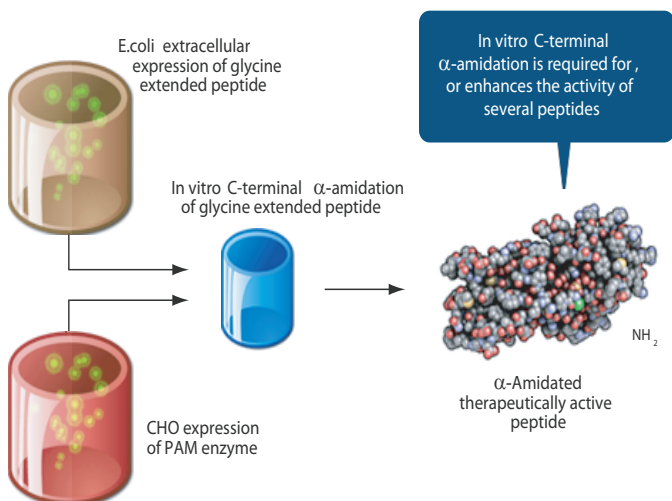




A leader in the design, delivery, manufacture and development of PEPTIDE-BASED THERAPEUTICS

Manufacturing larger peptides needs a more cost-effective option

SOLUTION: UNIGENE'S RECOMBINANT DIRECT EXPRESSION TECHNOLOGY



Advantages of Direct Expression of Peptides

PEPTIDE SECRETED DIRECTLY INTO CULTURE MEDIUM:

No Need for Cell Lysis

Reduced endotoxin

Decreased bio-burden downstream

No Fusion Partner

Removes expensive cleavage step

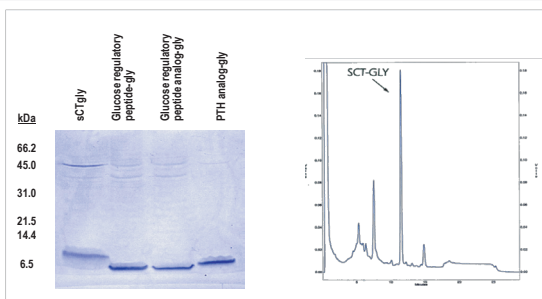
Higher peptide yield

Streamlined Purification

Fewer purification steps

Higher overall yields

Higher purity



SDS PAGE and HPLC Trace of Crude Medium

- Enriched starting material for purification
- Extracellular yields of 400 to 1300 mg/L
- Reduced purification steps

DIRECT EXPRESSION OFFERS:

Robust yields from 400 to greater than 1000 mg/L of culture

Final purity generally > 97%

Scalable to >100 kg/year

Efficient

Cost-effective

Successful Partnerships Start with Unigene

- Current supplier of API and Final product to UpsherSmith for Fortical™ sCT Nasal product
- Novartis completing Phase 3 trials of oral calcitonin using Unigene's manufacturing technology
- Partnership with GSK for PTH API and oral PTH development

A CLEAR PATH: FEASIBILITY TO MANUFACTURING

Step I. Feasibility

- Peptide sequences cloned and expressed
- Assays developed for amidated and non-amidated peptides
- Short turnaround time

Step II. Process Optimization

- Optimization of expression system
- Upstream and downstream development
- Technology transfer to cGMP production

Step III. cGMP Manufacturing

- 32,000 sq. ft. cGMP multiple product manufacturing facility
- 1000-liter cGMP peptide production process
- Clinical trial and commercial production of peptide API

Feasibility can be completed
within 3 months

unigene

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