

Your partner for success

# Contract Research & Development Laboratory



THE J. MOLNER  
COMPANY  
The Chemistry People

# Who we are

The J. Molner Company provides you complete development service

- Fully equipped GMP product development laboratory in Estonia established in 2016
- Experienced in small molecule generic injectable and topical pharmaceuticals development
- Knowledge of U.S and Canadian market and experience working with FDA and Health Canada
- Working according to ICH, USP, Ph.Eur requirements
- Competent and dedicated scientists
- Strong Quality Management System
- Agile and flexible organization





# Pharmaceutical Formulation & Process Development

The J. Molner Company helps you get products to market faster while reducing site specific risks and lowering costs

- Pre-Formulation and material science
- Formulation development
- Analytical method development, validation, and testing services
- R&D and commercial stability studies
- Analytical & Technical Transfer

# Analytical Method Development & Validation

- Potency & Purity Methods
  - Method Transfer
  - Method Development
  - Complex Method Validation:
  - Method Verification
  - Testing services
- ✓ Accuracy & Recovery
  - ✓ Precision (Test/Re-Test Reliability & Intermediate Precision)
  - ✓ Specificity & Selectivity
  - ✓ Limit of Detection (LOD)
  - ✓ Limit of Quantitation (LOQ)
  - ✓ Linearity & Range Samples
  - ✓ Stability in Matrix
  - ✓ Stock Solutions Stability
  - ✓ Specificity
  - ✓ Robustness



# Analytical Testing Services



- Chromatography
- Material testing
- Micrometrics
- Residual Solvents
- Water analysis
- Particle characterization



# Full Stability Program Support

- ICH Stability Testing Services: Stability studies in controlled temperature and humidity conditions according to ICH (climatic zones I to IV)
- Real-Time & Long-Term Stability
- Accelerated Stability
- Forced Degradation Studies
- Stress Stability Testing
- R&D Stability Testing
- In-Use Stability Studies: Stability studies to determine periods of use in multidose or reconstituted drugs



# Full Stability Program Support (cont.)

- Photostability: Stability studies to evaluate the resistance to light radiation
- Comparative/Comparator Stability
- Formulation Evaluation Stability
- Cycling Chamber Stability Studies: Freeze-Thaw and Stress
- Commercial Product Stability Studies & cGMP Stability Testing Meeting ICH Guidelines: Stability studies on already marketed products

**The J. Molner Company conducts your full stability program with Nordic quality at half the cost in US.**

# Our approach to Product Development

Proven generic pharmaceutical development methodology out of one of the most successful development teams in US



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# Pre-formulation and Reverse Engineering

- Investigate the chemical and physical properties of pharmaceuticals
- Physicochemical characterization of drug substances and drug product (RLD/RS)
- Reverse engineering for topical products
- Initial Regulatory/submission/technical risks evaluation
- Identification of suitable APIs and excipients

# 01

If you have an idea, The J. Molner Company can turn it into a product





02

# Formulation and Process Development

- Sensitivity studies
- Sterilization method development
- IVRT testing/ bioequivalence for topical products
- Primary packaging determination
- Process optimization
- Technical transfer support into scale-up manufacturing
- Contract manufacturing identification, qualification and support

# Analytical Support

- Method Development & Validation
- Stability, Degradation
- Release Studies
- Physical & Chemical Characterization
- API Analytical Profiling
- Technical Consulting

# 03



# 04

## R&D Stability Testing

- Photostability testing by ICH Q1B
- Ambient/Controlled Room Temperature: 15°C to 25°C  
Refrigerator: 2°C to 8°C
- Deep-freeze: below -15°C
- Accelerated Stability Testing: 40°C ± 2°C/ 75% RH ± 5% RH  
Intermediate: 30°C ± 2°C/ 65% RH ± 5% RH  
Long-Term Stability: 25°C ± 2°C/ 60% RH ± 5% RH
- Stress Stability Testing: 50°C
- Cycling Chamber Stability Studies: Freeze-Thaw and extreme temperature stability studies

# SAMPLE INJECTABLE DEVELOPMENT PLAN FOR U.S MARKET

## Client: Confidential

All projects start with preliminary plan and literature search



	API sourcing	Material sourcing	Start API method development and Validation	Start FP method development & Validation	RLD Characterization	FDA Scientific Advice	Formulation Development	Process Development	Analytical method transfer	Product technical transfer	Manufacture engineering batch	Manufacture exhibit batch	Stability testing	Elemental Impurities	Support ANDA submission	ANDA approved
CRL	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓		✓	
Outsourced							✓	✓						✓		
Client	✓					✓					✓	✓	✓	✓	✓	

6 months

2 months

1 month

7 months

10 months

Confirm with FDA  
Regulatory aspects

Completion of  
stability  
batches

Acceptance of  
ANDA

Approval and  
launch

# Please contact us:



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