
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

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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

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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

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Analytical Testing Services

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

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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

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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.

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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

01

- 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

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

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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

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Analytical Support

03

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

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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

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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 Characteri-zation	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

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