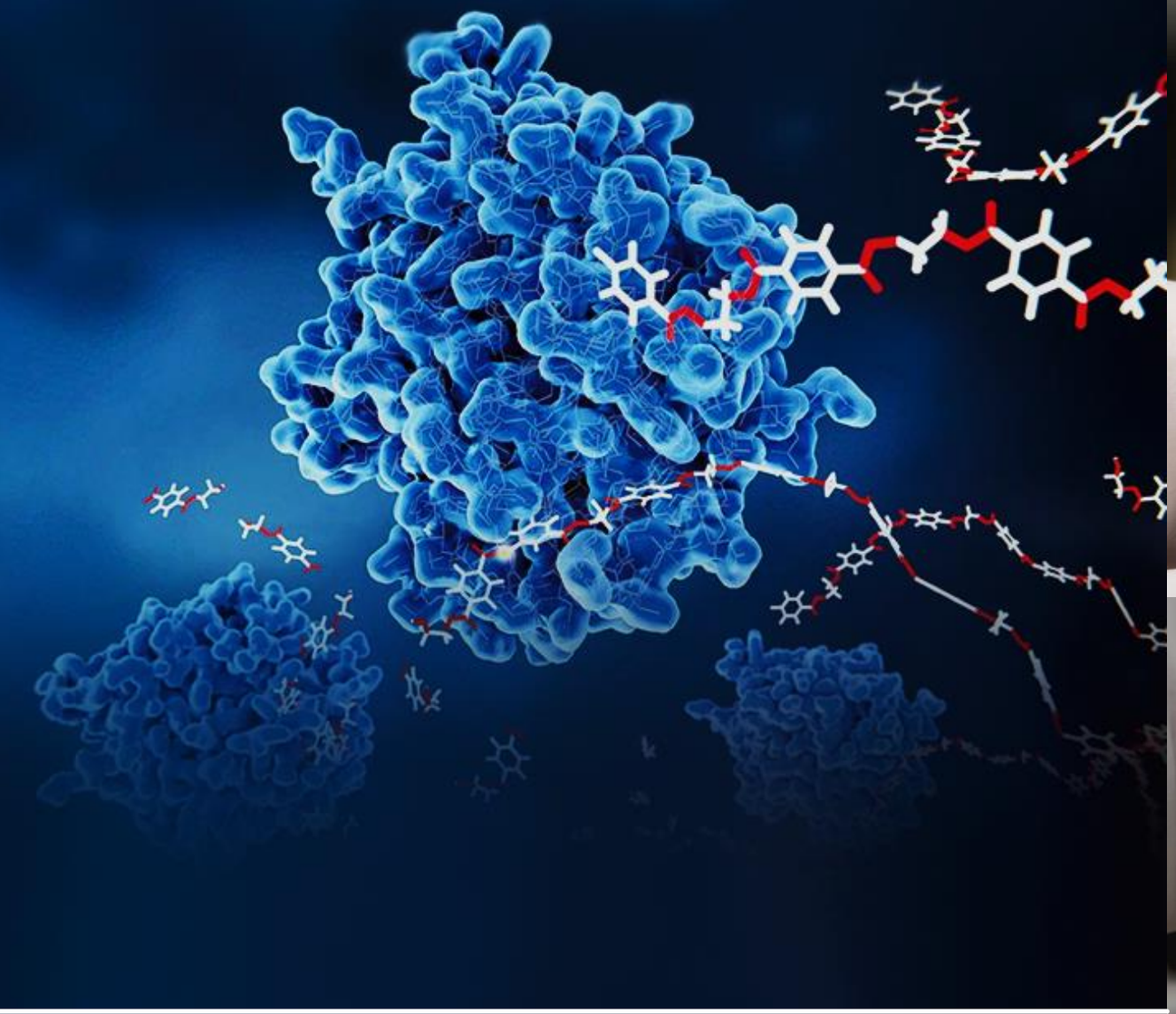
Customized Peptide & Protein Production Service

PEPGENE
Biopharmaceutical Innovation

ver 1.1.2

Just provide a protein sequence,
We will do the rest.



http://www.pepgene.net

PEPGENE
Biopharmaceutical Innovation

Contact PEPGENE Inc.

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Contents

Overview

PEPGENE provides CDO and CRO services for recombinant production of peptides and proteins which is based on twenty years of research and development experience.

About PEPGENE Inc.

Logo	PEPGENE	
CEO	Chang-Seok Roh	
Date of Fundation	Feb 27, 2017	
Location	R&D center	2F ABN Tower, 331, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Rep. of Korea
	Office	5F Daeyoung building, 223, Hakdong-ro, Gangnam-gu, Seoul, Rep. of Korea
Website	Homepage	http://www.pepgene.net
	Blog	http://blog.naver.com/pepgene
E-mail	info@pepgene.net	
Tel	+82 31-8039-5505	

Vision	Pepgene's innovative technology contributes to the quality of human life	
Core value	**Honesty**	Follow the base of principle and honesty
	Challenge	Create new values with a challenging spirit
	Cooperation	Strong teamwork to overcome difficulties and achieve greater progresses
Pipeline	**PG001**	Liraglutide biosimilar (obesity and diabetes)
	PG002	Teriparatide biosimilar (osteoporosis)
	PG003	Teduglutide biosimilar (short bowel syndrome)
	PG004	Semaglutide biosimilar (obesity and diabetes)

Company History

2017

- Established
- Selected government supported company

2018

- Qualified venture company
- Selected TIPS R&D program

2019

- M&A of T&K BioInnovation
- Established Pangyo R&D center

2020

- Awarded 2 cases of government R&D Grants
- Amt. of Grants : $370,000

2021

- Pre-A investment
- Inv. Amt. : $ 2,200,000
- Awarded 3 cases of government R&D Grants
- Amt. of Grants : $ 606.000
- CRO & CDO service
- Sales amt. : $ 65,000

2022

- Awarded 6 cases of government R&D Grants
- Amt. of Grants : $ 1,095,000
- Sales of 3 bioprocessing enzymes
- 4 cases of CRO & CDO services
- 3Q sales : $300,000

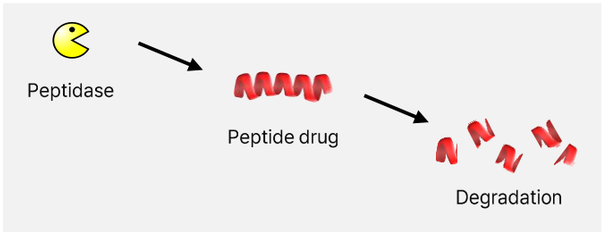
PG Tag

Partner for Great expression

01

Problem

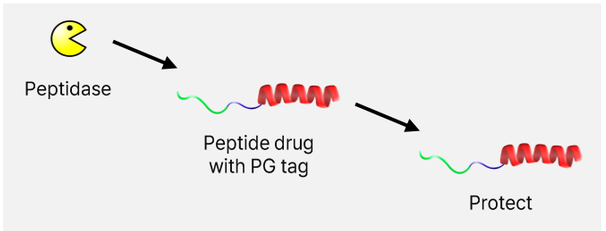
- Recombinant peptides in cells are easy to be degraded by peptidases
- Contamination by endotoxins from bacterial
- Difficulty in purification of due to the low molecular weight and unstable structure



02

Solution

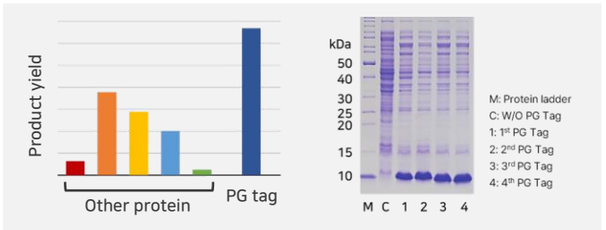
- Fusion of PG tag to target peptide to induce peptide aggregation to protect degradation in cells
- Endotoxins are easily removed from the PG tag-fused peptides during chromography steps



03

Result

- Aggregated PG tag-fused peptides are accumulated in cells, resulting in the highest yield of peptide production
- PG tag shows the best peptide production yield



Patents

No.	Patents	Patent #
1	NOVEL FUSION POLYPEPTIDE AND METHOD OF PREPARING HUMAN PARATHYROID HORMONE 1-34 USING THE SAME	10-2011291
2	N-TERMINAL FUSION PARTNER FOR PREPARING RECOMBINANT POLYPEPTIDE AND METHOD OF PREPARING RECOMBINANT POLYPEPTIDE USING THE SAME	10-2064810
3	FUSION TAG FOR PREPARING GLUCAGON-LIKE PEPTIDE-1 OR ANALOGUES	10-2301136
4	FUSION TAG FOR PREPARING GLUCAGON-LIKE PEPTIDE-2 OR ANALOGUES	10-2301137
5	FUSION TAG FOR PREPARING OXYNTOMODULIN	10-2301138
6	N-TERMINAL FUSION PARTNER FOR PRODUCING RECOMBINANT POLYPEPTIDE, AND METHOD FOR PRODUCING RECOMBINANT POLYPEPTIDE SGING SAME	US 011,267,863 B2

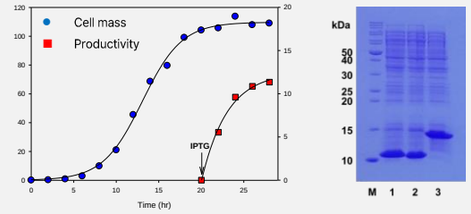
HYPER Technology

High Yield Protein Expression & Refolding

01

Fermentation

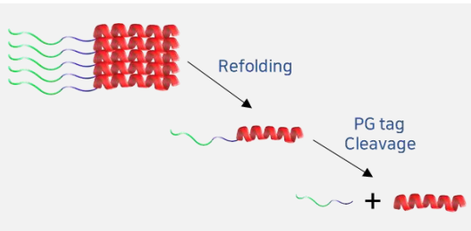
High cell density culture through fed-batch culture method



02

Refolding & Cleavage

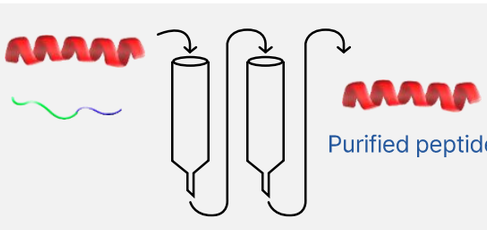
High refolding yield (>95%)
High cleavage yield (>95%)
※ High specific and efficient protease



03

Efficient purification of peptides

High recovery yield via 2-step chromatography process
※ At least 5-step chromatography process is required in common purification process

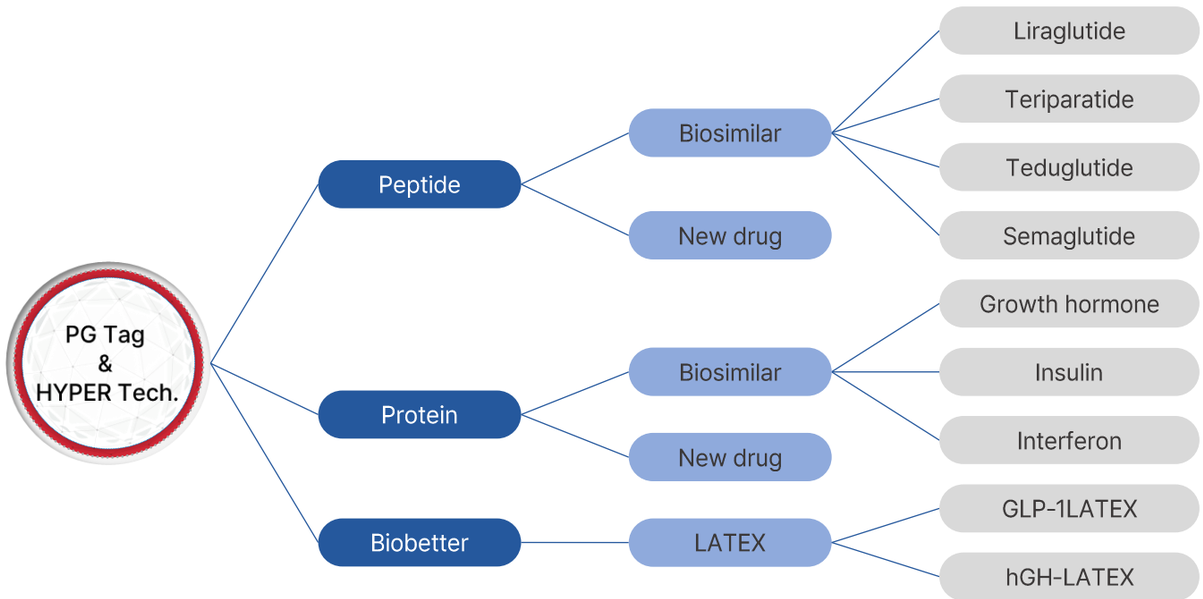


- HYPER technology is the core platform technology of PEPGENE Inc.
- HYPER technology ensures the highest recombinant protein production yield.
- HYPER technology decreases production cost significantly.

Cell conc.	Refolding	Cleavage	Purity	Yield
100 g/L	**> 95%**	**> 95%**	**> 99.5%**	**1.1 g/L**

Technology Excellence

Applicability of PG Tag & HYPER Technology



* LATEX
Long-Acting Technology using Extension of Protein-X

Expression level

> 40%

Target protein expression level in host cells : > 40%

High purity

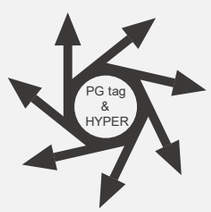
> 95%

Protein purity : > 95%
(endotoxin: < 0.05 EU/μg)

Production scale

Manufacturing size: from 10 mg to 1 kg
(Capacity: max. 1 kg/month)

Performance



Successfully produced more than 50 cases of recombinant proteins and peptides

Technology Excellence

Pipeline development

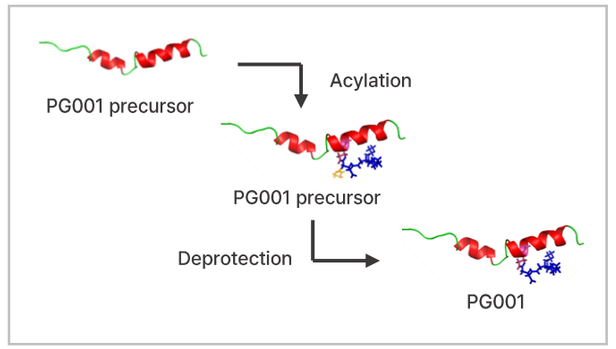
PG001

Liraglutide biosimilar (obesity and diabetes)

01

Production strategy

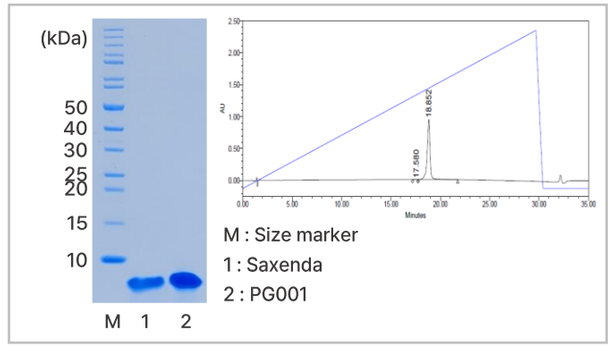
- Expression of GLP-1 with PG tag
- 1st chromatography
- Refolding & cleavage
- 2nd chromatography
- Acylation & deprotection
- 3rd chromatography



02

Production

- Production yield : 850 mg/L
- Purity : > 99.5%
- RP-HPLC : > 99%
- Peptide mapping : > 99%
- MALDI-TOF MS : > 99%
- Bio-assay : > 99%



03

R&D Milestone

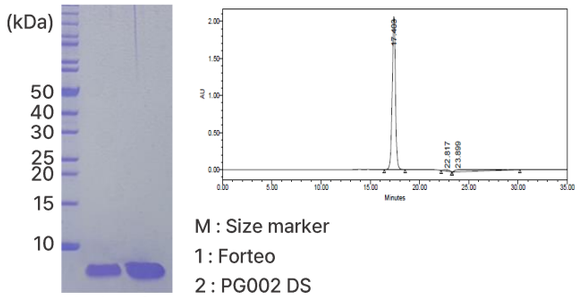
2020	2021	2022	2023	2024	2025
Development	Partnering clinical study collaboration				

Technology Excellence
Pipeline development

PG002
Teriparatide biosimilar (osteoporosis)

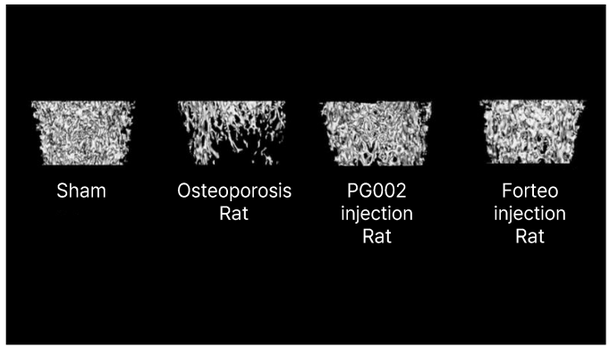
01
Production

- Production yield : 750 mg/L
- Purity : > 99.5%
- RP-HPLC : > 99%
- MALDI-TOF MS : > 99%
- Peptide mapping : > 99%
- Circular dichloism : > 99%
- Bio-assay : > 99%



02
Non-clinical efficacy (Bone mineral density)

- Sham : 953 g/cm3
- Osteoporosis rat : 236 g/cm3
- PG002 injection rat : 492 g/cm3
- Forteo injection rat : 508 g/cm3



03
R&D Milestone

2020	2021	2022	2023	2024	2025

GMP manufacturing

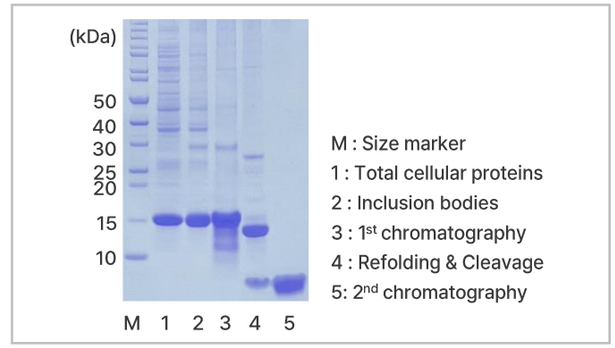
Development / Non-clinical → Production of clinical sample → IND application → Phase 1 clinical trial

Technology Excellence
Pipeline development

PG003
Teduglutide biosimilar (short bowel syndrome)

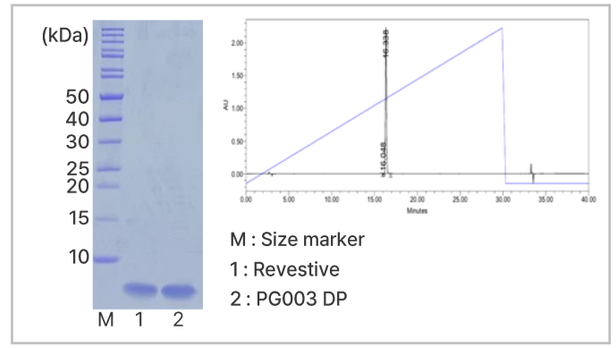
01
Production strategy

- Expression of PG003 with PG tag
- 1st chromatography
- Refolding & cleavage
- 2nd chromatography



02
Production

- Production yield : 850 mg/L
- Purity : > 99.5%
- RP-HPLC : > 99%
- Peptide mapping : > 99%
- MALDI-TOF MS : > 99%
- Bio-assay : > 99%



03
R&D Milestone

2020	2021	2022	2023	2024	2025

Efficacy test in progress

Development → Non-clinical → IND application → Phase 1 clinical trial

Why PEPGENE?

01
Prominent development capabilities

- Reliable expertises in recombinant peptide and protein production
- R&D experience over 20 years

02
High quality products

- Promising over 98% purity
- Low endotoxin (<50 EU/mg)
- No chemical modification

03
Customized service

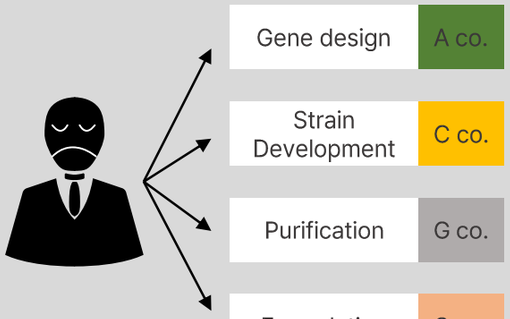
- Stable isotope labeling with ^{15}N, ^{13}C and $^{15}N+^{13}C$
- Selective modification at N-terminus and lysine residue in peptides and proteins
- 10 mg to 1 kg scale production

04
One-stop service

- All processes from gene synthesis to purification and formulation can be performed at PEPGENE.
- Collaboration with specialized CROs
- Quality satisfaction guaranteed

One-Stop Service

Other Existing system



Clients waste time and effort finding a CRO to complete each step.

One-Stop Service

PEPGENE Inc.

1. Gene design & cloning
2. Strain development
3. Expression
4. Purification
5. Formulation

Clients provide a protein sequence only. PEPGENE will do all the rest.

What a peptide? Call me!

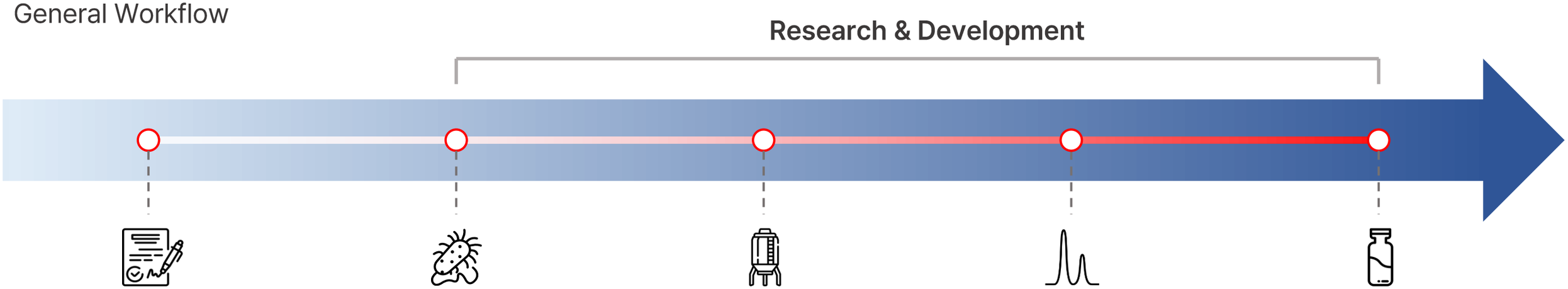
Service outline

PEPGENE has successfully produced many recombinant peptides and proteins fulfilled with the requirements of the clients.

Request

Introduction

General Workflow



Contract

Contract process

- R&D scope
- Quotation
- Contract

Strain

For High stability and expression

- Gene design and cloning
- Expression system optimization
- Colony selection
- RCB/MCB manufacturing

Fermentation process

For high cell density

- Media optimization
- Culture condition optimization
- Small scale culture
- Scale-up

Purification process

For high-purity protein

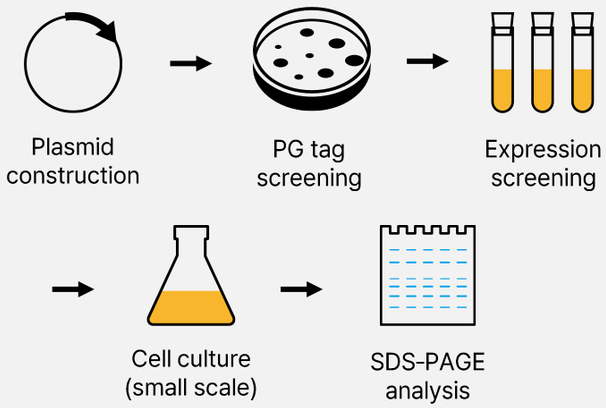
- Resins, buffers, other parameters screening
- Chromatography, TFF optimization
- Scale-up

Formulation process

For stability

- Buffer pH, excipients, other parameters screening
- Optimization
- Stability tests

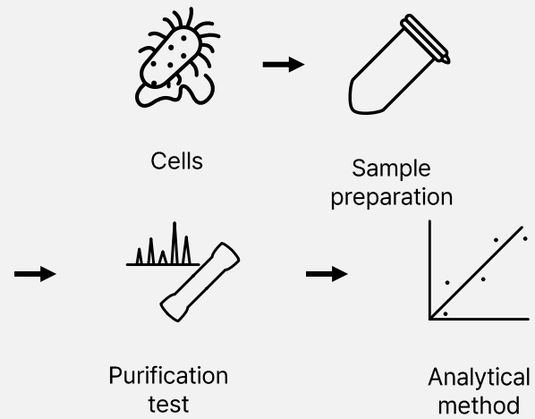
Expression test



Establishment of optimal expression conditions

Service time : about 2 weeks

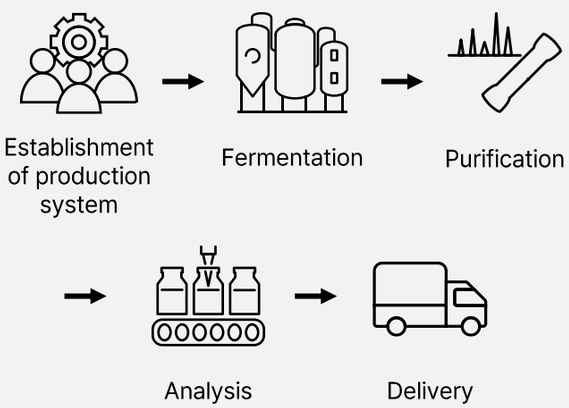
Purification test



Establishment of optimal purification and analysis method

Service time : about 4 weeks

Manufacturing



Recombinant protein production through optimization process method

Service time : about 2~3 weeks

Upstream Process

From strain development to large-scale fermentation

Purpose

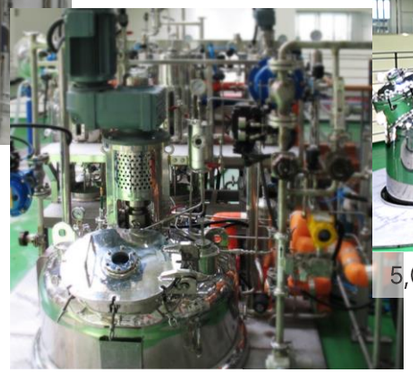
- Screening of an optimal PG tag for production of recombinant protein

Parameter

- Media
- Temperature
- Inducer concentration
- Other relevant parameter

Equipment

50 L, 500 L Fermenter



1,500 L Fermenter

5,000 L Fermenter

Process

1. PG tag screening
2. RCB
3. Culture condition
4. Upstream optimazation
5. Pilot run
6. Validation

Downstream Process

From purification to formulation

Purpose

- High-yield & purity protein purification
- Formulation to maintain long-term stability
- Refolding process development if needed

Parameter

- Purification process
  - Resin
  - Buffer ingredient
  - Buffer & Sample pH
  - Linear velocity
  - Etc
- Analytical process
  - Resin
  - Buffer ingredient
  - Method validation

Development list

- Chromatography & TFF
  - Resin selection
  - TFF membrane selection
  - Binding capacity test
  - Purification yield
  - Etc
- Analysis
  - SDS-PAGE
  - RP-HPLC
  - SE-HPLC
  - Endotoxin
  - HCP, HCD
  - Etc (MS, ELISA)

Equipment

Purification process

FPLC

- AKTA prime plus (Cytiva)
- AKTA pure 25M (Cytiva)

Analytical process

HPLC & UPLC

- Waters system

Performance

Pepgene has successfully produced many recombinant proteins and peptides that fulfilled with the requirements of the clients.

Clients

Korea Disease Control and Prevention Agency

Agency for Defense Development

SAMSUNG MEDICAL CENTER

ASAN Medical Center

DAEWOONG

K BIO HEALTH 오송첨단의료산업진흥재단

KRIBB Korea Research Institute of Bioscience & Biotechnology

KITECH 한국생산기술연구원

connexT Innovation for Regeneration

Quratis

(주)카보엑스퍼트 CARBOEXPERT

Advanced Protein Technologies Corp.

TMS HEALTHCARE TOTAL MEDICAL SOLUTIONS

GeneChem Glycosylation Company Specialized in Sialylation

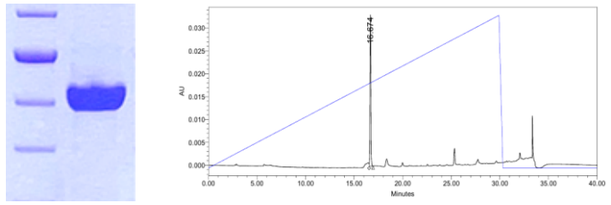
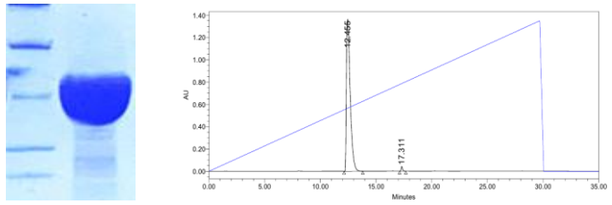
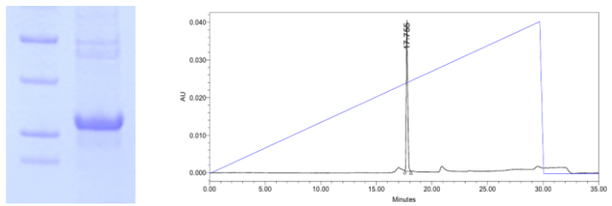
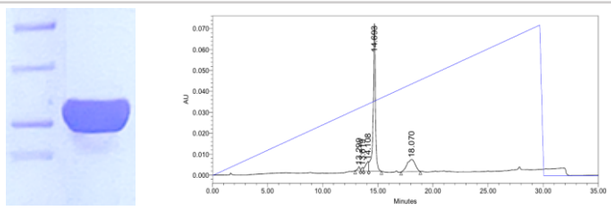
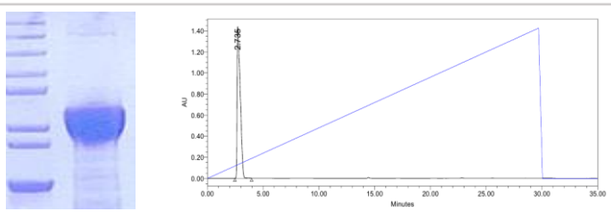
The Stemcell Biogenic Gear – PROSTEMICS

Results of CDO & CRO

G company

Request : Production of seven recombinant proteins for non-clinical/clinical test

- Result
  - High purity (> 95%)
  - High Yield (> 20 g)
- Contract period : 5 month
  - Process development : 1 month
  - Production : 1.5 month

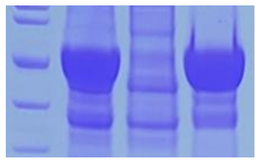
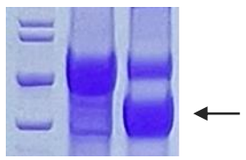
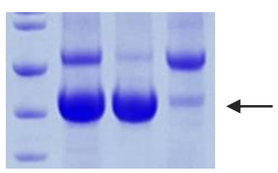
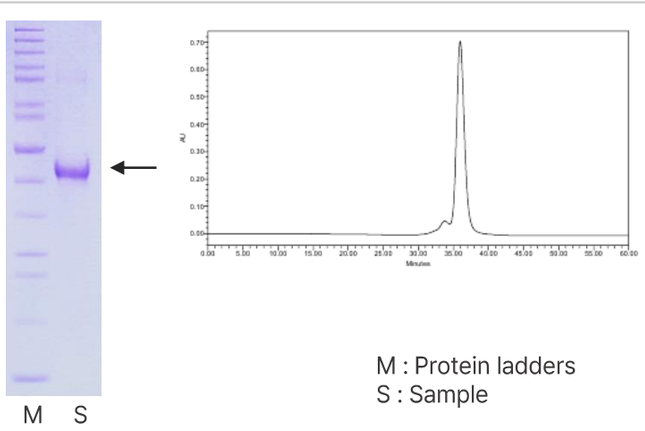
Code	Purity	Amounts	Results
PGG-02	> 95%	3. 66 g	
PGG-03		2.39 g	
PGG-04		2.95 g	
PGG-05		4.83 g	
PGG-06		4.44 g	

Results of CDO & CRO

T company

Request : Production of tissue regeneration protein (Amount > 20 g)

- Result
  - High purity (> 95%)
  - High Yield (> 20 g)
- Contract period : 5 month
  - Process development : 1 month
  - Production : 1 month

Step	Value	Results
Expression	Expression form : Insoluble	 M : Protein ladders T : Total proteins S : Soluble proteins I : Insoluble proteins
Fusion partner cleavage	Cleavage yield : > 90%	 M : Protein ladders BC : Before Cleavage AC : After Cleavage
Purification	Final amount : 21 g	 M : Protein ladders Inj: Injection sample 1 : Target protein 2 : Impurity
Purity	> 95%	 M : Protein ladders S : Sample

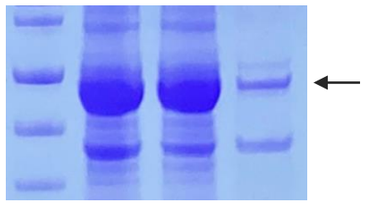
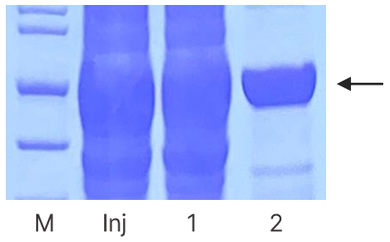
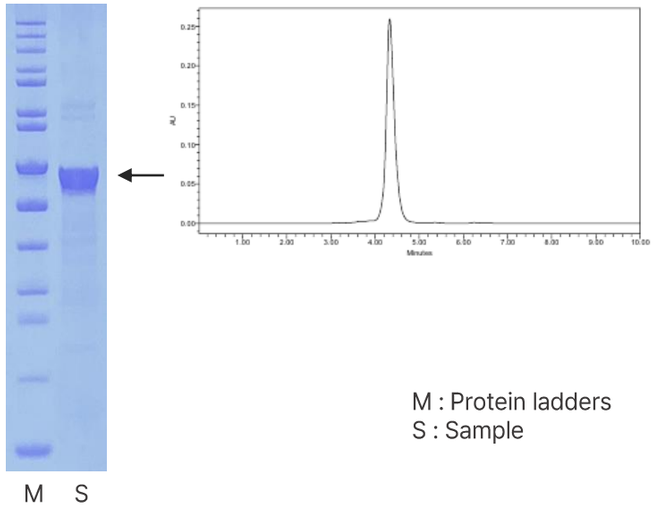
Results of CDO & CRO

National Institute of Infectious Diseases

Korea Disease Control and Prevention Agency

Request : Production of vaccine candidate proteins for an infectious disease

- Result
  - High purity (> 95%)
  - High yield (> 20 mg)
- Contract period : 3 month
  - Process development : 1 month
  - Production : 1 month

Step	Value	Results
Expression	Expression form : Soluble	 M : Protein ladders T : Total proteins S : Soluble proteins I : Insoluble proteins
Purification	Final amount : 21.6 mg	 M : Protein ladders Inj: Injection sample 1 : Impurity 2 : Target protein
Purity	> 95%	 M : Protein ladders S : Sample

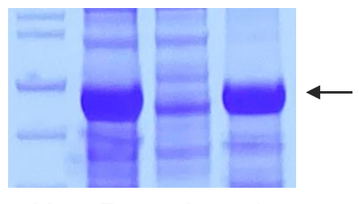
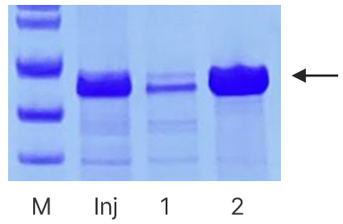
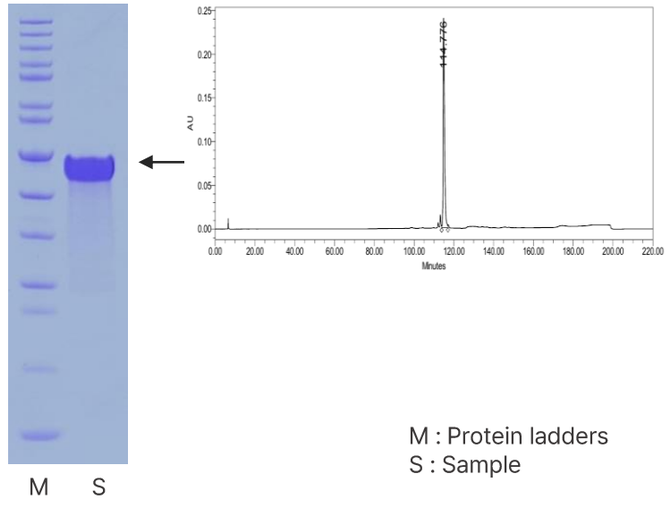
Results of CDO & CRO

Daewoong pharmaceutical company

DAEWOONG

Request : Production of target proteins for screening of new drug for fibrosis

- Result
  - High purity (> 95%)
  - High yield (> 40 mg)
- Contract period : 3 month
  - Process development : 1 month
  - Production : 1 month

Step	Value	Results
Expression	Expression form : Insoluble	 M : Protein ladders T : Total proteins S : Soluble proteins I : Insoluble proteins
Refolding & Purification	Final amount : 41.3 mg	 M : Protein ladders Inj: Injection sample 1 : Impurity 2 : Target protein
Purity	> 95%	 M : Protein ladders S : Sample