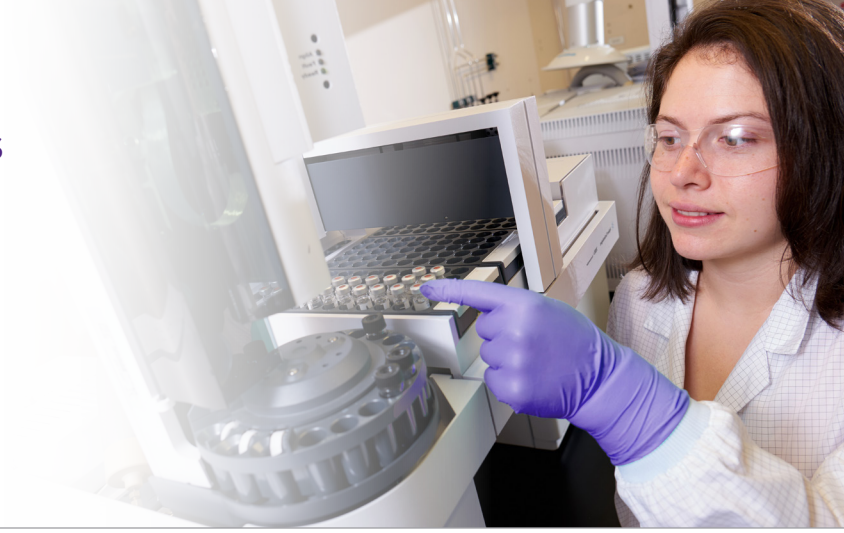
PPD® LABORATORIES
GMP LAB

Analytical Capabilities Athlone, Ireland



PPD Laboratories GMP Lab in Athlone, Ireland provides **comprehensive services for pharmaceutical and biopharmaceutical products**. **A leading provider** of CMC laboratory services, we focus on responding to our clients' needs with **high-quality testing** by the GMP analytical lab, qualified person (QP) release services, and an **unwavering commitment to pharmaceutical development.**

GMP analytical testing services

- Development and validation for drug substance, drug products, and devices
- Stability testing and storage
- Release and quality control (QC) testing
- Inhaled pharmaceuticals testing
- Oligonucleotide testing
- Physiochemical characterisation
- Extractables and leachables (E&L) analysis

Small molecule and specialty testing

- Commercial release and stability in the EU
- Tablets, capsules, lyophilised powders, pre-filled syringes (PFS), vials, solutions, stents, catheters, and devices
- Oligonucleotide analysis
- Assay, purity, content uniformity, impurities, and residual analysis

Biologics testing

- Commercial release and stability in the EU
- Solutions, lyophilized powders, PFS, preservative free nasal pumps (PFPs), and vials
- Antibodies, proteins, peptides, and antibody-drug conjugates (ADCs)
- Mass, identity, purity, activity, binding protein content, and impurities
- Bioassay lab

Industry-leading inhalation testing

- Commercial release and stability in the EU
- Device performance, aerosol, and particle characterisation
- Dry powder inhalers (DPI)
- Pressurised metered dose inhalers (pMDI)
- Nasal and nebuliser testing

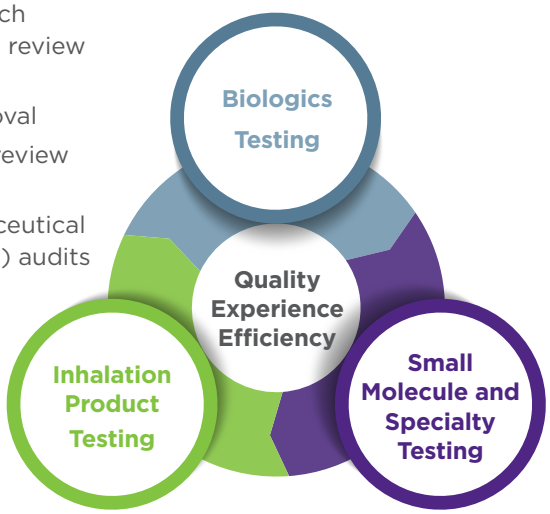
Dedicated quality assurance (QA) team

The independent QA staff in Athlone, Ireland conducts in-process system/facility audits and out-of-specification/ atypical data investigations. It also provides quality metrics, corrective and preventive action (CAPA) plans, document control, data archives, and training for both new and current employees.

QP services

for investigational medicinal products:

- Associated batch documentation review
- EU clinical trial products approval
- Partial testing review and release
- Active pharmaceutical ingredient (API) audits
- Vendor audits



Comprehensive Services for Pharmaceutical and Biopharmaceutical Products

Discipline/Methodology	Testing Services	Key Instrumentation/Platform
Inhalation testing	**Our service offering includes:** • Drug content assay • Dose content uniformity • Net content or fill weight • Microscopic evaluation • Foreign particulate matter • Particle size distribution • Impurities and degradation products • Moisture content • E&L testing	• Andersen and Next generation impactors • Multi-stage liquid impinger (MSLI) • Copley (CITDAS) software, TPK critical-flow controller • PPD-patented dose collection tubes for foreign particulate matter analysis • Humidity and temperature controlled testing rooms • Malvern Spraytec® droplet-size analyser • MDI FD-10 automated wasting station • Malvern Mastersizer 3000 solid particle size and distribution analysis • NGI chiller unit
Biologics testing	**Our service offering includes:** • Drug substances • Drug products • Identity • Purity, activity • Potency • Product/process related impurities • Safety Our cell-based assay capabilities include method transfer, validation, GMP release and stability testing, and statistical analysis (JMP, PLA). Methods include: • Cell proliferation and cytotoxicity assays • ADCC assays • Reporter gene assays	• HPLC (Waters and Agilent), UPLC, • ELSD/CAD/UV/FLR/RI • Beckman Coulter PA-800 Plus • ProteinSimple iCE™ 280 and iCE™ 3 • Coagulation analysers • SoloVPE • Molecular devices SpectraMax®, M5, Bio-Rad GS-800™ GS-900 • HACH turbidimeterMoisture analyser • Molecular devices SpectraMax® and M5
Small molecule and speciality testing	**Our service offering includes:** • Drug substances and drug products • Release, stability and validation • Identity and purity • Content uniformity • Microscopic evaluation • Foreign particulate matter • Particle size distribution • Moisture content • Impurities and degradation products • Genotoxic impurity anaysis • Trace metal and elemental impurity analysis • Residual solvents • E&L (vials, syringes, mouthpieces, foils, stoppers) • Oligonucleotide analysis • Oligonucleotide LC-MS impurity analysis	• HPLC (Waters and Agilent), UPLC, HClass • Wide range of detectors ELSD/CAD/UV/FLR/RI/PDA/UV • FTIR • Dissolution Ap I/II and Ap IV • HIAC • Volumetric and coulometric Karl Fischer • Malvern Zetasizer • Microscope • Disintegration • GC-FID/headspace • GC-MS • LC-MS • ICP-MS Mass spectrometry specific equipment detail • GC-MS Agilent (1 x 7890A, 5975C), (1 x7890B 5977A) • LC-MS Agilent (2 x G6130) • ICP-MS Agilent 7700

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