

#### 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.





# 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







## Formulation and Process Development

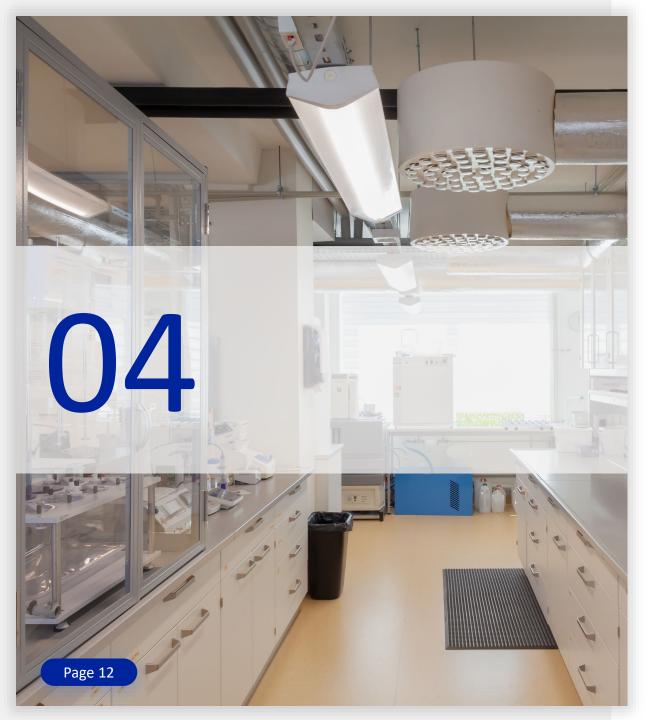
- Sensitivity studies
- Sterilization method development
- IVRT testing/ bioequivalence for topical products
- Primary packaging determination
- Process optimization
- Technical transfer support into scale-up manufacturing
- Contract manufacturing identification, qualification and support



#### **Analytical Support**

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





#### **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:  $30^{\circ}C \pm 2^{\circ}C/65\%$  RH  $\pm 5\%$  RH

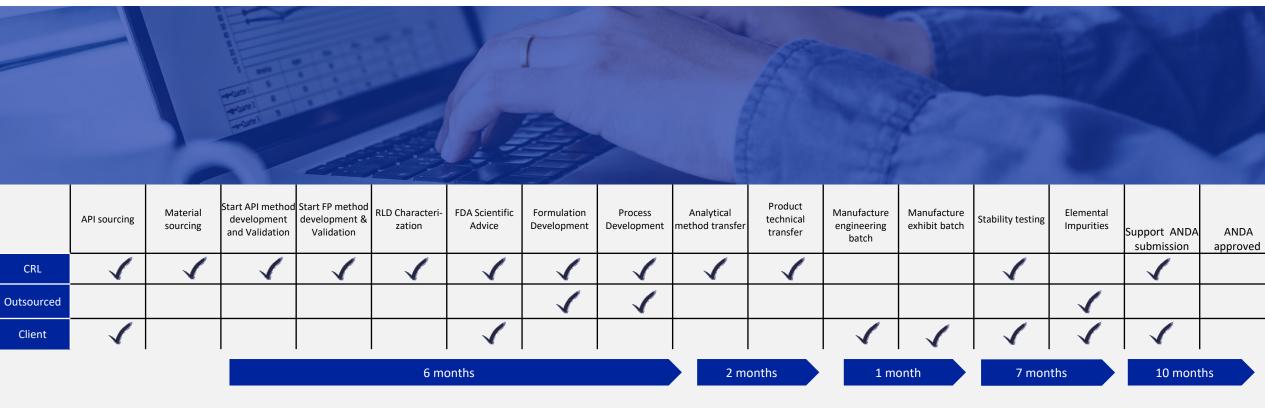
Long-Term Stability: 25°C ± 2°C/ 60% RH ± 5% RH

- 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



Confirm with FDA Regulatory aspects

Completion of stability batches

Acceptance of ANDA

Approval and launch



#### Please contact us:





www.jmolner.com



jmolner@jmolner.com