ROYALMOUNT
BIOPHARMA SERVICES

AN AFFILIATED DIVISION OF pharma science

Our Divisions

PHARMASCIENCE CANADA

Providing a broad range of high-quality generic medications to Canadians coast to coast.

PHARMASCIENCE INTERNATIONAL

Manufacturing and bringing a broad range of high-quality generic & branded medications to patients around the world.

PENDOPHARM DIVISION

Specialty pharmaceutical company that brings proven medicines to the marketplace, products healthcare professionals and patients rely on.

ROYALMOUNT
BIOPHARMA SERVICES

ROYALMOUNT CDMO

Drug Product fill, label and packaging CDMO and CMO services for a wide range of injectable products

ROYALMOUNT LABORATORIES

State of the art Bioanalytical testing laboratories.

pharma science

ROYALMOUNT
LABORATORIES

Bioanalytical Testing Services

Quality, Compliance & Reliability You Can Trust

Audited and Certified Laboratory **Since 1994**

QUALITY ASSURANCE PROGRAM

Study-based inspections (study plan, in-process, study data and report for every study and validation), performing regular facility-based and process-based inspections

COMPLIANCE BY INTERNATIONAL REGULATIONS

Strict adherence to Health Canada, ICH, EMA, and US FDA guidelines, ensuring the highest-quality procedures and results

STRINGENT QUALITY CONTROL

Quality Assurance / Compliance Internal Auditors functions as an independent Quality Assurance Unit for Biopharmaceutics and average over 15 years of experience

We adhere and operate under

GLP, GCP & GMP conditions

AND

best industry practices

ROYALMOUNT LABORATORIES

Bioanalytical Mass Spectrometry Lab

Top of the Line Equipment

- Revolutionary sensitivity, speed, and performance for your most challenging methods
- Fully IQ, OQ, PQ

More than
450,000
Samples per year

Up to
10
New assays developed per month

Over
300
validated methods

- Endogenous compounds and assays at low pg/mL levels
- Derivatizations

2 - Robots *(Hamilton Star)*

12 - LC/MS/MS systems with Shimadzu Prominence HPLCs:

8 - API 5000	2 - 6500 Qtraps
2 - 6500+	1 - ICP-MS

ROYALMOUNT
LABORATORIES

Large Molecule Bioanalysis

Lab Footprint
1500 sqft. of state-of-the-art laboratory BSL-2

Key Platforms

Watson LIMS
- Bioanalytical software

Hamilton Microlab STAR
- Robotic liquid handlers

ROYALMOUNT
LABORATORIES

Multidisciplinary team supporting a wide-array of services

Drug Pharmacokinetics/Toxicokinetic

- **Quantitative ligand-binding assays (LBA)**
  - Biotherapeutics and Biosimilars
    - Monoclonal antibodies, recombinant peptides, antibody
    - drug conjugates (ADC), bispecific antibodies, etc.
  - Oligo-therapeutic modalities (Gene Therapy)
    - Antisense oligonucleotides (ASO), free or encapsulated small interfering RNAs (siRNA) and microRNAs (miRNA).
- **Qualitative / Semi-Quantitative (LBA)**
    - Immunogenicity: anti-drug antibodies (ADA) and characterization (nAb, isotype, etc.)

Drug Pharmacodynamics (primary or exploratory endpoints)

- Inflammatory, cancer or metabolic biomarkers, etc.
- mRNA expression profiling by RT-qPCR

Unmatched Customer Focused Delivery Timelines

New program lead-in time: **10** days

Sample analysis lead-in time from day of sample receipt: **5** days

Method **transfer:** **10** days

Method **optimization:** **10** days

Method **development:** **15** days

Method **validation:** **15** days

QC'd data: **3** days after completion of lab work

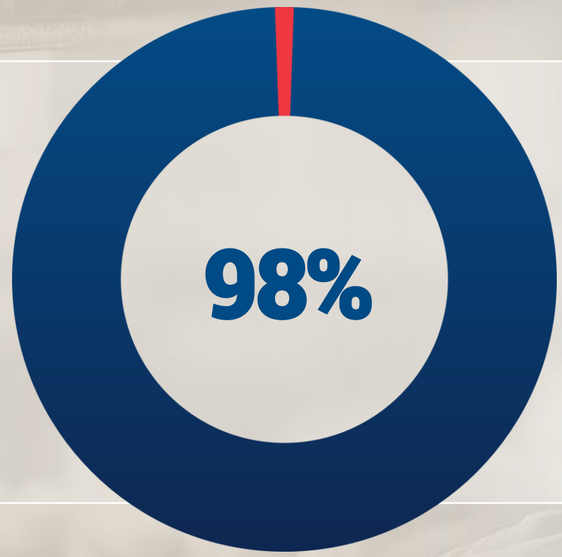
QA'd data: **5** days after QC'd data

Audited **draft** report: **4** days after completion of lab work

Audited **final** report: **2** days after request for finalization

ROYALMOUNT LABORATORIES

Exceptional Results in Analytical Acceptance Rate



Overall Analytical Run Acceptance Rate 2024

Individual samples rejection rate was at 2%. ALQ or inconsistent IS response

2018-2024 Overall Analytical Run acceptance rate was over 95%

Incurred Samples Reproducibility Analysis Acceptance

2012-2024 Incurred Samples Reproducibility Analysis acceptance was 100%

ROYALMOUNT
LABORATORIES

Large Molecule Validated Assays

Top of the Line Equipment

- Revolutionary sensitivity, speed, and performance for your most challenging methods
- Fully IQ, OQ, PQ

ROYALMOUNT
LABORATORIES

Frequently Requested Generic Assays

Biomarkers

- **GLP-1** in Monkey Plasma (K2EDTA) ELISA
- **Insulin** in Monkey Plasma (K2EDTA) ELISA
- Human **CRP** in Human Plasma (K2EDTA) ELISA
- Human **IL-6** in Human Plasma (K2EDTA) ELISA
- Human **hGH** in Human Plasma (K2EDTA) ELISA
- **BSA** in buffer for protein quantitation (colorimetric)
- Human **IFNy** and IL-6 in Human Plasma (K2EDTA) by Luminex.

PK LBA

- Validated generic total **human IgG** quantitative ELISA in rodents
- Generic antisense oligonucleotide (**ASO**) quantitative cutting Hybridization-ELISA in plasma and artificial CSF
- Generic antisense oligonucleotide (**ASO**) quantitative cutting Hybridization-ELISA in rodent tissues using an extraction approach
- Generic antisense oligonucleotide (**ASO**) quantitative sandwich Hybridization-ELISA in plasma

mRNA Expression Profiling

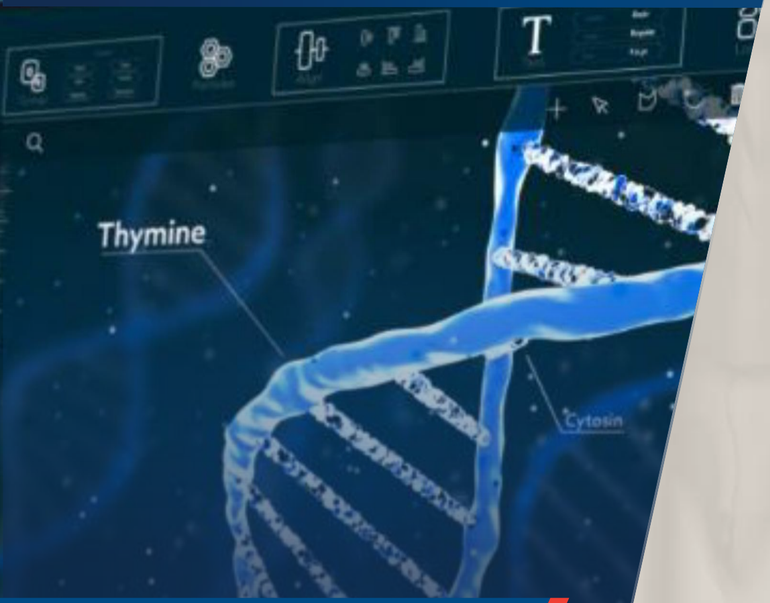
- Generic **GAPDH** mRNA expression levels by RT-qPCR in rodent tissues

Agilent (BioTek) Synergy Neo2 Hybrid (Abs, Fluo, Lum, AlphaLISA / Screen)

Luminex INTELLIFLEX SR (Multiplex)

Meso Scale Discovery Sector S 600MM (ECL, multiplex)

In House Toxicokinetic / Pharmacokinetic Services



ROYALMOUNT
LABORATORIES

EXPERTISE IN:

- PK/BE study design
- BE study management
- GCP/GLP compliance
- Preclinical TK and Clinical PK/PD analysis and reporting (TFL), CDISC SDTM and SEND file preparation, PK modeling, Population PK modeling.
- Validated Phoenix 8.4
- Clinical/BE report review

CRA / PK Scientists

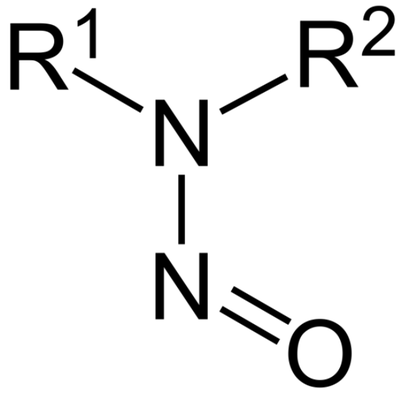
20+

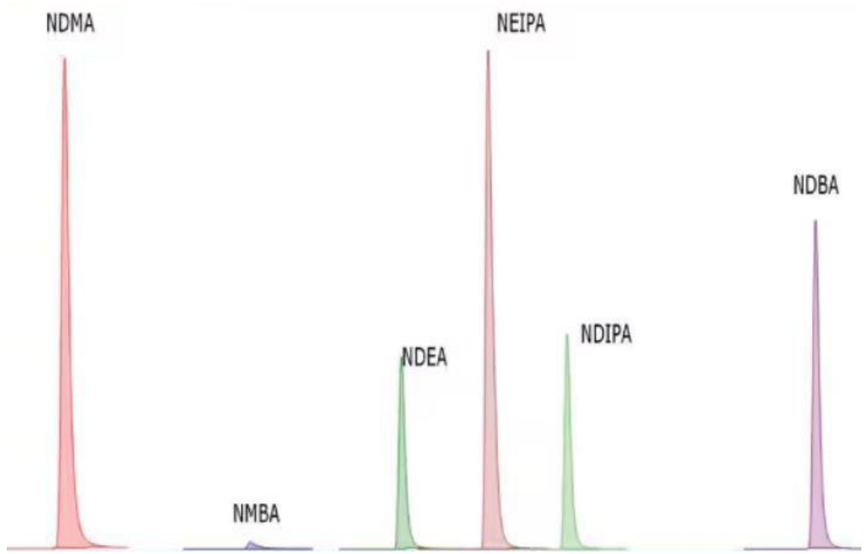
years industry experience

Nitrosamine Impurity Analysis by Mass Spectrometry

ROYALMOUNT
LABORATORIES

- NDMA, analogs, and NDSRI’s at ppm levels
- Highly specific methods avoids false positive OOS NDMA results
- Meets stringent Health Canada requirements and FDA requirements
- Applying 40+ years of our pharmaceutical experience to ensure reliable quantification of nitrosamines





Customer Testimonial

"Royalmount **provides key CRO services we rely on for advancing our preclinical development program.** We are highly impressed with their professionalism, responsiveness and technical capabilities.

They have met or exceeded expectations at every step. We brought them **a challenging project that they have executed within the promised timelines and budgets.** We highly recommend Royalmount for preclinical development projects of all kinds and sizes."

JOCASTA NEUROSCIENCE

Reverb THERAPEUTICS

"Working with **the Royalmount team has been a productive experience. They are a friendly and professional team.** Stephanie brings hands-on experience, is hard working and has positively contributed to the development of our project. Renée offers **a wealth of insightful and practical experience to assay development.** She is strategic in her approach and efficient drives the project to meet Reverb's goals."

ROYALMOUNT LABORATORIES

ROYALMOUNT
CDMO

Delivering the Highest Quality Complex Solutions

From formulation to commercial manufacturing

Sterile liquid Facility

- Small Molecules & Peptides
- Highly potent products (Oncologic and cytotoxic products)
- Suspension formulations(Bead Milling) with Lyophilization
- Complex formulations from R&D to Commercial supply
- Small to large batch volumes
- Biologics (ADCs, mAbs, Oligo’s)

ROYALMOUNT
CDMO

Liquid & Lyophilized vials, Pre-filled syringes with labeling, packaging and serialization capabilities

Injectable Manufacturing Capabilities

ROYALMOUNT
CDMO

Current Injectable Plant	**Future (2026)** Injectable Plant
✓ **PFS** and **Vial Line** in single room	**Dedicated PFS room** and **Vial room**
✓ **Lyophilization capacity** ~7M^2	**Lyophilization capacity** 2 x 16M^2
✓ **Batch Sizes** <10L up to 400L	**Batch Sizes** up to 650L
✓ **Manual** visual inspection	**Automated** Visual Inspection
✓ **Vial Filling:** 0.5ml to 100ml	
✓ **Prefilled Syringe Filling:** 0.2ml to 10ml	
✓ **Lyophilization Fill:** 0.5ml to 100ml	

Full Service CRO Solutions with Exclusive Partner Relationships

ROYALMOUNT LABORATORIES

We offer Pre Clinical studies through our exclusive CRO partner, Attentive Biosciences

Animal models offered:

- Cats
- Dogs
- Mice
- Rats
- Minipigs
- Non Human Primates (NHP)

ATTENTIVE SCIENCE

We offer Phase 1-3 Human Clinical Trials through our exclusive partner, Tranquil Clinical Research

- 36 free standing beds
- Located in the Clear Lake NASA Medical Center, Houston TX
- Three million sick patient database
- **Specializing in:** Device, Dermatology, Gastroenterology, Oncology, Infectious disease, Pulmonology, Rheumatology, CNS, etc

TRANQUIL CLINICAL RESEARCH

Other Partners:

ALTASCIENCES

PHARMA MEDICA RESEARCH INC.

Pharos Labs

Evestia Clinical

Partner of Choice Delivering Turnkey Solutions

CDMO Competitive Advantages for high potency injectables

ROYALMOUNT
CDMO

1

Formulation, Development & Tech Transfer

Clinical manufacturing (Phase I to Phase IV):

- Highly potent products
- Peptides
- Suspensions (including nano-suspensions)

2

Manufacturing Support with Leading Edge Expertise

- Sterile & HPAPI Capabilities
- Cold-chain manufacturing & storage
- Labelling up to serialization and aggregation
- Narcotics and controll*ed substances* License
- FDA, EMA & HC Approved

3

Alternate Business Models with CDMO+ available

Create more value in partnering with PMS globally

- Access to global market distribution/sales
- Co-Development opportunities
- Finchley Healthcare Ventures

Venture Capital Partnerships

Synergies between the RBS and VC partners provides mutual opportunities for success

RBS's Client Base

Biotech
(Pre-clinical or Clinical)

Small Molecules and Biologics

Benefits for VC

- Better quality and timelines to **enhance likelihood of success** for companies
- Offers a turnkey solution for companies and investors to **access scientific experts** in formulation, fill/finish, and bioanalysis

Benefits for RBS

- **New Leads (Introductions)** from Venture Capital's existing portfolio or opportunities
- **Marketing and Advertising tool** for CRO/CDMO through organic word of mouth

ROYALMOUNT
BIOPHARMA SERVICES

Our commitment to high quality, compliance and safety has delivered

Government Health Agency
Audit Performance excellence
for our injectables facility

ROYALMOUNT
CDMO

Health Canada

FDA U.S. FOOD & DRUG ADMINISTRATION

PIC/S

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ICH
harmonisation for better health

Candiac CDMO Sterile Injectables Expansion

Key Vial Line Equipment Suppliers:

- **Isolator** – Franz Ziel
- **Filler** – *Bausch and Strobel*
- **Lyophilizer** – *GEA*

x3

Tripling capacity by 2027

Increased production (Vials, PFS & Lyo) intended for **third parties**

FDA

One of a few **FDA approved** site in North America with **cytotoxic capabilities**

State-of-the-art New Equipment

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Injectable Expansion

Enhanced Capabilities & Capacity (Starting 2H2026)

Enhanced Capabilities

- Automated visual inspection for Vial and PFS Formats
- Automated label, packaging and cartoning technologies
- 2x Lyophilization size x 2 Lyophilizers

Increased Injectable supply Capacity

- ~5M → ~16M Units / Year
- Dedicated PFS line
- Dedicated Vial Line
- Higher throughput and automation using isolator technology (Annex 1 compliance)
- Redundant/Increased utilities capacity

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Thank you

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