ENVIRONMENTAL LABORATORY
SINCE 1990

MICROBIOLOGICAL &
CHEMICAL ANALYSIS

ANALYTICAL TESTING SERVICES

Specialist Analytical Testing

Trace-level, regulatory-driven methods for pharmaceutical quality, product safety and environmental analysis — delivered with Nexalab Research Center.

01 Nitrosamine & NDSRI
02 Method Development
03 Extractables & Leachables
04 PFAS Analysis
05 Pesticide Residues
06 Heavy Metals & Elemental
07 Diffusion Studies (IVRT)
08 Dissolution Profile Testing
09 Microbiology Testing
10 Cytotoxicity (MTT)

ISO/IEC 17025 · PJLA & JAS ACCREDITED · GLP-SUPPORTED

NEXALAB

WHO WE ARE

Credible testing, clear reports.

For more than three decades, Environmental Laboratory has delivered chemical and microbiological analysis that pharmaceutical and industrial customers can act on. Together with Nexalab Research Center, we match the right method, technology and report format to your product stage, market and regulatory need.

1990	80+	17025	GLP
Established & operating since	Validations submitted to authorities	ISO/IEC · PJLA & JAS accredited	Supported study delivery

TEN SPECIALIST FOCUS AREAS

01 Nitrosamine & NDSRI

02 Method Development

03 Extractables & Leachables

04 PFAS Analysis

05 Pesticide Residues

06 Heavy Metals & Elemental

07 Diffusion Studies (IVRT)

08 Dissolution Profile Testing

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TECHNOLOGY PLATFORM

LC-MS/MS · HPLC · PDA/FLD/RID · GC-MS/MS · ICP-MS · Atomic Absorption · Ion Chromatography · FT-IR · Dissolution · PCR · ELISA

01

GENOTOXIC IMPURITIES

Nitrosamine & NDSRI Analysis

Trace-level quantification of nitrosamine impurities and N-nitroso drug-substance-related impurities (NDSRIs), backed by more than 80 method validations submitted to regulatory authorities.



WHAT WE ANALYZE

- NDMA, NDEA, NMBA, NDIPA, NEIPA & NDBA
- Drug-substance-specific NDSRIs
- APIs, finished products & high-risk matrices

REGULATORY DRIVERS

- EMA Art. 5(3) referral & Q&A
- US FDA nitrosamine guidance
- ICH M7(R2) — acceptable-intake assessment

TECHNIQUES & INSTRUMENTS

- LC-MS/MS & GC-MS/MS
- High-resolution accurate-mass MS
- Compound-specific sample preparation

WHAT YOU RECEIVE

- Validated, submission-ready methods
- Acceptable-intake (AI) limit assessment
- Regulatory-response documentation

02

FIT-FOR-PURPOSE METHODS

Method Development & Validation

Stability-indicating, fit-for-purpose analytical methods developed, optimised and validated to ICH Q2(R2) — from early formulation decisions through routine release and method transfer.



WHAT WE ANALYZE

- Assay & related substances
- Residual solvents & impurities
- Dissolution & content uniformity

REGULATORY DRIVERS

- ICH Q2(R2) validation characteristics
- ICH Q14 procedure development
- USP general chapters & pharmacopoeial methods

TECHNIQUES & INSTRUMENTS

- HPLC — PDA, FLD & RID detection
- LC-MS/MS, GC & ion chromatography
- ICP-MS & atomic absorption (AAS)
- Forced-degradation / stability-indicating

WHAT YOU RECEIVE

- Validation protocol & report
- Specificity, linearity, accuracy, precision, LOD/LOQ, robustness
- Method transfer & verification support

CONTAINER, PACKAGING & DEVICES

Extractables & Leachables

Risk-based extractables and leachables (E&L) programmes for container-closure systems, packaging, single-use systems and medical devices — from controlled extraction studies to targeted leachables on stability.



WHAT WE ANALYZE

- Parenteral, ophthalmic & inhalation products
- Elastomers, films, plastics & adhesives
- Single-use & process-contact materials

REGULATORY DRIVERS

- USP <1663> / <1664>
- ICH Q3E framework (emerging)
- ISO 10993 for device materials

TECHNIQUES & INSTRUMENTS

- GC-MS & headspace GC
- LC-MS/MS with HRMS screening
- ICP-MS for elemental leachables

WHAT YOU RECEIVE

- Controlled extraction study design
- AET-based screening & identification
- Targeted leachables on stability

PER- & POLYFLUOROALKYL SUBSTANCES

PFAS Analysis

Trace PFAS quantification across water, food-contact materials and environmental matrices using isotope-dilution LC-MS/MS against targeted analyte panels.



WHAT WE ANALYZE

- Drinking, ground & waste water
- Food-contact & packaging materials
- Soil, sludge & environmental samples

REGULATORY DRIVERS

- US EPA 533 & 537.1
- US EPA 1633 (multi-matrix)
- EU Drinking Water Directive 2020/2184

TECHNIQUES & INSTRUMENTS

- LC-MS/MS with isotope dilution
- SPE & matrix-specific extraction
- Targeted PFAS analyte panels

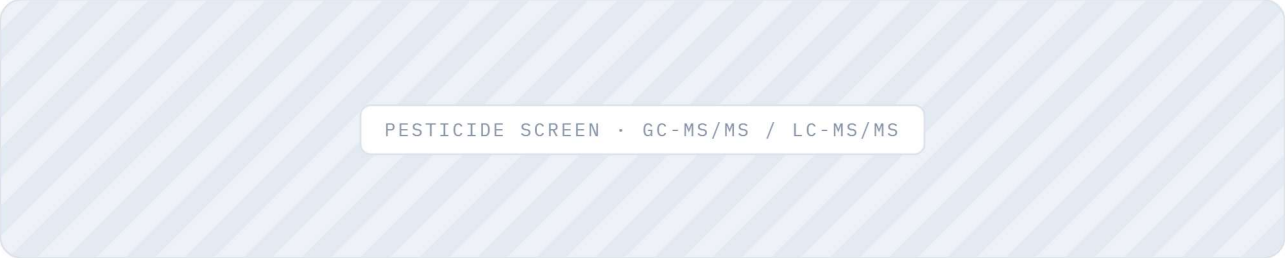
WHAT YOU RECEIVE

- Quantitative residue reports
- Method & matrix suitability assessment
- Scope expansion in progress — confirm current accreditation

MULTI-RESIDUE SCREENING

Pesticide Residues

Wide-scope, multi-residue pesticide screening for botanical raw materials, herbal medicines, dietary supplements and water, using QuEChERS extraction with tandem mass spectrometry.



WHAT WE ANALYZE

- Herbal & botanical raw materials
- Dietary supplements & nutraceuticals
- Water & agricultural samples

REGULATORY DRIVERS

- USP <561> / <565> botanicals
- EU maximum residue levels (MRLs)
- Codex Alimentarius limits

TECHNIQUES & INSTRUMENTS

- GC-MS/MS & LC-MS/MS
- QuEChERS sample preparation
- Wide-scope multi-residue panels

WHAT YOU RECEIVE

- Multi-residue quantitative reports
- MRL compliance assessment
- Raw-material & supplier qualification

06

ELEMENTAL IMPURITIES

Heavy Metals & Elemental Analysis

Elemental impurity and heavy-metal determination for pharmaceuticals, raw materials, water and environmental samples — to ICH Q3D and USP <232>/<233>.



WHAT WE ANALYZE

- APIs, excipients & finished products
- Drinking & environmental water
- Raw materials & contaminant checks

REGULATORY DRIVERS

- ICH Q3D elemental impurities
- USP <232> / <233> & <2232>
- EPA elemental methods (environmental)

TECHNIQUES & INSTRUMENTS

- ICP-MS
- Atomic absorption spectroscopy (AAS)
- Dedicated mercury analysis

WHAT YOU RECEIVE

- PDE-based risk assessment
- Validated quantitative methods
- Routine release & monitoring

IN VITRO RELEASE TESTING

Diffusion Studies (IVRT)

Franz-cell diffusion testing for topical, semisolid and transdermal products — in vitro release testing (IVRT) to support formulation development, scale-up and post-approval changes.

FRANZ DIFFUSION CELL · IVRT

WHAT WE ANALYZE

- Creams, gels & ointments
- Transdermal & topical patches
- Semisolid & dermatological formulations

REGULATORY DRIVERS

- US FDA SUPAC-SS
- USP <1724> semisolid performance tests
- FDA IVRT bioequivalence guidance

TECHNIQUES & INSTRUMENTS

- Vertical Franz diffusion cells
- Automated diffusion / sampling systems
- HPLC & LC-MS quantification

WHAT YOU RECEIVE

- Release-rate (slope) profiles
- Statistical (90% CI) comparison
- Formulation & post-approval change support

DRUG RELEASE PERFORMANCE

Dissolution Profile Testing

Single-point and full-profile dissolution with f1/f2 similarity comparison across formulations, batches, media and conditions — for development, release and post-approval change support.

WHAT WE ANALYZE

- Immediate- & modified-release solid orals
- Profile comparison & bridging studies
- Multimedia & biorelevant conditions

REGULATORY DRIVERS

- USP <711> / <724> dissolution
- ICH Q6A specifications
- FDA dissolution & SUPAC guidance

TECHNIQUES & INSTRUMENTS

- USP apparatus I–IV
- Automated sampling & media handling
- HPLC & UV/Vis quantification

WHAT YOU RECEIVE

- Full dissolution profiles
- f1 / f2 similarity factors
- Method development & validation

MICROBIOLOGICAL QUALITY & SAFETY

Microbiology Testing

Compendial microbiological testing for product safety and batch release — microbial limits, sterility, bioburden, bacterial endotoxin and antimicrobial effectiveness.

WHAT WE ANALYZE

- Non-sterile microbial limits (TAMC / TYMC)
- Sterility, bioburden & objectionable organisms
- Water & environmental monitoring

REGULATORY DRIVERS

- USP <61> / <62> / <71>
- USP <85> bacterial endotoxin
- USP <51> antimicrobial effectiveness

TECHNIQUES & INSTRUMENTS

- Membrane filtration & plate count
- LAL endotoxin — gel-clot & kinetic
- Antimicrobial effectiveness testing

WHAT YOU RECEIVE

- Microbial enumeration & identification
- Sterility & endotoxin reports
- Preservative efficacy (AET) data

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IN VITRO BIOCOMPATIBILITY

Cytotoxicity Assay (MTT)

In vitro cytotoxicity and cell-viability testing to support biocompatibility and safety assessment of materials, extracts, leachates and devices.

CYTOTOXICITY · MTT CELL-VIABILITY ASSAY

WHAT WE ANALYZE

- Material, device & packaging extracts
- Leachate & extractable solutions
- Raw materials & process-contact materials

REGULATORY DRIVERS

- ISO 10993-5 cytotoxicity
- USP <87> biological reactivity, in vitro
- Confirm current assay scope

TECHNIQUES & INSTRUMENTS

- MTT colorimetric viability assay
- Cell-based reactivity testing
- Mammalian cell culture

WHAT YOU RECEIVE

- Cell viability (% / IC values)
- Biological-reactivity pass / fail
- Emerging service — confirm accreditation

GET STARTED

Start with your product question.

Tell us your product, market and timeline — we translate it into a practical testing plan, clear timelines and reports you can use.

01

Share your need

Product type, market, timeline and the decision you need to make.

02

Select the tests

We align method, technology, sample quantity and report format.

03

Receive results

Reports prepared for QC, QA, R&D, regulatory or customer discussions.

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