Peptide APIs
Custom Peptides
FMOC/Z - Building Blocks

NEULAND
WHERE OPPORTUNITY BECOMES REALITY

# Our Peptide Synthesis Services

Synthetic Peptides are finding increasing use as therapeutics, diagnostics, for antibody production, and as tools for understanding biological processes. Neuland's peptide synthesis services include production of peptides from milligrams to multi-kilogram scale by standard sequential chemical peptide syntheses and segment condensation strategies.

Most peptides between five and sixty amino acids are produced by standard solid phase peptide synthesis (SPPS) procedures. Multiple kilos of shorter length (up to 9 amino acids) are produced by solution phase methods. For longer peptides, containing up to 120 amino acids, segment condensation and ligation techniques are employed.

Neuland has expertise in both solution phase and solid phase synthesis methodologies. We have recently produced 35 kg of a Decapeptide NCE cGMP for a US based company by solution phase segment condensation of two pentapeptide key starting materials. The N-terminal KSM utilized a pseudoproline at its C terminus. (Further details of this project can be found in 'Projects Realised'.)

Neuland has also developed a preparative HPLC technique which is 10 to 20x better in throughput compared to the standard preparative HPLC technique. This makes purification less laborious and economical due to increased output, lower purification related cost.

These aforementioned abilities enable Neuland to offer the highest quality peptide products at competitive prices. Please put us to work for you.

## Capabilities

### Synthesis of Peptide APIs, NCEs & Other Services

- cGMP manufacture of peptide APIs, NCEs, and impurities
- Process development; route scouting; optimization & validation; and impurity profiling
- Large scale manufacture of complex amino acids and Fmoc-building blocks such as Pseudoprolines, Isoacyl Peptides, Dmb-derivatives, N-Methyl amino acids, etc.

### Drug Development Support

- Supply of material for clinical trials
- Scale up from lab to pilot to commercialisation

### Analytical R&D

- Analytical method development and validation
- Impurity profiling and validation
- Stability studies
- Supply of analytical reference standards

### Regulatory Support

Filing DMF with the appropriate regulatory agencies

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## Neuland's Peptide World

From building blocks to commercial production of peptide APIs

| | | |
|---|---|---|
| **Process R&D Center** | Aid in Drug Design and Analog Synthesis | Custom Process Development |
| **Intermediates and Peptide Fragments** | Novel Routes for Synthesis | Supply of protected Amino Acids and Building Blocks |
| **Manufacturing Services** | Scale up supply of Clinical Trial Material | Scale up from Lab to Pilot and Commercialization |
| **Analytical and Regulatory Support** | Analytical Method Development and Validation | Impurity Profiling, Validation<br><br>Analytical Reference Standards |
| **Generic Peptide API Manufacturing** | cGMP Manufacturing of Peptide APIs with Regulatory Support | |

## Core Expertise

- Solution Phase Synthesis
- Solid Phase Synthesis
- Hybrid Technology for Complex Peptides

Demonstrated expertise in the manufacture of people APIs (5-50 AAs) using solution Phase and hybrid technologies.

Difelikefalin Leuprolide, Octreotide and Eptifibatide (solution synthesis products)

Semaglutide, Liraglutide and Tirzepatide (hybrid technology products). Evaluation samples available on request.

Your partner for developement and cGMP manufacture of Fmoc building blocks (Isoacyl Dipeptides, *N*-Methyl amino acids, Azido and other high value amino acids.)

## List of Building Blocks

- Isoacyl Dipeptides
- Dmb Derivatives
- Hmb Derivatives
- Lysine Derivatives
- *N*-Methyl Amino Acids

**Other Products**

- 30- Pseudoprolines


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