

# ASEPTIC PROCESSING FOR YOUR INJECTABLES



Aseptic environment from clinical development  
to commercial production

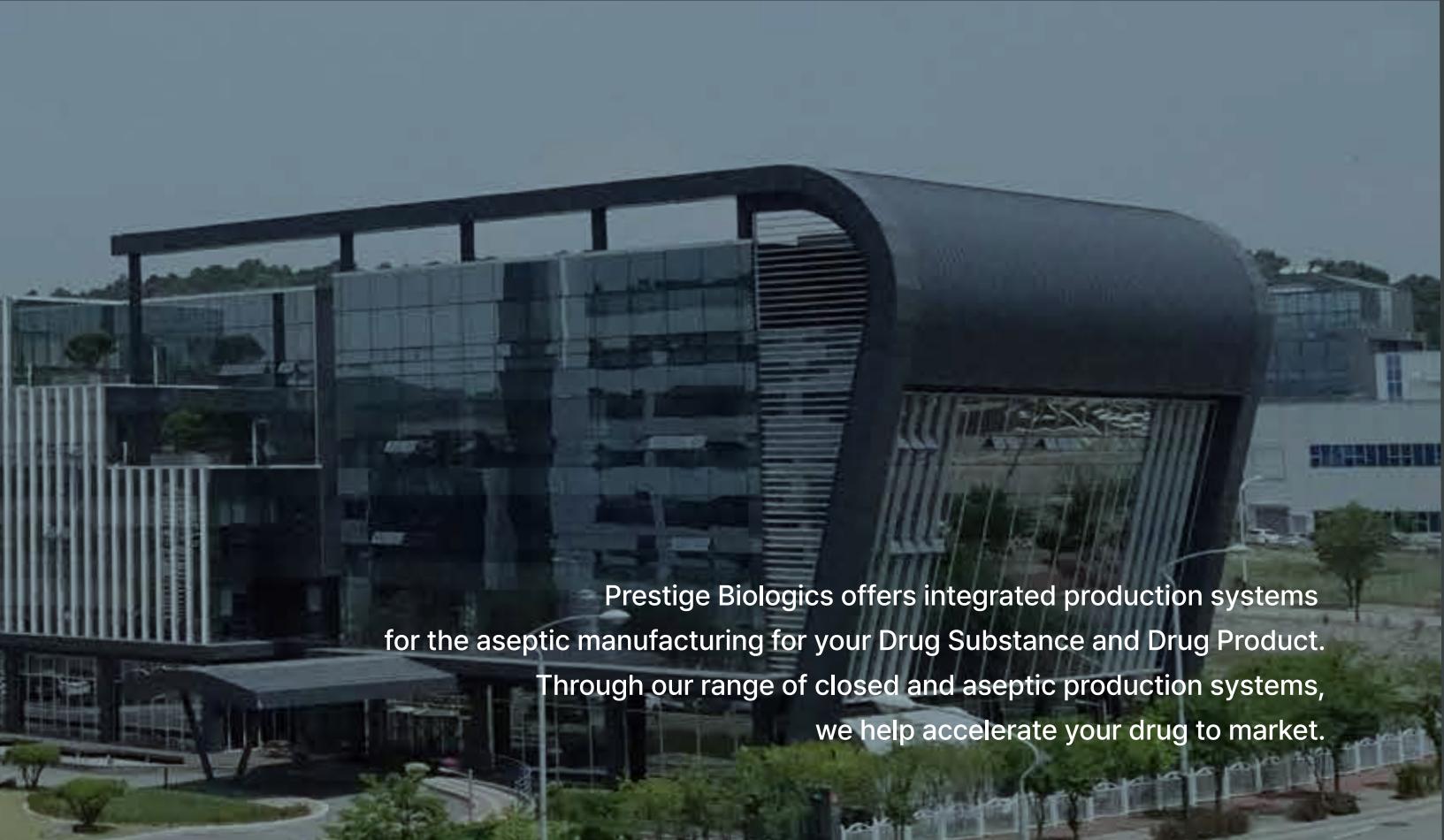
# COMPREHENSIVE SUPPORT OF THE ASEPTIC DRUG PRODUCT



## Integrated connectivity and independent closed manufacturing environment in Plant 2.

A highly flexible production facility enabling rapid and exceptional connectivity as well as independent manufacturing.

1F	2F	3F
DS Manufacturing Suite #1 (8 x 2000L), Utilities	DS Manufacturing Suite #2 (Downstream)	DS Manufacturing Suite #2 (Upstream, 6 x 2000L)
	QC Lab, Warehouse	
	<b>Clinical DP</b> Manufacturing	<b>Commercial DP</b> Manufacturing with Automatic Packaging System (for liquid vials)



Prestige Biologics offers integrated production systems for the aseptic manufacturing for your Drug Substance and Drug Product. Through our range of closed and aseptic production systems, we help accelerate your drug to market.

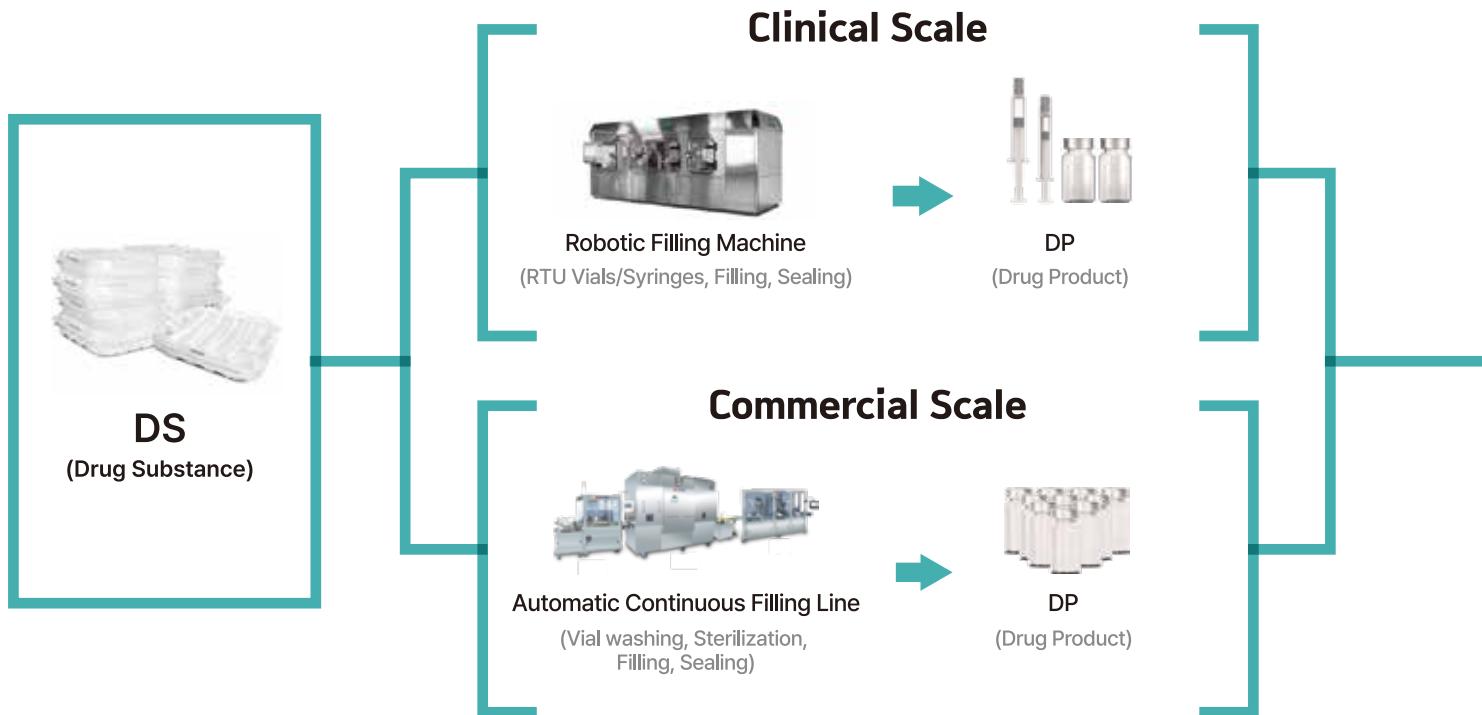
## Drug Product capacity

Location	Osong Biocluster, Korea	
Site Area	6,681	
Building Area	3,788	
Floor Area	11,530	
Clinical DP Fill	25 vials/min (vial, syringe)	Robotic Filling Machine
Commercial DP Fill	200 vials/min (vial)	Continuous Filling Machine
Vial Packaging Line	200 vials/min (vial)	

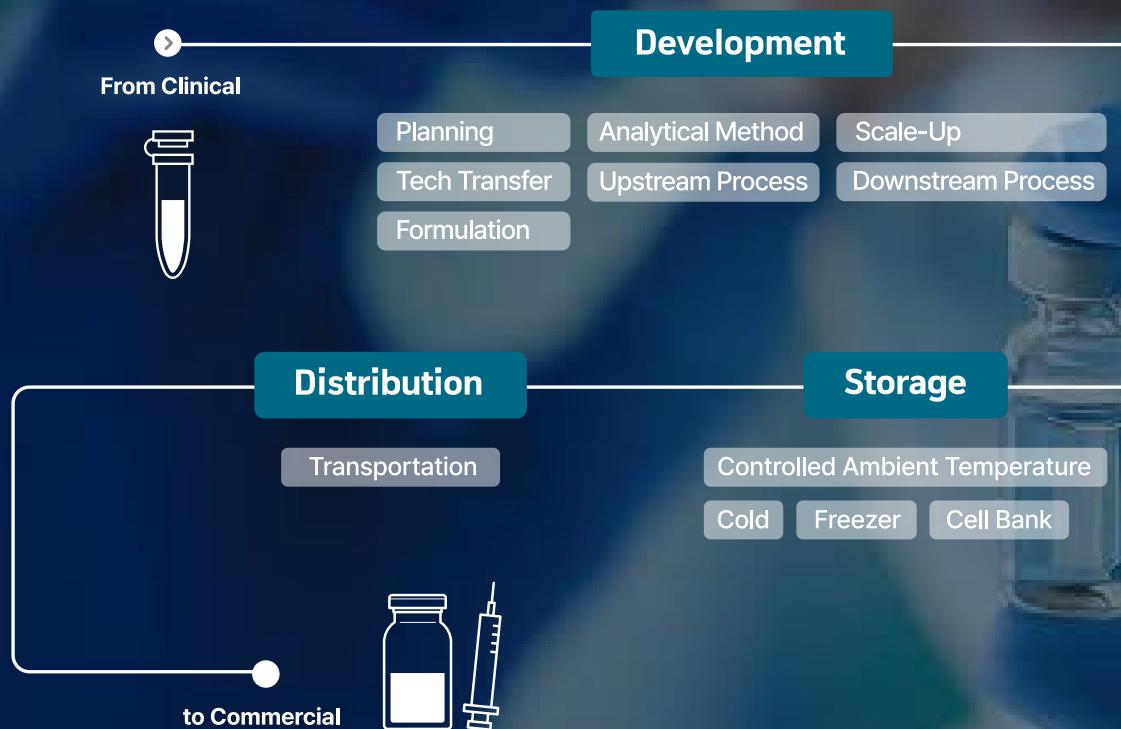
## Drug substance capacity 154,000L

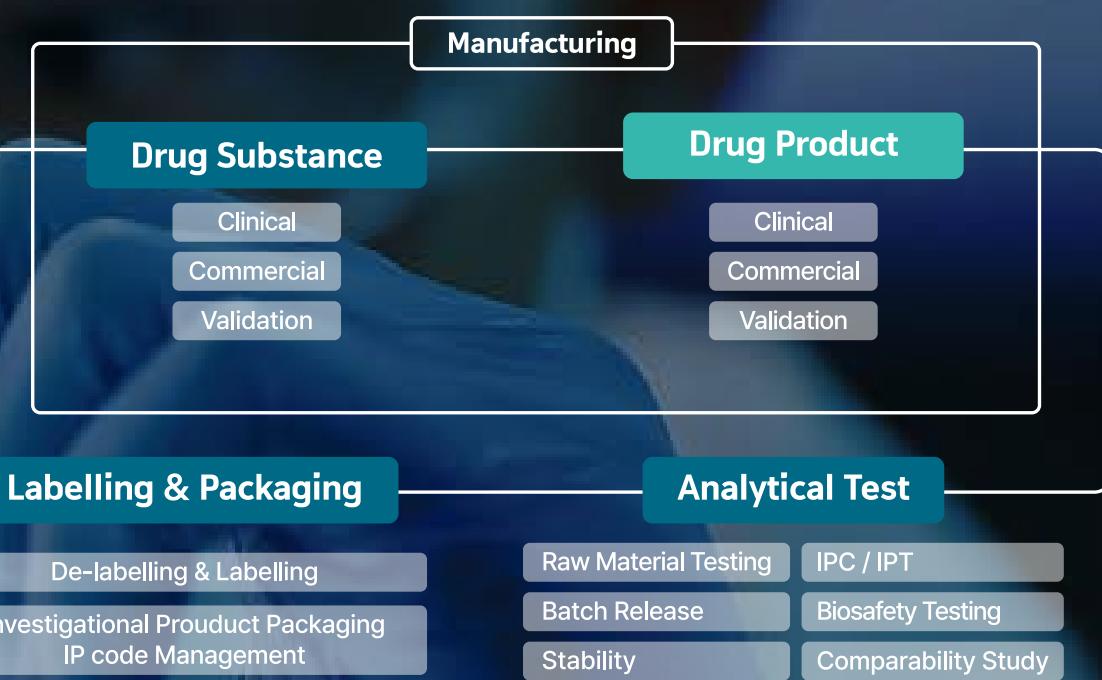
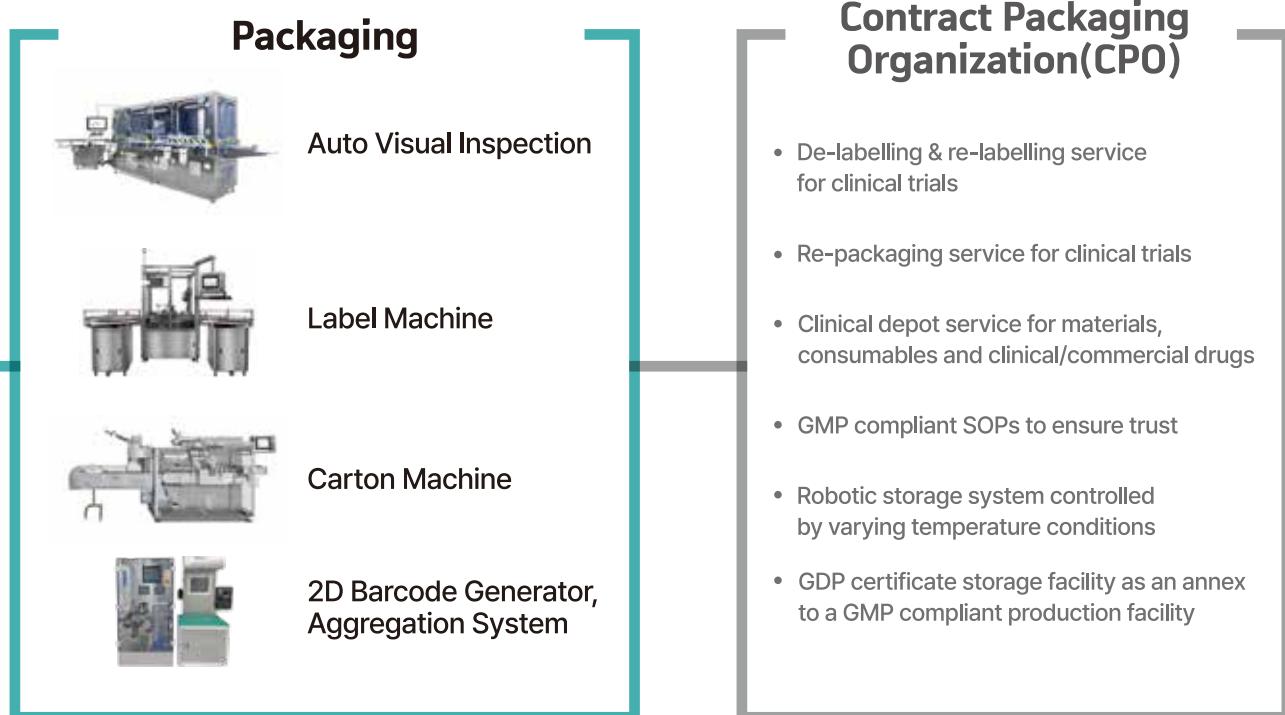
PLANT 1	PIONEER	PLANT 2	FRONTIER	PLANT 3	VOYAGER	PLANT 4	ADVANTURE
							
	6,000L		28,000L		88,000L		32,000L

# DP Manufacturing Packaging Process



## Integrated One-Stop Service





# CLINICAL TO COMMERCIAL MANUFACTURING

## Clinical Scale

### Robotic Filling Machine

- Minimizing Human Risk
- 100% Automatic IPC

### Aseptic Process in Isolator

- Closed System

### Less Workload

- Reduction Preparation Step
- RTU material used

### Less labor

### Flexibility

- Vials & Syringes available



Robotic Filling Machine



Aseptic Process in Isolator

## Development & Clinical Service

- Aseptic Filling Workcell supporting flexible vial, syringe, and cartridge filling
- GMP compliant isolated filling system
- Formulation support
- Process Development
- Clinical trial manufacturing for Drug Product
- Analytical test service
- Regulatory support

Preclinic

IND

Phase I, II, III

## Commercial Manufacturing

- Fill & Finish
- Analytical test service
- Regulatory support
- GMP compliant DP system
- Flexible DP systems supporting a wide variety of specifications
- Risk-reduction through closed environmental management
- Filling capacity that meet international market demands

NDA

Approval

Market access

# TECHNICAL SERVICES PROVIDING RELIABLE QUALITY ACROSS VARIOUS SPECTRUM



Full Automatic & Continuous process



Flexibility

## Commercial DP

### Full Automatic & Continuous process

- Suitable for Commercial Scale
- Automatic IPC
- Less workforce

### Single-use Assembly with Peristaltic pump

- CIP not required

### Flexibility

- 2R, 6R, 20R, 25R vials available

## Packaging Solutions

- Customized packaging development
- Advanced technology
- & platform for customer-centric support
- Packaging services
- Stable logistic services

( CPO : Contract Packaging Organization )  
**CPO service for Clinical trials / Clinical depot**

- De-labelling & re-labelling under GMP compliant environment
- Re-packaging service for clinical trials
- Fast & safe logistic services
- Clinical depot services with GDP storage facility as an annex of GMP compliant facility

Customized supporting system

Clinical trials

Clinical depot for supply chain

# Technological expansion

## Robotic Filling Machine for clinical scale

Equipment	Robotic Filling Machine
Manufacturer	Vanrx (Cytiva)
Model	SA-25 Aseptic Filling Workcell
Specification	
Capacity	25 vials/min (vial, syringe) *Clinical DP Filling Capacity
Barrier	Isolator
IPC	100% IPC
Fill Path	Single-use with peristaltic pump
Special Note	Robot handling system in Isolator
Container	RTU Vial, Syringe



## Accelerating your clinical development through small scale production

With our closed systems that comply with all cGMP standards, we can quickly and flexibly serve clinical or small-scale production needs.

# for end-to-end quality service

## **Vial Filling Line** for vial washing, sterilization, filling & capping

Equipment	Vial Filling Line : vial washing, sterilization, filling, & capping
Manufacturer	HD Pack (Korea)
Model	Ultrasonic Washing Machine (HDVUW-400) Sterilizing & Dry Tunnel Machine (HDSDT-400) Liquid Filling & Rubber Stopper Machine (HDFS-400) AL-CAP Machine (HDACS-400)
Specification	
Capacity	200 vials/min
Barrier	O-rabs
IPC	1% IPC
Fill Path	Single-use with Peristaltic pumps (8 nozzles)
Container	Bulk vial: 2R, 6R, 20R, 25R



## Thinking of safety & quality

Safety and quality are our top priorities. Through strict hygiene and environmental controls, cGMP-compliant facilities and science-based SOPs, we achieve our goals related to employee safety, contamination risk control and product quality assurance.

# Technological expansion

## Visual Inspector

Equipment	Visual Inspector
Manufacturer	Stevanato Group Optrel (Italy)
Model	Plus 400 LKD Vials
Specification	
Capacity	max. 400 vials/min
Particle Inspection	for low & high viscosity products
Floating Particle Inspection	
Alu Seal Inspection	
Flip-off Inspection	
Container	2R, 6R, 20R, 25R vials



## Aseptic manufacturing system and closed environment

We establish a closed environment for the production system to minimize the risk of contamination and protect the health of workers. We implement robotic systems and rational process design to minimize contact between workers and products/equipment. We believe that by achieving the goals of worker safety and health, we can consistently meet the rigorous control requirements for quality demanded by cGMP.

# for end-to-end quality service

## Packaging System

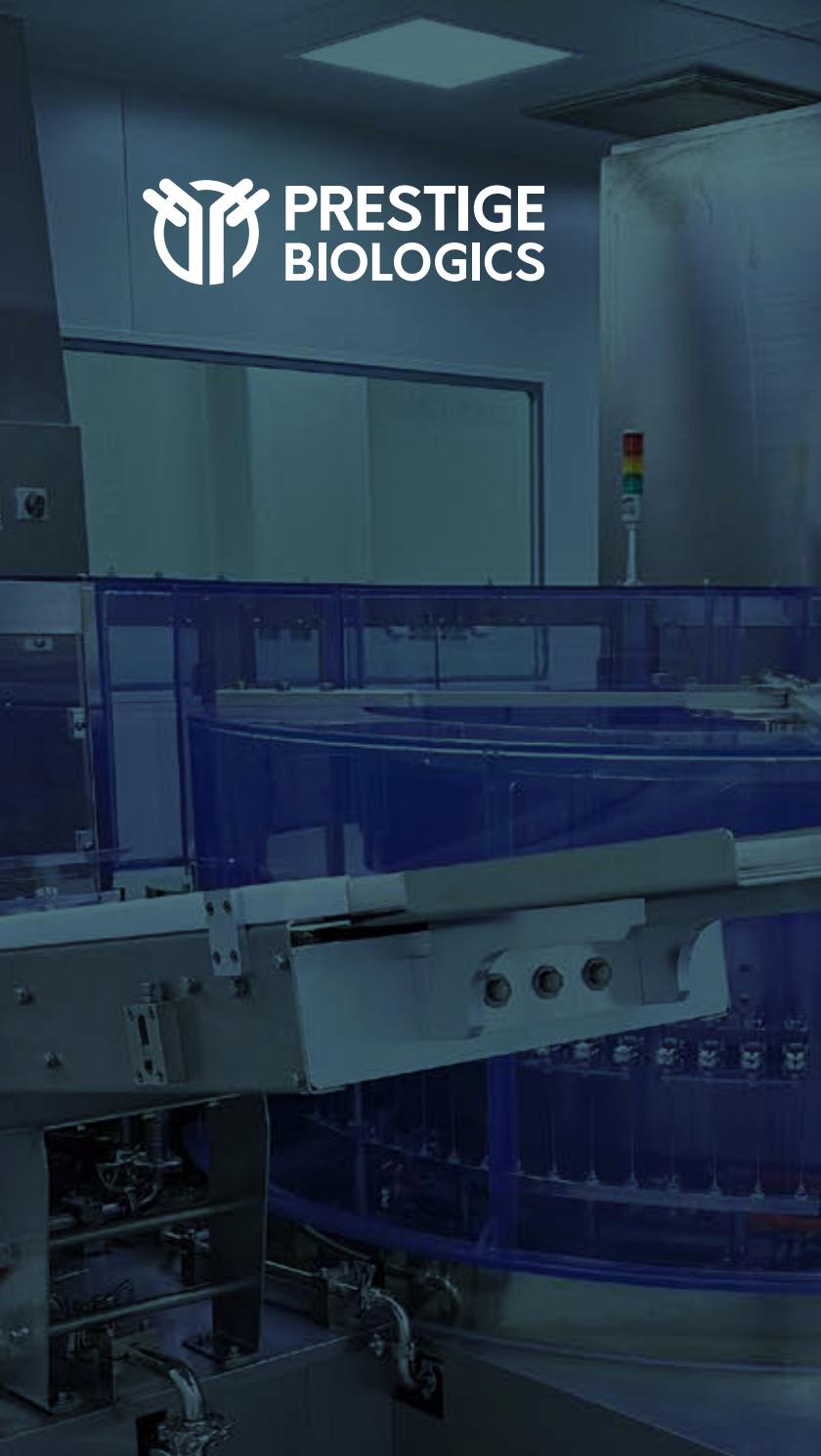
Equipment	Packaging System
Manufacturer	SUNJIN, Hoonga, Tasco (Korea)
Model	Vial Labeler (SP-3300W) Vial Cartoner (HC100(L)) Barcode Generation & Aggregation System (TCM-300/MT-250)
Specification	
Vial Cartoner Capacity 100 vials/min Automatic Conveyor System	
Container	Bulk vial: 2R, 6R, 20R, 25R



## Environmental & Social Responsibility (ESR)

We are committed to corporate social responsibility beyond regulations. We believe that by respecting diversity and inclusion, we can achieve our shared goal of solidarity in the industry. "We strive to collaborate with partners in the supply chain ecosystem to make a positive impact on people and the environment. Our ESR pillars are focused on:

Corporate transparency   Business sustainability   Employee and family health  
Environmental conservation efforts   Shared growth with stakeholders



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