FREEZE DRYER
for PHARMACEUTICAL & BIO SCIENCE/FOOD INDUSTRY
FREEZE DRYER 50 to 300kg/Batch
for PHARMACEUTICAL

[ Pharmaceutical Plant ]
Industrial Scale Freeze Dryer with automatic loading/unloading system

Lyoph–Pride SCM series provide satisfaction for specific customer’s needs. SCM series are designed upon various user requirements complying with eGMP and cGMP. From small scale to large scale, SCM series perform ultimate completion of freeze drying with uniformity and efficiency. Verified in–house technology of Cleaning in place and Sterilization in place guarantees perfect execution and SCADA control provides precision of standard control complying with 21 CFR11.

Being a great partner of your successful future, authentic full–automated loading/unloading system of ILSHIN BIOBASE shall improve your productivity.

SPECIFICATION
LP50-300 SCM SERIES

Process Control
1. Lyophilization process
   CIP → SIP → Loading → Freezing → Primary Freezing → Secodary Freezing
2. Manual control: Pre–Freeze ~1st/2nd Drying process parameter setup. Process is completed manually by user verification
3. Automatic control: Select recipe. Parameters of Pre–Freeze ~1st/2nd Drying process are automatically setup.
   Process is completed by P–rise test system inside of chamber after whole process is finished

Recording parameters
Sample temperature/shelf temperature/Condenser temperature/
CIP, SIP data/Vacuum level

Drying Chamber
1. Surface roughness: Less than 0.4 μm
2. Cooling speed: Within 60 minutes from 20℃ to −40℃ (1℃/min)
3. Shelf temperature uniformity: Less than ±1.5℃

Cold Trap Chamber: Condenser
1. Cooling speed: Within 30 minutes from 20℃ to −70℃

Vacuum System
1. Pull down time: Within 45 minutes from 760Torr to 100mTorr. Lower than 20mTorr eventually
2. Primary Vacuum Tester:
   Automatic vacuum tester before starting freeze drying process
3. Protection for Vacuum Pump:
   Automatic gas ballast system for protection from condensation and oil contamination

Remark
(1) SCM
   SCM stands for Stoppering, CIP and SIP: premium full function series
(2) BGMP/cGMP/SCADA
   - eGMP (Bulk Good Manufacturing Practices): standard of process and quality control complying with pharmaceutical material production requirements
   - cGMP(Current Good Manufacturing Practice): standard of quality control on pharmaceutical goods by the US FDA (Food and Drug Administration)
   - SCADA(Supervisory Control And Data Acquisition): Supervisory Control And Data Acquisition
(3) CIP testing method
   - Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device.
Main
Selection between Auto and Manual mode. Alarms, Lamp, Temperature set up are displayed. Entire process time, shelf temperature, cold trap temperature, vacuum level is monitored. The whole progress is visually monitored.

Progress
Current status must be monitored. Any event must be recorded and reported. Program status is displayed.

Setting
User can set up its own recipe step by step with each parameter along with duration of time. Programs can be saved so each recipe can be chosen by user anytime.

Auto loading/unloading system
Automatic shelf control is available. Both manual and automatic process can be selected for user’s convenience.

BLACK BOX
GLOBAL REAL TIME CARE SERVICE

IoT remote monitoring service
Internet of things technology, 24/7 monitoring service by manufacturer’s server as well as user’s smart phone. Real time diagnosis and data keeping.

Proactive service
Process data can be monitored all the time by smart phone application. Any incident shall be reported to authorized manager and service action can be instructed without visiting installation site. *App. OS: Android 2.3 (Gingerbread or latter), IOS 9.2 or latter.

Command room data monitoring
- Temperature: Sample, shelves, condenser, refrigeration system
- Pressure: Vacuum, chamber
- Alarms: Sensor failure, condenser overheat, over current, oil circulation failure, motor overheat, heater malfunction, condenser temperature error, vacuum failure, heat media circulation problem
- General data: Process status including pre-freezing, vacuum status, 1st or 2nd drying process

*Refer to page no.16 for more details.
DETAIL & FEATURES
for PHARMACEUTICAL

Spiral oil path plate
Less than RA 0.4㎛ surface roughness spiral design plate shelves provide the best efficiency and uniformity of temperature by internal heat exchange. Cooling from 20℃ to -40℃ less than 60 minutes by degree of 1℃. Uniformity of shelf temperature convinces reliable drying quality of samples.

Automatic Pizza-Door System
Minimizing chance of contamination from external atmosphere during loading/unloading process as well as energy loss by automatic control of Pizza door.

Stoppering system
Sealing is completed under vacuum condition (0.3mBar) automatically.
- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/㎠

Condenser Chamber
- STS316L interior
- Overlap door system for monitoring condensing process
- Low as -85℃ condenser temperature
- Cooling speed is within 30 minutes from 20℃ to -70℃
**Defrost system**

Prompt and efficient defrosting process by combination of steam and hot water with hot gas solenoid method. Process completes within 60 minutes.

**SIP (Sterilization In Place)**

- Sterilizing temperature at 122°C with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour

**CIP (Clean In Place)**

- RO water: 0.001~0.0001㎛
- Operating condition: +50 ~ +90°C, 2~5kgf/cm²
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device

**Vacuum system**

- Primary Vacuum Tester is equipped for automatic testing on vacuum status before freeze drying process.
- Pull down time: within 45 minutes from 760Torr to 100mTorr. Eventually maintained lower than 20mTorr
AUTOMATIC LOADING/UNLOADING SYSTEM (Row By Row)

1. Loading System
   1) Loading Array Device
   2) Vials Stopper Device
   3) Vials Positioner Counter Device
   4) Docking Device
   5) Buffering Device

2. Loading/Unloading Device

3. Pusher Device

4. RABS/cRABS/Isolator (option)

5. Flexible liner

6. Automatic Pizza Door

1. 1) Loading Array Device
   Vials are safely lined up and standby at buffer zone before and after drying process.

1. 2) Vials Stopper Device
   Complete sealing with rubber cap is executed without chance of contamination from external atmosphere.
1. 3) Vials Positioner/Counter Device
Specially designed vial location controller and positioner with photo optical sensor. Precision control is guaranteed with 0% counter error rate.

1. 4) Docking Device
Within ±0.1 mm deviation, docking device insures safe and precise transportation between shelves and conveyor belt.

1. 5) Buffering Device
Buffer device provides enough space for vials in order to maintain optimal flow of production process without chance of congestion or over filling.

2-1. Loading Device
Loading device lines up vials from conveyor belt and delivers through bridge by cylinder.

2-2. Unloading Device
Unloading device brings vials back to conveyor belt by cylinder.

3. Pusher Device
Pusher system moves vials between shelves and conveyor belt by docking device before and after drying process without chance of error.

4. RABS/cRABS/Isolator (option)
Contamination protection system to guarantee germ/bacteria free production.

5. Flexible liner
Flexible liner provides flexibility on vial transportation: from 2 ml to 100 ml.

6. Automatic Pizza Door
Automatic pizza door minimizes the exposure to external atmosphere during loading/unloading. Less chance of contamination and less energy consumption.

Row By Row Method
Comparing to AGV method, row by row type requires less space. Convenient maintenance and economical management bring more benefit to customers.
Plant Type Lyophilizer

Industrial scale freeze dryer for Bio/food application. Equipped with high quality stainless interior/exterior, automatic process program with various recipes, powerful refrigeration system and low energy consumption, Bio/food plant type lyophilizer is optimal solution for your application on probiotics, extract mixture, functional food and long term storage adaptation.

SPECIFICATION

LP50-500 SERIES

**Process Control**

1. Lyophilization process
   Loading → Freezing → Primary Freezing → Secondary Freezing
2. Manual control: Pre-Freeze → 1st/2nd Drying process parameter setup. Process is completed manually by user verification
3. Automatic control: Select recipe. Parameters of Pre-Freeze → 1st/2nd Drying process are automatically setup. Process is completed by P-rise test system inside of chamber after whole process is finished

**Vacuum System**

1. Pull down time: Within 45 minutes from 760Torr to 100mTorr. Lower than 20mTorr eventually
2. Primary Vacuum Tester
   Automatic vacuum tester before starting freeze drying process
3. Protection for Vacuum Pump
   Automatic gas ballast system for protection from condensation and oil contamination

**Recording parameters**
Sample temperature/shelf temperature/Condenser temperature/CIP, SIP data/Vacuum level

**Drying Chamber**

1. Surface roughness: Less than 0.4 μm
2. Cooling speed: Within 60 minutes from 20°C to -40°C (1°C/min)
3. Shelf temperature uniformity: less than ±1.5°C

**Cold Trap Chamber: Condenser**

1. Cooling speed: Within 30 minutes from 20°C to -70°C
2. Defrosting System
   Hot gas solenoid method. Fast defrosting by steam and hot water
CONTROL SYSTEM
10 to 12" TFT LCD TOUCH SCREEN - PLANT SERIES

Main
Selection between Auto and Manual mode. Alarms, Lamp, Temperature set up are displayed. Entire process time, shelf temperature, cold trap temperature, vacuum level is monitored. The whole progress is visually monitored.

Progress
Current status must be monitored. Any event must be recorded and reported. Program status is displayed.

Setting
User can set up its own recipe step by step with each parameter along with duration of time. Programs can be saved so each recipe can be chosen by user anytime.

IO Test
Each compartment of equipment is tested by sending electric signal for monitoring the process and functionality.

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Proactive service
Process data can be monitored all the time by smart phone application. Any incident shall be reported to authorized manager and service action can be instructed without visiting installation site. *App. OS: Android 2.3 (Gingerbread or latter), IOS 9.2 or latter.

Command room data monitoring
- Temperature: Sample, shelves, condenser, refrigeration system
- Pressure: Vacuum, chamber
- Alarms: Sensor failure, condenser overheat, over current, oil circulation failure, motor overheat, heater malfunction, condenser temperature error, vacuum failure, heat media circulation problem
- General data: Process status including pre-freezing, vacuum status, 1st or 2nd drying process

*Refer to page no.16 for more details.
**Spiral oil path plate**

Less than RA 0.4㎛ surface roughness spiral design plate shelves provide the best efficiency and uniformity of temperature by internal heat exchange. Cooling from 20℃ to -40℃ less than 60 minutes by degree of 1℃. Uniformity of shelf temperature convinces reliable drying quality of samples.

**Drying Chamber**

- STS304
- Vessel pressure standard: qualified chamber under vacuum gauge pressure lower than 5x10⁻³ Torr
- Illuminator is installed for visual inspection of inside of chamber

**Automatic Door Lock**

Complete sealing and vacuum protection are guaranteed by hydraulic power one touch door lock system.

**Condenser Chamber**

- STS316L interior
- Overlap door system for monitoring condensing process
- Low as -85℃ condenser temperature
- Cooling speed is within 30 minutes from 20℃ to -70℃
### SIP (Sterilization In Place)
- Sterilizing temperature at 122°C with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour

### CIP (Clean In Place)
- RO water: 0.001~0.0001㎛
- Operating condition: +50~+90°C, 2~5kgf/cm²
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device

### Defrost system
Prompt and efficient defrosting process by combination of steam and hot water with hot gas solenoid method. Process completes within 60 minutes.

### Vacuum system
- Primary Vacuum Tester is equipped for automatic testing on vacuum status before freeze drying process.
- Pull down time: within 45 minutes from 760Torr to 100mTorr. Eventually maintained lower than 20mTorr
# SPECIFICATIONS

for PHARMACEUTICAL & BIO SCIENCE/FOOD INDUSTRY

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<thead>
<tr>
<th>Pharmaceutical Industry</th>
<th>LP50</th>
<th>LP100</th>
<th>LP200</th>
<th>LP300</th>
<th>LP500</th>
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<tr>
<td>Totally ice capacity</td>
<td>50 liters</td>
<td>100 liters</td>
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<td>Vial quantity (10ml Standard)</td>
<td>6,700 ea</td>
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<td>Shelf temperature</td>
<td>-45 to +80°C</td>
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<td>Shelf areas</td>
<td>3.2m² (0.4m²/EA)</td>
<td>6.4m² (0.8m²/EA)</td>
<td>13.2m² (1.2m²/EA)</td>
<td>19.8m² (1.8m²/EA)</td>
<td>33.6m² (2.5m²/EA)</td>
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<td>Shelf quantity</td>
<td>8 + 1</td>
<td>11 + 1</td>
<td>14 + 1</td>
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<td>Material</td>
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<tr>
<td>Shelf, Dimensions (WxDxH mm)</td>
<td>500 x 800 x 18</td>
<td>805 x 1005 x 18</td>
<td>1005 x 1205 x 25</td>
<td>1210 x 1510 x 25</td>
<td>1510 x 1650 x 25</td>
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<tr>
<td>Ext. Dimensions (WxDxH mm)</td>
<td>1450 x 2003 x 2140</td>
<td>1600 x 2415 x 2210</td>
<td>2970 x 2855 x 2160</td>
<td>3500 x 3390 x 2375</td>
<td>3516 x 4616 x 2347</td>
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<tr>
<td>Electrical</td>
<td>380/400/440/480V 3Ph 50/60Hz</td>
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<tr>
<td>Refrigeration system</td>
<td>7.5HP x 2EA</td>
<td>10HP x 2EA</td>
<td>30HP x 2EA</td>
<td>40HP x 2EA</td>
<td>30HP x 4EA</td>
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<tr>
<td>Vacuum Vol. (LPM)</td>
<td>841</td>
<td>1,600</td>
<td>4,000</td>
<td>6,680</td>
<td>14,000</td>
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Options

- (1) Pizza door with automatic loading/unloading system
- (2) Stoppering system
- (3) CIP system
- (4) SIP system
- (5) Loading/Unloading System
- (6) Dual-safety system
- (7) Isolation system
- (8) Monitoring system
- (9) Validation support

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*Feature in parenthesis is optional and selectable by customer. *Model name index: LP 200 S C M P U
OPTIONAL DESCRIPTION

GLOBAL REAL TIME CARE SERVICE

Option (1)
Automatic Pizza-Door System

Automatic pizza door minimizes the exposure to external atmosphere during loading/unloading. Less chance of contamination and less energy consumption.

Option (2)
Stoppering system

Sealing is completed under vacuum condition (0.3mBar) automatically.
- Stoppering devices are hydraulic cylinder and bellows type (anti-contamination)
- Hydraulic pressure: 70~110kgf/㎠

Option (3)
CIP (Clean In Place)

- RO water: 0.001~0.0001㎛
- Operating condition: +50~+90℃, 2~5kgf/㎠
- Automatic rotating spray nozzle method by water pressure
- Spray by Riboflavin solution (10g/L). After CIP process, no residue must be found by Ultra Violet device
- Providing a Chamber Drying after finished CIP process

Option (4)
SIP (Sterilization In Place)

- Sterilizing temperature at 122℃ with more than 20 minutes duration by steam from PSG (Pure Steam Generation)
- Air Pocket Exhaust more than 3 times
- Initial ventilation completes within 1 hour

Option (5)
Loading/Unloading system

1. Loading Integration System
2. Loading System
   1) Loading Array System
   2) Vials Stopper System
   3) Vials Position Half-shift System
   4) Flexible Bridge System
   5) Transition System
3. Unloading System
4. Unloading Integration System
5. RABS/cRABS/Isolator(option)

Option (6)
Dual-safety system

Dual safety system protects your production from any chance of failure with independent pre-freezing and refrigeration system. It brings best efficiency during production process and easy maintenance for long term use.

Option (7)
Isolation system

Butter fly or Mushroom type isolation protects system from any chance of cross over contamination by black out during process or condenser malfunction.
Option (8) Monitoring system

Internet of things technology, 24/7 monitoring service by manufacturer’s server as well as user’s smart phone. Real time diagnosis and data keeping are available.

*Refer to page no. 16 for more details.

Option (9) Validation support

Lyophilization requires precise control and management especially for sensitive samples. Based upon accumulated experience and GMP standard, ILSHIN BIOBASE shall bring successful solution with verified validation complying with user specification.

Why LP MASTER

Stability and credibility are first priority for biological and pharmaceutical application of freeze drying. Therefore precise and reliable control and monitoring are very critical for successful freeze drying process and such precise monitoring software must be required.

Our authentic monitoring/control software is designed to comply with FDA guideline with flexibility to meet various changes. It also gives abundant libraries to meet satisfactory compliance for user’s various requirements.

Software Library

- Process monitoring
  Comprehensive data supply through entire drying process allows you to have optimal condition and best recipe.
- Recipe management
  Automatic operation is available by selection of saved recipe that can be expanded further.
- Audit Trail: All data from system is traced and monitored.
- User Access
  Only authorized user can manage operation, control and monitoring by security library access.
- SCADA System
  Choice of data management and record management period are available.
- Vacuum Integrity Test Library
  Test on vacuum of chamber before drying process.
- Trend: Graphic data management of accumulated real time data (drying / SIP / CIP - Conductive)
Main Content of **MOBILE APPLICATION**

- **Main window**
  General view on operation status. Current process is indicated. Process data is displayed at real time.

- **Trend window**
  Variation of drying process is displayed. 24 hours previous trend can be reviewed.

- **Event window**
  Real time event is displayed for observation on any malfunction.

**QUALIFICATION & VALIDATION SUPPORTING**

- **Design verification**
  - Verification/documentation service for system design compliance with user’s requirement
  - Master plan support service for project
  - User’s requirement specification support service
  - Specification and design development service
  - Risk analysis service
  - Evaluation protocol support for design compliance

- **Operation verification**
  - Verification service for each operational condition and category
    * Evaluation protocol/execution support for operation compliance (Empty, Full—load, cooling, uniformity, etc)
    * Worst Case simulation service
    * CAPA (Corrective action & Preventive action) support

- **Installation verification**
  - Installation verification for design/functional specification
  * SOP development support
  * Evaluation protocol support for installation compliance
  * Calibration support service
  - Maintenance/training support service

- **Software system verification**
  - Software system verification for design/functional specification
  - Master plan support service
  - Protocol development for design/installation/operation compliance
  - Verification & validation on execution for design/installation/operation compliance
  - Program risk analysis support service
## Product Inquiry

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<thead>
<tr>
<th>Base</th>
<th>Address</th>
<th>Telephone</th>
<th>Fax</th>
</tr>
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<tbody>
<tr>
<td>Overseas Sales</td>
<td>Lee Jong Ho / Deputy General Manager – <a href="mailto:jhlee@1sbb.com">jhlee@1sbb.com</a></td>
<td>+82-70-4354-3951</td>
<td>+82-70-7950-3951</td>
</tr>
<tr>
<td>Department</td>
<td>84 Samyuksa-ro 548 Street, Dongduchon city, Kyungki do, Korea. ZIP 11341</td>
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## ilShinBioBase Locations

<table>
<thead>
<tr>
<th>Base</th>
<th>Address</th>
<th>Telephone</th>
<th>Fax</th>
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<tr>
<td>본사 및 생산</td>
<td>경기도 동두천시 삼육사로 548번길 84</td>
<td>031-867-1384</td>
<td>070-7950-3911</td>
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<td>서울/경기지사</td>
<td>서울특별시 중랑구 중랑천로 77</td>
<td>1577-4053</td>
<td>02-491-4073</td>
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<tr>
<td>수원지사</td>
<td>경기도 화성시 봉담읍 안당하리길 34</td>
<td>031-298-8147</td>
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<td>대전지사</td>
<td>대전시 유성구 테크노8로 58 1F</td>
<td>042-824-1145/6</td>
<td>042-824-1147</td>
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<td>영남지사</td>
<td>대구광역시 동구 동호로 75, 4F</td>
<td>070-4354-3977/5000</td>
<td>070-7950-3941</td>
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<tr>
<td>호남지사</td>
<td>광주광역시 광산구 신가삼효로 20-15</td>
<td>062-951-8010</td>
<td>062-951-8011</td>
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**Global website:** [www.1sbb.com](http://www.1sbb.com)