B. Particulate Contamination: Visible Particles

Appendix XVI

A. Test for Sterility
B. Microbiological Examination of Non-sterile Products
   1. Tests for Specified Micro-organisms
   2. Total Viable Aerobic Count
C. Efficacy of Antimicrobial Preservation
D. Microbiological Quality of Non-sterile Pharmaceutical Preparations and Substances for Pharmaceutical Use

Appendix XVII

G. Friability
H. Resistance to Crushing of Tablets
EP Methods of Analysis (Cont.)

Physical and physicochemical methods
2.2.1 Clarity and degree of opalescence of liquids
2.2.2 Degree of coloration of liquids
2.2.3 Potentiometric determination of pH
2.2.4 Reaction of solution, pH and indicator colour
2.2.5 Relative density
2.2.6 Refractive index
2.2.7 Optical rotation
2.2.8 Viscosity
2.2.9 Capillary viscometer method
2.2.10 Rotating viscometer method
2.2.11 Distillation range
2.2.12 Boiling point
2.2.13 Melting point: Capillary method
2.2.14 Drop point
2.2.15 Freezing point
2.2.16 Potentiometric titrations
2.2.17 Infrared spectrophotometry
2.2.18 Visible and ultraviolet spectrophotometry
2.2.19 Paper chromatography
2.2.20 Gas chromatography
2.2.21 Thin-layer chromatography
2.2.22 Liquid chromatography
2.2.23 Size-exclusion chromatography
2.2.24 Electrophoresis
2.2.25 Loss on drying
2.2.26 Conductivity
2.2.27 Mass spectrometry
2.2.28 Chromatographic separation techniques
2.2.29 Isoelectric focussing

Limit Tests
Assays
2.5.1 Acid value
2.5.2 Ester value
2.5.3 Hydroxyl value
2.5.4 Iodine value
2.5.5 Peroxide value
2.5.6 Saponification value
2.5.30 Oxidising substances
2.5.33 Total protein assay
**EP Methods of Analysis (Cont.)**

**Biological Tests**
- 2.6.1 Sterility
- 2.6.12 Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests
- 2.6.13 Microbiological Examination of Non-Sterile Products: Test for Specified Micro-Organisms
- 2.6.14 Bacterial endotoxins

**Biological Assays**
- 2.7.1 Immunochemical methods
- 2.7.2 Microbiological assay of antibiotics

**Pharmaceutical Technical Procedures**
- 2.9.1 Disintegration: tablets and capsules
- 2.9.3 Dissolution: solid oral dosage forms
- 2.9.5 Uniformity of mass
- 2.9.6 Uniformity of content
- 2.9.7 Friability of uncoated tablets
- 2.9.13 Particle size by microscopy (limit test)
- 2.9.17 Extractable volume of parenteral preparations
- 2.9.18 Aerodynamic assessment of fine particles
- 2.9.19 Particulate contamination: sub-visible particles
- 2.9.20 Particulate contamination: visible particles
- 2.9.27 Uniformity of mass of delivered doses from multidose containers
- 2.9.28 Test for deliverable mass or volume of liquid and semi-solid preparations

**Containers**
- 3.2.9 Closed container Integrity Test

**EU Batch Release and ICH Stability Testing and Storage**

We provide stability storage for all key ICH climatic zones. Our available conditions and storage solutions are suitable for long term, intermediate, accelerated, photo-stability, in-use and FUST stability trials.

Additionally we provide Accelerated Stability Assessment Programmes (ASAP) facilitating an accelerated aging process that provides faster and more accurate prediction for drug substance and drug product shelf-life.

**Active Pharmaceuticals**

**Biopharmaceuticals**
- Microbial tests
- Potency tests
- Tests for purity and impurities
- Identity tests
- Tests for quantity / content
- Physicochemical characterization
- Tests for appearance and description

**Small Molecule**
- Microbiology tests
- Potency tests
- Tests for purity and impurities
- Identity tests
- Tests for quality/content
- Physicochemical characterization
- Tests for appearance and description
EU Batch Release and ICH Stability Testing and Storage (Cont.)

IMP’s and Finished Product
Pharmaceuticals
Inhalation Products
   Nebulised Solutions
      - Microbiology
      - Chemistry
   Dry Powder Inhalers
      - Microbiology
      - Chemistry
      • Aerodynamic assessment of fine particles
      • Uniformity of dose
      • Number of deliveries per inhaler
   Metered Dose Inhalers
      - Microbiology
      - Chemistry
      • Aerodynamic assessment of fine particles
      • Uniformity of dose
      • Number of deliveries per inhaler

Topical Formulations
   Creams and Ointments
      - Microbiology
      - Chemistry
      • Viscosity
      • Uniformity of dosage units

Parenteral Products
   Lyophilised Vials
      - Microbiology
      • Sterility
      • Endotoxins
      - Chemistry
      • Uniformity of dosage units
      • Uniformity of content
      • Uniformity of mass
   Injectable Liquids
      - Microbiology
      • Sterility
      • Endotoxins
      - Chemistry
      • Particulate Contamination: sub visible particles
      • Uniformity of dosage units
      • Uniformity of content
EU Batch Release and ICH Stability Testing and Storage (Cont.)

Enteral Products

Oral Liquids
- Microbiology
- Chemistry
  - Uniformity of dosage units
  - Uniformity of content
  - Uniformity of mass
  - Dose and uniformity of dose of oral drops
  - Uniformity of mass of delivered doses from multidose containers

Capsules
- Microbiology
- Chemistry
  - Uniformity of dosage units
  - Uniformity of content
  - Uniformity of mass
  - Dissolution
  - Disintegration

Tablets
- Microbiology
- Chemistry
  - Uniformity of dosage units
  - Uniformity of content
  - Uniformity of mass
  - Dissolution
  - Disintegration

Biopharmaceuticals

Others
- Molecular Biology
- Immunoochemistry
- Microbiology
- Chemistry

Vaccines
- Immunoochemistry
- Microbiology
- Chemistry
  - pH
  - Adjuvant
  - Aluminium
  - Calcium
  - Free formaldehyde
  - Phenol
  - Water
  - Extractable Volume
Method Development and Validation

ICHQ2A(R)
- Quantitative analysis of the active ingredient in drug substance or drug product
- Limit tests for the control of impurities
  - Quantitative analysis for content of impurities
  - Identification tests
  - Fusion Analytical Method Validation™ for QbD alignment

Method development includes: the screening of method parameters, evaluation of stationary phase, evaluation of elution systems, optimisation for resolution and sensitivity and data reporting & development report compilation.

Method optimisation includes: the fine tuning of the method conditions for resolution and sensitivity which will be evidenced through the analytical assessment of thermal stressed solutions of the active and peroxide stressed solution of the active in the presence of any preservatives.

Method Validation includes: SST, specificity (including carry over), specificity (stability indicating - stressed samples), linearity, accuracy (range), precision – repeatability, precision intermediate precision, LOD/LOQ, robustness, solution stability, data reporting & validation report compilation and data checking, report proofing, & QA approval. Validation will meet with the requirements as detailed in ICH Q2 (R1).

Method qualification includes: SST, specificity, linearity, accuracy (Range), precision – repeatability, precision - intermediate precision, data reporting & validation report compilation and data checking, report proofing, & QA approval.
1. High Performance Liquid Chromatography

- 13 Waters Alliance 2690 separation modules
- 2 Waters Alliance 2695 separation modules
- 1 Waters Alliance 2695-2 separation modules
- 4 Waters Acquity UPLC chromatographic systems with TUV or PDA
- 3 Waters SQD MS detectors
- 1 Waters Acquity H class chromatographic systems
- 15 Waters 2487/2489 Ultra violet detection units
- 3 Waters Fluorescence detection unit
- 3 Waters M2414 Refractive Index detection unit
- 2 Waters ELSD HPLC detectors evaporative light scattering
- 1 Thermo Fisher Scientific CAD (Charged Aerosol Detection) HPLC detector
- Waters Empower® chromatography data acquisition software
- OMNISEC REVEAL advanced analytical GPC/SEC triple-detector for the characterization of synthetic and natural polymers and proteins inc, Light Scattering detector for the sensitive and accurate measurement of absolute molecular weight of synthetic and natural polymers and proteins

2. Gas Chromatography

- 2 Shimadzu GC2010 Gas Chromatograph
- 1 Shimadzu HTA200H Headspace Autosampler with 40 position tray
- Linked and controlled by Waters Empower® chromatography data acquisition software

3. Dissolution Testing

- 3 Distek 2100B six-vessel dissolution baths with USP/Ph Eur paddle and basket capability

4. General and Wet Chemistry Equipment

- Shimadzu 1800 spectrophotometer
- Perkin Elmer R spectrophotometer
- Andersen cascade impaction units with pre-separator for MDI and DPI capability
- Next Generation Pharmaceutical Impactor
- Single Stage Glass Impinger with MDI and DPI capability
- Cadar microstat micrometer
- Tablet/capsule Disintegration apparatus
- Suppository disintegration apparatus
- Optical Activity AA-10 polarimeter
- 1 Mettler Toledo DL38 Karl Fisher Moisture Meter
- 1 Mettler Toledo V30 Karl Fisher Moisture System
- 1 Mettler Toledo DL39 Karl Fisher Moisture Meter with Stromboli sample oven
- 1 Mettler C30 Karl Fisher Coulometric Titrator
- 1 Mettler T50 Titralab
- 1 Metrohm Coulometric meter
- Mettler Toledo Densitometer
- Schleuniger Tablet hardness unit
- Radiometer Titralab Automated Titrimeter
- Brookfield Viscometer
- Gonotec Osmat 030D Osmometer
- Tablet friability tester unit
- Royco HIAC sub visible particle counting unit
- Abbe Refractometer
- Carbolite Moffle Furnace
5. Microbiology Capability

- 1 Bacterial Endotoxin by gel clot with both kinetic chromogenic and turbidimetric methodology
- Cecil 2020 UV spectrophotometer
- Kinetic BET system with 21CFR 11 compliant software
- Flexible film sterility testing isolators with Clarus L VHP gaseous sterilisation
- Antibiotic assay by radial diffusion to both Ph.Eur. and USP methods using Trinity V3 including plate counting
- Image analysis system
- Microbiological Class II A Safety Cabinet
- LAL Workstation Cabinets
- Endotoxin and Sterility suites

6. Bio-Pharmaceutical

- Unicam UV4 spectrophotometer
- ELX Microplate Reader
- Novex I-Blot Blotting system
- Stuart Incubator SI119
- Gel Tank XCell Surelock
- Microplate Washer Biotek ELX405RS
- 1 BioRad Chemdoc MP
- 1 GE image scanner 3
- 1 IEF Gel Tank
- 1 Beckman Coulter CE
- Thermo mixers

Supporting Drug Development, Improving Patient Outcomes

As part of a leading global healthcare and diagnostics company, our people strive to provide quality control laboratory analysis which helps advance the realisation of precision medicine and a value healthcare system which improves patient outcomes.

We believe that it is our responsibility to provide our customers with high quality, regulatory compliant data. Customers gain access to our knowledge, experience and ability to help them simplify their studies which facilitates diagnostic solutions that can work to achieve both incremental and transformational progress towards improving patients’ lives.

We are successful because of our People. We are Progressive in our way of thinking. We believe in our Principles.

Together we are better