PORTON

Antibody Drug Conjugate (ADC) CDMO Services

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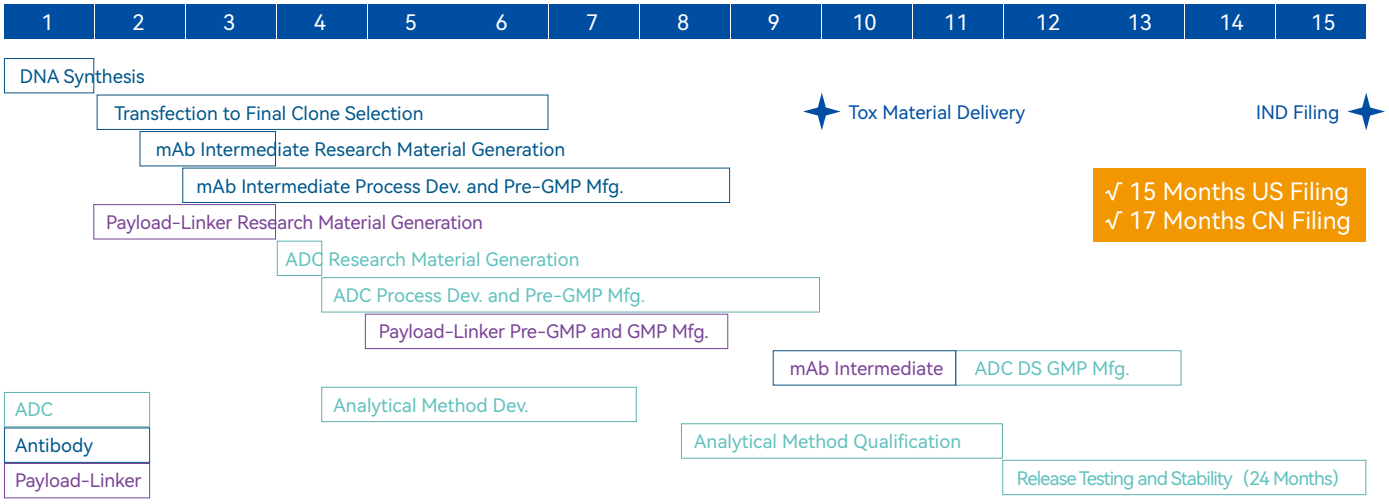
As a subsidiary of the globally recognized CDMO——Porton Pharma Solutions, Porton Biologics CDMO Platform is designed to provide one-stop drug development and manufacturing services for antibodies and antibody drug conjugates (ADCs).

Payload-Linker

Antibody

ADC

Typical Timeline for ADC IND Enabling



Note: The project schedule may be adjusted based on specific circumstances and client requirements.

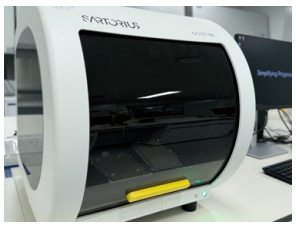
CATALOGUE

01.
Cell Line Development

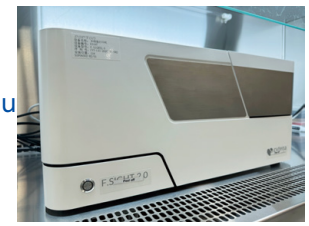
Starting from DNA sequences, we provide customers with high-titer, high-quality, and stable cell lines for subsequent process and GMP production.

Project Design > Vector Construction > Pool Screening > Single Clone Screening > Stability Study > Final Clone

Efficient cell line development equipment for high-throughput and automated single clone sorting.



High-throughpu >



Automation >

Protein Analysis System (Octet, Sartorius)

Used for high-throughput pool screening, high-throughput, automated detection of plate titer.

Single Cell Printer (F.sight, Cytena)

Used for automated clone plating, high monoclonal rate and recovery rate.

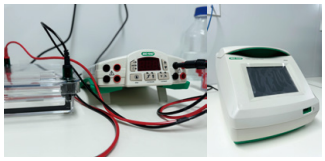
Single Cell Imager (Cell Metric, Solentim)

Used for monoclonal imaging to provide proof of monoclonal origin.

02.
Fast Protein Expression

Starting with the DNA sequence, the gram-scale protein can be obtained in about 7 weeks to meet the customer's testing needs.

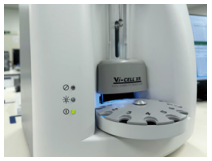
Project Design > Vector Construction > Stable Pool Expression



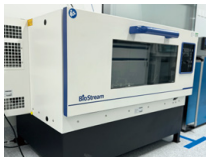
Nucleic Acid Electrophoresis and PCR >

GelDoc Go Imager >

Electroporator >



Vi-cell >



Kuhner Shaker

Sequences are constructed into vectors through code optimization, sequence synthesis.

Used for nucleic acid gel imaging, automatic image capture and analysis.

Transfer target gene into host cells, high transfection efficiency and cell viability.

Automatic detection of cell density/viability, standardized cell test platform.

For cell culture, with precise temperature, CO_2 and humidity control systems.

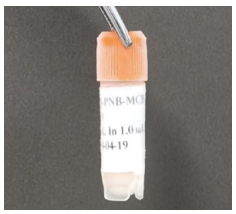
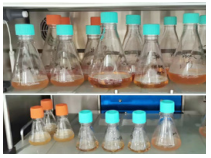
Platform Advantage

- CHO cell expression system, consistent with CMC development.
- Stable expression system to evaluate protein performance.
- Rapid expression of mAb, BsAb and fusion protein.

03.
Lab Scale Protein Generation

Provide protein generation services in 3 L to 15 L bioreactors according to the request of the clients, including mAb, BsAb, fusion protein, etc.

Vial Thaw > Seed Expansion > Protein Generation > Protein Purification





04.
Formulation and Drug Product Process Development Service

- High-throughput, low-dose, multi-parameter and rapid characterization of protein stability evaluation.
- Customized formulation development strategy for different molecule types: antibody, ADC, fusion protein, etc.
- Formulation and drug product production process development platform for different drug product forms: liquid, lyophilized, pre-filled syringe.

Formulation Development

Pre-formulation Development and Developability Assessment > Formulation Development > Primary Container Screening > Formulation Confirmation

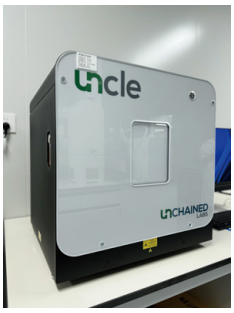
Drug Product Process Development

DS Freeze-thaw Process Development > DS Mixing Process Development > Filtration Process Development > Filling Process Development > Lyophilization Process Development, Optimization and Scale-up

05.

Key Parameter Testing Service for Formulation Development

Testing Items	Method	Minimum Sample Volume
T_m, T_{onSet}, Isothermal Stability, Thermal Recovery, $C_{1/2}$, ΔG	Differential Scanning Fluorimetry (DSF)	9 μL/Sample
Tagg (266 & 473), Isothermal Stability, B_{22} & G_{22}, Thermal Recovery	Static Light Scattering (SLS)	9 μL/Sample
Isothermal Stability, Sizing & Polydispersity, Sizing with Thermal Ramp, T_{size} & T_{agg660}, k_D	Dynamic Light Scattering (DLS)	9 μL/Sample
Viscosity	Pressure Driven Methods (USP 914)	20 μL/Sample
Density	U-tube oscillation (Meet ChP, USP, EP, JP)	1 mL/Sample



UNcle

Stereomicroscope

Viscometer

Density Meter

UNagi

Enclosure

Dynamic Climate Chambers

Mixer Scale-down Model

Constant Climate Chambers

Peristaltic Filling Pump

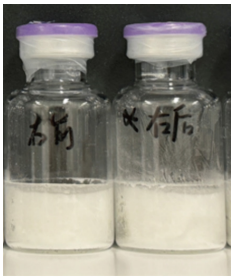
06.
Lyophilization Process Development and Optimization Service

Provide lyophilization process development services for antibody, ADC, fusion protein, etc., including lyophilized product formulation development, lyophilized product key parameter analysis, lyophilization process development and optimization, and product quality testing (moisture, the strength of freeze-dried cakes, etc.).

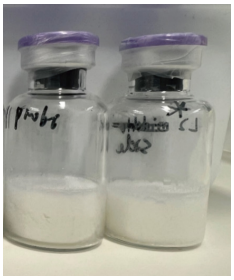
Lyophilized Product Key Parameter Testing: Tc, Tg', Teu, Tg > Lyophilization Process Development > Lyophilization Process Optimization > Lyophilization Process Scale-up and Tech-transfer

Case Study

Optimization of lyophilization process: Adjusting key process parameters of the freezing and primary drying (shelf temperature, chamber pressure, etc.), effectively improves the appearance problem of collapse and shrinkage of the cake.



Before



After

Lyophilized Drug Product

07.
High Concentration Drug Product Development Service

The laboratory has a comprehensive platform for high concentration drug product formulation and production process development, which can provide services for the high concentration drug product development.

Pre-formulation Development

- $B_{22}/k_D/G_{22}$
- Solubility Prediction
- Conformational Stability
- Colloidal Stability

Formulation Development

- Excipients Screening
- Stabilizer Screening
- PFS Development (If Needed)
- Large Volume Drug Product Development (If Needed)

Process Development

- UFDF Process Development
- Filling Process Development
- Lyophilization Process Development (If Needed)
- Clinical In-use Stability Study

08.
Multiple Bio-conjugation Services, ADC Library Generation Included

We provide milligram scale customized conjugation services for customers' Proof of Concept ADCs. We can help assess innovative antibodies or linker-payloads, with various antibody and linker-payload combinations.

Type of Antibody Intermediates

- Monoclonal antibody
- Bispecific antibody
- Nanobody
- Fusion protein
- etc.

Type of Linker Payloads

- Camptothecin and its derivatives
- Maytansinoids
- Auristatins
- Oligonucleotide
- Chelator for RDC
- etc.

Conjugation Methods

- Cysteine conjugation
- Lysine conjugation
- Enzymatic conjugation
- Site-specific conjugation of engineered antibodies
- etc.

Range of DAR

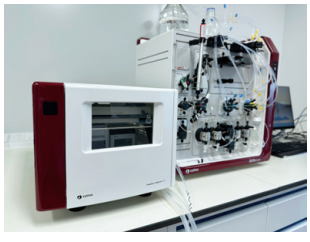
2/4/8 or customised drug antibody ratio (DAR)

09.
Lab Scale ADC Generation

We provide lab-scale ADC conjugation and purification services to help customers to generate gram-scale ADC materials.

Rigid Isolators

Conjugation Reactors and TCU



ÄKTA Pure

Sartoflow Smart TFF

10.

Analytical Services for Antibody and ADC

Provide services of assay development and sample analysis, satisfying client's analytical expectations.

Quality

- Concentration
- Titer

Particle

- Visible Particles
- Subvisible Particulate Matter

Potency

- ELISA Binding
- Cell Based
- Affinity (ADCC, ADCP, CDC)

Safety

- Endotoxin
- Sterility
- CCIT
- Bioburden

Raw Material

- Compendial Method

General Attribute

- Appearance, Color, Clarity
- pH, Osmolality
- (Liquid) Extractable Volume
- (Lyo) Reconstitution Time, Water Content, Uniformity
- PS20/80

Purity

- SEC
- IEX
- DAR (ADC)
- NR & R CE
- icIEF

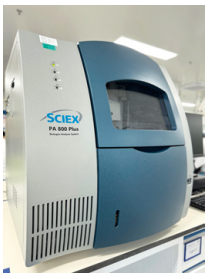
Impurity

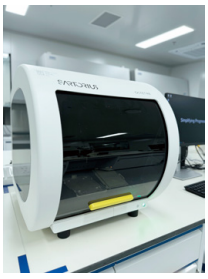
- Residual HCP
- Residual DNA
- Residual Protein A
- Residual Free Drug (ADC)
- Residual Solvent (ADC)

Characterization

- MASS: IM, RM, DM, DRM, Peptide Mapping, Disulfide Bond Linkage Confirmation, Conjugation Site Confirmation (ADC), DAR Distribution (ADC)
- SEC – MALS, AUC
- N/O – Glycan Analysis
- DSF/DSC
- UV – CD
- Extinction Coefficient








11.
Antibody DP Filling (Vials & PFS)

An advanced 2-in-1 filling line equipped with an aseptic isolator, is capable for the DP filling into the vials and PFS of various sizes. The filling line is composed of internationally renowned peristaltic pumps, which guarantee the filling precision to achieve high yields and minimize wastage.

Vial Size	Liquid Capacity (vials/hour)	PFS Size	PFS Capacity (Pcs/hour)
2R	4500	1 ml	4500
6R	2100	2.25 ml	4500
10R	1500	3 ml	4500
20R	720	5 ml	3300
50R	450		

12.
ADC DP Filling & Lyophilization

A dedicated ADC DP filling line is equipped with an aseptic isolator that meets OEB 4 & 5 requirement. The filling line is capable for the processes of filling, lyophilization, capping and outer wall cleaning. It is also fitted with a world-leading KYOWA (Japan) Brand lyophilizer, and achieves 100% online IPC, which is more suitable for the aseptic filling of ADC drug products.

Vial Size	Liquid Capacity (vials/hour)	$5m^2$ Lyo Capacity (vials/batch)
2R	3600	23000
6R	3000	12000
10R	3000	10000
20R	2400	6400
50R	1200	3500

A Customer-Centric, Innovative, and Reliable CDMO with Global Solutions

Root, Switzerland
Office

Shanghai 1, Minhang
Payload-Linker PD Center
- OEB 4 & 5
- 50 L
- Pre-clinical to Tox Batch

Shanghai 3, Fengxian
Payload-Linker GMP MFG
- OEB 4 & 5
- 200 L
- Phase I to Commercial

Shanghai 4, Waigaoqiao
Biologics PD & GMP MFG
- Antibody (200 to 500 L)
- Bioconjugation (10 to 200 L, OEB 5)
- Pre-clinical to Phase II

New Jersey 2, Cranbury
Payload-Linker PD & GMP MFG
- Payload-Linker (10 to 100 L, OEB 4 & 5)
- Pre-clinical to Commercial

Your Reliable Partner

One-stop ADC CDMO Platform
- Chemical & Biological Capabilities
- Better Supply Chain and Cost Control

Professional
- Experienced Technical Team with ADC IND, Late Stage, BLA Experience
- Global Customer Service Experience

Reliable
- Global Standard Quality and EHS System
- Pure CDMO, Strict IP Protection System

Speed
- Efficient Internal Collaboration and Quick Response
- Customer Centric Project Management

Operational Excellence: IP | QA | EHS | RA | PM | Supply Chain

Global Site Compliance: FDA U.S. FOOD & DRUG ADMINISTRATION | World Health Organization | EUROPEAN MEDICINES AGENCY | pmda | 国家药品监督管理局 National Medical Products Administration

Enabling the Public's Early Access to Good Medicines

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