

Quality Laboratories



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1 Equipment List

General Chemistry

| <i>Equipment</i> | <i>Manufacturer</i> |
|---------------------------------------|---------------------|
| Analytical Balances 0.1 mg resolution | Mettler-Toledo |
| Micro-balance 0.001 mg resolution | Mettler-Toledo |
| Thermo-balances | Mettler-Toledo |
| Average mass Balances | Mettler-Toledo |
| Volumetric class A Glassware | Various |
| Volumetric titration | Various |
| Rotating Evaporator | Büchi |
| Thermostatic Bath 20-90°C | Julabo |
| Melting Point Apparatus | Electrothermal |
| Centrifuges | Hettich/Heraeus |

Electrochemistry

| <i>Equipment</i> | <i>Manufacturer</i> |
|--------------------------------------|---------------------|
| pH Meters | Metrohm |
| Conductimeter | Metrohm |
| Ion-Meter | Metrohm |
| Universal and Karl Fischer Titrators | Metrohm |
| Micro-Coulometer | Mettler-Toledo |

Thermal Treatment/Storage

| <i>Equipment</i> | <i>Manufacturer</i> |
|---------------------------|---------------------|
| Rotating Evaporator | Büchi |
| Thermostatic Bath 20-90°C | Julabo |
| Vacuum Oven 30-250°C | Salvis |
| Muffle Furnace 200-1150°C | Nabertherm |
| Dry Heater | Thermoblock |

Spectroscopy

| <i>Equipment</i> | <i>Manufacturer</i> |
|--------------------------|---------------------|
| UV/Vis Spectrophotometer | Perkin Elmer |
| FT/IR Spectrophotometer | Perkin Elmer |
| FT/NIR Spectrophotometer | Büchi |
| Automatic Photometer | Merck |

Chromatography

| <i>Equipment</i> | <i>Manufacturer</i> |
|---------------------------|---------------------|
| UV/Vis HPLC | Jasco/Dionex |
| UV/Vis HPLC, DAD equipped | Dionex |
| RI/HPLC | Jasco/Dionex |
| FD/HPLC | Jasco/Dionex |
| FID/GC (HS) | Agilent |
| UHPLC | Thermo Scientific |

Pharmaceutical Technology

| <i>Equipment</i> | <i>Manufacturer</i> |
|----------------------------------|---------------------|
| Tablet Hardness Tester | Erweka |
| Tablets Friabilometer | Erweka |
| Tablets Disintegrator | Sotax |
| Dissolution Tester | Pharmatest |
| 2 Stability Chamber 25°C / 60%RH | Alpex |
| Stability Chamber 30°C / 65%RH | Alpex |
| Stability Chamber 30°C / 75%RH | Alpex |
| Stability Chamber 40°C / 75%RH | Alpex |
| Stability Incubator 40°C / 75%RH | Heraeus |
| Stability Refrigerator 2-8°C | Liebherr |
| Stability Freezer < -18°C | Siemens |
| Sieving Equipment | Retsch |
| Sieving Equipment | Alpine |
| Tapped Volumeter | Erweka |
| Optical Microscope | Olympus |
| Powder Mixer | Erweka |

Quality Laboratories

| | |
|--|--------|
| Tabletting Machine single stamp | Ronchi |
| Tabletting Rotating Machine 18 stamps | Ronchi |
| 4 Laboratory Fluid Bed Strea 1 Granulators | Strea |

Microbiology

| <i>Equipment</i> | <i>Manufacturer</i> |
|------------------|----------------------------|
| Autoclaves | Fedegari |
| Incubators | Incucell/Thermaks/ Heraeus |
| Refrigerators | Liebherr/ ECP 200 Expert |
| Air Samplers | Mass 100 NT |

Metrology

| <i>Equipment</i> | <i>Manufacturer</i> |
|--|---------------------|
| Certified weights | Mettler-Toledo |
| Certified Gauges and Calipers | Mitutoyo |
| Certified Manometers/Vacuum Meters | Various |
| Certified Temperature and Humidity Recorders | Kaye |
| Certified rpm Meters | Jaquet |

2 Pharmaceutical Tests

Test Performed in Accordance to Pharmacopoeias
(EU, USP, JP, Ph. Helv., DAB, etc.)

| <i>Activity</i> | <i>Reference</i> |
|--|------------------|
| Complete analysis according to individual monographs | Pharmacopoeia |
| Identification tests | Pharmacopoeia |
| Purity tests | Pharmacopoeia |
| Assays | Pharmacopoeia |

Physical and Physicochemical Methods

| <i>Activity</i> | <i>Reference</i> |
|--|--|
| Boiling point | Pharmacopoeia |
| Clarity and degree of opalescence of liquids | Pharmacopoeia |
| Conductivity | Pharmacopoeia |
| Degree of coloration of liquids | Pharmacopoeia |
| Flavors Distillation and Identification | Pharmacopoeia |
| Gas chromatography GC | Pharmacopoeia or developed methods |
| Infrared absorption spectroscopy IR | Pharmacopoeia or developed methods |
| Ionic concentration | Pharmacopoeia or validated methods (ionic selective electrode) |
| Loss on Drying | Pharmacopoeia, gravimetric method |
| Melting point | Pharmacopoeia, capillary method |
| pH | Pharmacopoeia |
| Potentiometer titration | Pharmacopoeia, micrometric |
| Relative density | Pharmacopoeia, picnometer |
| Thin-layer chromatography TLC | Pharmacopoeia, TLC different methods |
| Total Organic Carbon | Pharmacopoeia, Oxidative |
| UV/VIS absorption spectroscopy | Pharmacopoeia, UV/VIS spectroscopy |
| Viscosity | Pharmacopoeia, Capillarity |

Identification

| <i>Activity</i> | <i>Reference</i> |
|---|------------------|
| Identification Reactions of Ions and Functional Groups | Pharmacopoeia |
| Identification of Fatty Oils by Thin-Layer Chromatography | Pharmacopoeia |
| Identification of Phenothiazines by Thin-Layer Chromatography | Pharmacopoeia |
| Odour | Pharmacopoeia |

Limit Tests

| <i>Activity</i> | <i>Reference</i> |
|--------------------------------------|------------------|
| Aluminum | Pharmacopoeia |
| Ammonium | Pharmacopoeia |
| Arsenic | Pharmacopoeia |
| Calcium | Pharmacopoeia |
| Chloride | Pharmacopoeia |
| Ethylene oxide and dioxan | Pharmacopoeia |
| Florides | Pharmacopoeia |
| Free formaldehyde | Pharmacopoeia |
| Heavy metals | Pharmacopoeia |
| Iron | Pharmacopoeia |
| Lead in sugars | Pharmacopoeia |
| Limit test on fatty oils | Pharmacopoeia |
| Magnesium | Pharmacopoeia |
| Magnesium and alkaline –earth metals | Pharmacopoeia |
| Nickel in polyols | Pharmacopoeia |
| Organic volatile impurities | Pharmacopoeia |
| Phosphates | Pharmacopoeia |
| Potassium | Pharmacopoeia |
| Residual solvents | Pharmacopoeia |
| Sulphated ash | Pharmacopoeia |
| Sulphates | Pharmacopoeia |
| Total ash | Pharmacopoeia |

Assay

| <i>Activity</i> | <i>Reference</i> |
|-------------------------------------|---|
| Acid value | Pharmacopoeia, titrimetric |
| Complexometric titration | Pharmacopoeia, titrimetric |
| Ester value | Pharmacopoeia, titrimetric |
| Hydroxyle value | Pharmacopoeia, method A or B, titrimetric |
| Iodine value | Pharmacopoeia, titrimetric |
| Nitrogen by sulfuric acid digestion | Pharmacopoeia, Kjeldhal |
| Peroxide value | Pharmacopoeia, method A or B, titrimetric |
| Saponification index | Pharmacopoeia, titrimetric |
| Total proteins | Pharmacopoeia, different methods |
| Unsaponifiable matter | Pharmacopoeia, titrimetric |
| Water , semi –micro determination | Pharmacopoeia, Karl-Fischer |

Pharmaceutical Technical Procedures

| <i>Activity</i> | <i>Reference</i> |
|---|--|
| Apparent volume | Pharmacopoeia, gravimetric |
| Disintegration | Pharmacopoeia, visual, n=6 |
| Dissolution test | Pharmacopoeia, n=6, paddle or basket apparatus |
| Extractable volume | Pharmacopoeia, volumetric |
| Friability of uncoated tablets | Pharmacopoeia, gravimetric |
| Resistance to crushing of tablets | Pharmacopoeia, gravimetric n=10 |
| Sieve test | Pharmacopoeia, gravimetric |
| Microscopic examination | Internal test , microscopy |
| Uniformity of content of single-dose preparations | Pharmacopoeia, different methods |
| Uniformity of mass of single-dose preparations | Pharmacopoeia, gravimetric n=20 |

Container and Container Closures

| <i>Activity</i> | <i>Reference</i> |
|--|----------------------------------|
| Materials used for the manufacture of containers | Pharmacopoeia, different methods |
| Containers | Pharmacopoeia, different methods |

Water

| <i>Activity</i> | <i>Reference</i> |
|-----------------|----------------------------------|
| City water | Pharmacopoeia, different methods |
| Purified water | Pharmacopoeia, different methods |
| TOC | Pharmacopoeia |

Stability Testing

| <i>Activity</i> | <i>Reference</i> |
|--|----------------------------------|
| Materials used for the manufacture of containers | Pharmacopoeia, different methods |
| Containers | Pharmacopoeia, different methods |

Stability Testing

| <i>Activity</i> | <i>Reference</i> |
|--|--|
| Long-term study | ICH – Guideline 25±2°C; 60±5%RH 30±2°C; 75±5%RH (Tropical conditions) 3-8 °C (Refrigerator) -18°C (Freezer) |
| Accelerated condition (Different condition, on request) | ICH – Guideline 30±2°C; 65±5%RH 40±2°C; 75±5%RH |
| Documentation | Temperature and Humidity monitoring, provision of sample collection dead lines (Price per year) |
| Sample collection (Not applicable if analysis are performed in house) | Sample tracking and shipping |

| | |
|--|-------------------|
| Complete stability study included storage and analytical determination | Different methods |
|--|-------------------|

3 Spectroscopy & Spectrometry

Spectroscopy and Spectrometry

| <i>Activity</i> | <i>Reference</i> |
|--|--------------------------------|
| Infrared Absorption Spectroscopy IR 4000-400 cm ⁻¹ | Pharmacopoeia, FTIR spectrum |
| Infrared Absorption Spectroscopy IR Interpretation included | Pharmacopoeia, FTIR spectrum |
| Ultraviolet / Visible Spectroscopy UV/VIS Profile 800-180 nm | Pharmacopoeia, UV/VIS spectrum |
| Ultraviolet / Visible Spectroscopy Interpretation included | Pharmacopoeia, UV/VIS spectrum |

Elementar Analysis

| <i>Activity</i> | <i>Reference</i> |
|--|--------------------|
| Aluminum | AAS |
| Lead in Sugars | Pharmacopoeia, AAS |
| Nickel in Polyols | Pharmacopoeia, AAS |
| Determination of Metals and Half-Metals according to request | Different Methods |

4 Chromatography

Thin Layer Chromatography TLC

| <i>Activity</i> | <i>Reference</i> |
|--|---|
| TLC Quantitative, Semiquantitative, Qualitative determination- Photodocumentation on request | Pharmacopoeia, TLC, different detection methods. |

Gas Chromatography GC

| <i>Activity</i> | <i>Reference</i> |
|-------------------------------------|--|
| Assay | Pharmacopoeia and/or internally developed Methods |
| Identification tests | Pharmacopoeia and/or internally developed Methods |
| Related substances | Pharmacopoeia and/or internally developed Methods |
| Degradation products | Pharmacopoeia and/or internally developed Methods |
| Organic volatile impurities (OVI) | Pharmacopoeia |
| Residual solvents | Pharmacopoeia |
| Residual Ethylene oxide and Dioxane | Pharmacopoeia |

High Pressure Liquid Chromatography HPLC

| <i>Activity</i> | <i>Reference</i> |
|----------------------|---|
| Assay | Pharmacopoeia and/or internally developed Methods |
| Identification tests | Pharmacopoeia and/or internally developed Methods |
| Related substances | Pharmacopoeia and/or internally developed Methods |
| Degradation products | Pharmacopoeia and/or internally developed Methods |

Ultra High Performance Liquid Chromatography UHPLC

| <i>Activity</i> | <i>Reference</i> |
|----------------------|---|
| Assay | Pharmacopoeia and/or internally developed Methods |
| Identification tests | Pharmacopoeia and/or internally developed Methods |
| Related substances | Pharmacopoeia and/or internally developed Methods |
| Degradation products | Pharmacopoeia and/or internally developed Methods |

Ion Chromatography IC

| <i>Activity</i> | <i>Reference</i> |
|----------------------|---|
| Assay | Pharmacopoeia and/or internally developed Methods |
| Identification tests | Pharmacopoeia and/or internally developed Methods |

**Total Organic Carbon
TOC**

| <i>Activity</i> | <i>Reference</i> |
|-----------------|---|
| Assay | Pharmacopoeia and/or internally developed Methods |

Vitamins in Pharmaceutical/Nutritional Dosage Forms

| <i>Activity</i> | <i>Reference</i> |
|------------------------|--|
| β-Carotene | Internally developed HPLC Method |
| A Retinol | Internally developed HPLC Method |
| B1 Thiamine | Internally developed HPLC Method |
| B2 Riboflavine | Internally developed HPLC Method |
| B5 Panthotenic acid | Internally developed HPLC Method |
| B6 Pyridoxine | Internally developed HPLC Method |
| B12 Cyanocobalamine | Internally developed AAS or Microbiological Method |
| C Acorbic acid | Internally developed HPLC Method |
| D2 Ergocalciferol | Internally developed HPLC Method |
| D3 Cholecalciferol | Internally developed HPLC Method |
| E α-Tocopherol | Internally developed HPLC Method |
| Folic Acid | Internally developed HPLC Method |
| H Biotine | Internally developed HPLC Method |
| K1 Phyllochinone | Internally developed HPLC Method |
| PP Niacin, Niacinamide | Internally developed HPLC Method |

Minerals in Pharmaceutical/Nutritional Dosage Forms

| <i>Activity</i> | <i>Reference</i> |
|-----------------|--|
| Calcium | Internally developed AAS Method |
| Phosphorus | Internally developed AAS Method |
| Magnesium | Internally developed AAS Method |
| Potassium | Internally developed AAS Method |
| Chloride | Internally developed Potentiometric Method |
| Zinc | Internally developed AAS Method |
| Iron | Internally developed AAS Method |
| Manganese | Internally developed AAS Method |
| Copper | Internally developed AAS Method |
| Iodine | Internally developed HPLC Method |
| Chromium | Internally developed AAS Method |
| Selenium | Internally developed AAS Method |
| Molybdenum | Internally developed AAS Method |

5 Microbiology

Dosage forms
Analysis of Micro-Organisms
Single analysis

| <i>Activity</i> | <i>Reference</i> |
|--------------------------------------|---|
| Total Aerobic Microbial Count (TAMC) | Pharmacopoeia, Plate count method |
| Total Aerobic Microbial Count (TAMC) | Pharmacopoeia, Filtration method |
| Total Yeast and Mould Count (TYMC) | Pharmacopoeia, Plate count method |
| Total Yeast and Mould Count (TYMC) | Pharmacopoeia, Filtration method |
| Bile Tolerant Gram Negative Bacteria | Pharmacopoeia, qualitative determination |
| Bile Tolerant Gram Negative Bacteria | Pharmacopoeia, quantitative determination |
| Escherichia coli | Pharmacopoeia, detection |
| Pseudomonas aeruginosa | Pharmacopoeia, detection |
| Salmonella | Pharmacopoeia, detection |
| Staphylococcus aureus | Pharmacopoeia, detection |

Purified water ,
Microbiological tests

| <i>Activity</i> | <i>Reference</i> |
|-------------------------------------|---|
| Total viable aerobic count | Pharmacopoeia, membrane filtration |
| Absence of Pseudomonas Aeruginosa | Internal method |
| Absence of total Coliforms | Internal method |
| Absence of fecal Enterococci | Internal method |
| Differentiation of suspect colonies | Biochemical tests, Gram stain, Catalase and Oxidase, API tests. |

Other Microbiological Determinations

| <i>Activity</i> | <i>Reference</i> |
|---|---|
| Air monitoring | Air dynamic sampling |
| Air Monitoring | Open Plate |
| Surface monitoring | Contact plate and Swab method |
| Differentiation and identification of micro-organisms | Biochemical tests, Gram tests, Catalase and Oxidase, tests API. |

Microbial Determination on Dosage Forms According to EP/USP

| <i>Activity</i> | <i>Reference</i> |
|--|---|
| Non-aqueous preparation for oral use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Escherichia coli |
| Aqueous preparation for oral use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Escherichia coli |
| Rectal use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) |
| Oromucosal use/Gingival use/ Cutaneous use/Nasal use/Auricular use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Staphylococcus aureus Pseudomonas aeruginosa |
| Vaginal use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Staphylococcus aureus Pseudomonas aeruginosa Candida albicans |
| Transdermal patches (limit for one patch including adhesive layer and backing) | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Staphylococcus aureus Pseudomonas aeruginosa |
| Inhalation use (special requirements apply to liquid preparation for nebulization) | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Staphylococcus aureus Pseudomonas aeruginosa Bile tolerant Gram negative bacteria |

| <i>Activity</i> | <i>Reference</i> |
|---|---|
| Special Ph. Provision for oral dosage forms containing raw material of natural origin for which antimicrobial pretreatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10 ³ CFU/g or CFU/ml | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Staphylococcus aureus Escherichia coli Salmonella Bile tolerant Gram negative bacteria |
| Special Ph. Provision for premixes for medicated feeding stuffs for veterinary use using excipients of plant origin for which antimicrobial treatment is not feasible. | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) Escherichia coli Salmonella Bile tolerant Gram negative bacteria |

Microbial Determination on Raw Material According to EP/USP

| <i>Activity</i> | <i>Reference</i> |
|-----------------------------------|--|
| Substances for pharmaceutical use | Total Aerobic Microbial Count (TAMC) Total Yeasts and Moulds Count (TYMC) |

Validation of Microbiological Methods

| <i>Activity</i> | <i>Reference</i> |
|---------------------------------------|------------------|
| Validation of methods | Pharmacopoeia |
| Development and validation of methods | Pharmacopoeia |

Efficacy of Antimicrobial Preservation According to EU (Challenge test)

| <i>Activity</i> | <i>Micro-organisms</i> | <i>Reference</i> |
|--|--|--|
| Parenteral preparations, eye preparations, intrauterine preparations and intramammary preparations | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria: 6h, 24h, 28 days Fungi: 7days, 28 days. |
| Ear preparations, nasal preparations, preparations for cutaneous application and preparations for inhalation | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria: 2days,7 days, 28 days Fungi: 14days, 28 days. |
| Oral preparations, oromucosal preparations and rectal preparations | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 (E. coli ATCC 8739 recommended for all oral preparation and Z.rouxii NCYC 381 for oral preparation containing a high concentration of sugar) | Bacteria: 14 days, 28days Fungi: 14days, 28 days. |

Efficacy of Antimicrobial Preservation According to USP

| <i>Activity</i> | <i>Microorganisms</i> | <i>Reference</i> |
|--|--|---|
| Category 1 Injections, other parenterals including emulsion, otic product, sterile nasal products and ophthalmic products made with aqueous bases or vehicle | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria: 7days, 14days, 28days Yeasts & moulds: 7days, 14 days and 28 days. |
| Category 2 Typically used products made with aqueous bases or vehicle; non sterile nasal products and emulsions, including those applied to mucous membranes. | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria: 14 days, 28 days Yeasts & moulds: 14 days and 28 days |
| Category 3 Oral products other than antacids, made with aqueous bases or vehicle | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria: 14 days, 28 days Yeasts & moulds: 14 days and 28 days. |
| Category 4 Antacids made with an aqueous base | A. brasiliensis ATCC 16404 C. albicans ATCC 10231 P. aeruginosa ATCC 9027 S. aureus ATCC 6538 | Bacteria, yeast and molds 14 days, 28 days |

Air Monitoring

| <i>Equipment</i> |
|------------------|
| Viablen count |
| Non-viable Count |

6 Metrology

Calibration

| <i>Activity</i> | <i>Reference</i> |
|--|----------------------|
| PT 100 From -20°C up to +140°C | Different references |
| Thermocouple up to 1200°C | Different references |
| % RH probes From 0% up to 100% | Different references |
| Manometers From -1bar up to +10 bars | Different references |
| Hydrocarbons | Different references |
| Balances and Scales From 200 mg, up to 1500 Kg | Different references |
| Measurement and generation of electrical signal 4-20 milliamp 0-10 Volts | Different references |

Mapping

| <i>Activity</i> | <i>Reference</i> |
|-------------------|----------------------|
| Temperature | Different references |
| Relative Humidity | Different references |

Qualification of systems

| <i>Activity</i> | <i>Reference</i> |
|---------------------------|----------------------|
| HVAC | Different references |
| Incubators | Different references |
| Pressurized lines for gas | Different references |
| Autoclaves | Different references |

7 Acronyms

| | |
|-------|--|
| AAS | Atomic Adsorption Spectrometry |
| ATCC | Private nonprofit organization in the life sciences field whose mission focuses on the acquisition, authentication, production, preservation, development and distribution of standard reference microorganisms, cell lines and other materials for research and development |
| BP | British Pharmacopoeia |
| CFU | Colony-Forming Unit |
| DAB | German Pharmacopoeia |
| DAD | Photometric Detection with Diode Array |
| DIN | German Standard Institut |
| ECD | Electron Capture Detector |
| EP | European Pharmacopoeia |
| FD | Fluorescence Detector |
| FID | Flame Ionization Detector |
| GC | Gas Chromatography |
| HPLC | High-Pressure Liquid Chromatography |
| HS | Head Space |
| IC | Ion Chromatography |
| ICH | International Conference Harmonization |
| IR | Infrared Absorption |
| JP | Japan Pharmacopoeia |
| KF | Karl-Fisher |
| NIR | Near Infra Red absorption |
| RI | Refractive Index Detector |
| RH | Relative Humidity |
| SLMB | Swiss Food Manual |
| TLC | Thin-Layer Chromatography |
| TOC | Total Organic Carbon |
| UHPLC | Ultra High Performance Liquid Chromatography |
| USP | United State Pharmacopoeia |
| UV | Ultra Violet spectroscopy |
| VIS | Visible spectroscopy |