



Microbiological Testing

Bioburden & Microbial Enumeration Testing

- Bioburden testing, recovery & validation
- Non-sterile product quality control testing
 - Absence of specified organisms & pathogens
 - TAMC & TYMC
 - Microbial limits testing
 - Water testing (potable, WFI, purified)
- Growth promotion testing of media

Endotoxin & Pyrogen Testing

- Bacterial endotoxin testing (BET) – Limulus Amebocyte Lysate (LAL)
 - Kinetic turbidimetric
 - Kinetic chromogenic
 - Gel-clot method
- Recombinant testing
- Monocyte activation testing (MAT)

Other Microbiology Testing Services

- Antimicrobial & preservative efficacy testing
- Disinfectant efficacy testing
- Microbial identification
 - MALDI-ToF, MicroSEQ & VITEK
- Antibiotic microbial assay
- Biological indicator enumeration
- Reprocessing validation
- Method validation & batch release testing
- R&D support
- Bespoke & client specific testing protocols

Sterility Testing

- Sterility testing (including Millipore Steritest™)
- Rapid sterility testing
 - Celsis Bioluminescence
 - Celsis Advance for nonfilterable therapies
 - Celsis Adapt for cellular therapies
 - Scan RDI Chemiluminescence
- Particulate testing
- Container closure integrity testing (CCIT)
- Media fill incubation and analysis

Environmental Monitoring

- Cleanroom environmental monitoring support
 - EMPQ (performance qualification) & risk assessment
 - Sampling, incubation & enumeration
 - Reporting and trending
 - Culture preservation
- Cleaning validation support
- Total organic carbon (TOC) analysis

Regulatory Standards Including

- **USP:** <51>, <60>, <61>, <62>, <63>, <71>, <85>, <87>, <643>, <645>, <788>, <789>, <1072>, <1116>, <1911>
- **Ph. Eur.:** 2.2.44, 2.6.1, 2.6.12, 2.6.13, 2.6.14, 5.1.3, 5.1.6, 5.1.11
- **ISO:** 10993, 11137, 11737,
- **ICH / GMP:** ICH Q7, EU GMP Annex 15

Physical & Packaging Testing

Device Verification, Functional & Physical Testing

Injection & Delivery System Testing

- Prefilled syringe testing
- Needle-based injection system testing
- Break loose & glide force testing
- Needle cap removal force testing
- Injection force testing
- Dose accuracy testing

Device Performance & Functional Testing

- Catheter performance testing
- Infusion set testing
- Wound dressing performance testing
- Small-bore connector testing

Regulatory Standards including

- **USP:** <1207>
- **EN:** 12439, 13726, 13868
- **BS:** 6196

Packaging & Distribution Testing

Transit Simulation & Distribution Testing

- Pre-conditioning
- Drop & compression testing
- Random & sinusoidal vibration testing
- Concentrated impact testing
- High altitude (vacuum) testing

Packaging Integrity Testing

- Container closure integrity testing (CCIT)
- Dye penetration testing
- Contaminant migration studies
- Seal testing (peel strength & burst)

Ageing & stability testing

- Accelerated ageing
- Real-time ageing

- **ISO:** 10555, 11040, 11070, 11607, 11608, 20695, 20696, 20698, 23907, 80369, 8871, 8536, 7864
- **ASTM:** D4169, D4332, D4728, D5276, D6344, D642, D6653/D6653M, D7386, D999, F88, F1140, F1886, F1929, F1980, F2054, F2096, F2338
- **ISTA:** 2A, 3A



GMP Validated Analytical Equipment

Gas Chromatography (GC)

- PerkinElmer GC-FID
- Thermo Trace 1310 GC-FID
- Thermo TSQ EVO GC-MS/MS
- Thermo ISQ GC-MS
- Direct Injection, headspace & SPME
- SPME-GC-QQQ

Elemental & Other Analysis

- Agilent 7900 ICP-MS
- Thermo iCAP 6500 Duo ICP-OES
- Jasco FTIR 4600 CFR
- Netzsch Kinexus Ultra+ Rheometer
- PerkinElmer Lambda 365 UV/Vis
- Metrohm 852 Combined Karl Fischer with Oven
- Metrohm 904 Titrando
- SEM-EDX

Nanoparticle Sizing

- Zetasizer Ultra Red
- Nanosight NS300

Particle Size & Shape Analysis

- Malvern Mastersizer 3000
- Morphologi4-ID
- Sympatec HELOS / RODOS BR
- Microtrac S3500 with ASVR & USVR
- Malvern Spraytec
- Optical Microscopy

Solid State Analysis

- Bruker D8 & Empyrean S3 XRPD
- APSS Light Obscuration for Sub-visible Particles
- Micromeritics TriStar 3020 BET SSA
- Perkin Elmer DSC 4000 & TGA 8000
- SMS Discovery Aqua DVS
- Scanning Electron Microscopy

HPLC Systems

- Agilent 1260 HPLC
- Thermo Ultimate 3000 uHPLC
- Thermo Vanquish uHPLC
- Thermo Altis & Fortis TSQ LC-MS/MS
- Thermo ISQ LC-MS
- uHPLC-QTOF/ DAD

Detectors

- UV / DAD / PDA
- Refractive Index (RID)
- Charged Aerosol (CAD)
- Fluorescence (FLD)
- Electrochemical (ECD)

Additional Techniques

- Metrohm 940 Pro IC
 - CD, PAD, Cyanide, Sugars
- Dissolution Testing:
 - USP Apparatus I, II, IV

Our Analytical Testing Services

GXP Fundamentals

- Method development, validation and transfer
- QC release testing
- ICH, GMP, GLP and R&D storage stability
- physico-chemical properties
- Product safety registration

Physical / Materials Characterisation

- Particle size, shape, composition & association
- Generics support and IVBE
- X-ray diffraction
- Specialist solid state analysis
- Subvisible and visible particulate matter testing
- Nanoparticle analysis

Chemical Characterisation

- Extractables & leachables (E&L)
- Organic impurities
- Elemental impurities
- Residual solvents
- Volatile organic compounds (VOC & VOS)
- Nitrosamine analysis
- Carbonyls analysis

Manufacturing & Commercialisation

- Cleaning validation & verification
- Occupational hygiene
- Contaminants & foreign bodies
- Contaminant migration studies

Consultancy

- Biological evaluation plans & reports
 - BEP & BER
- Clinical evaluation plans & reports
 - CEP & CER
- Submission support
 - US FDA
 - UK & EU MDR
- Toxicological risk analysis
- Biological gap analysis
- PSUR (Periodic safety update report)
- Post market surveillance

ISO 10993 & 18562 Biocompatibility Testing

- Extractables & Leachables
 - Organic & elemental impurities
- Leachables in condensate
- Particulate Emission
- Volatile Organic Substances (VOC & Carbonyls)
- Cytotoxicity
- Irritation
- Sensitisation
- Material mediated pyrogenicity
- Acute Systemic Toxicity
- Subacute, Subchronic & Chronic toxicity
- Genotoxicity
- Carcinogenicity
- Hemocompatibility
- Implantation
- Reproductive / developmental toxicity
- Degradation studies

