

***Tofflon***



## Tofflon Solutions for Probiotics Processing

Expertise in Biopharmaceutical

## About Tofflon

Tofflon is a comprehensive pharmaceutical equipment supplier. We provide a wide range of core equipment, integrated system, process support and pharma engineering for the pharma and biotech industry.

Found in 1993, Tofflon has supplied more than 8,000 equipment and systems for more than 2,000 pharmaceutical companies over 40 countries and regions around the world specializing in the field of liquid and lyo injectables, chemical API, bioengineering and pharma packaging, etc.



## Tofflon in Europe

Tofflon has been expanding in Europe for decades since 2007. And we have installed equipment and systems in Germany, Switzerland, France, Netherland, Britain, Italy, Spain, Portugal, Greece, Poland and Hungary, etc. Tofflon equipment and systems are designed and manufactured with EU cGMP, PED, CE, 21 CFR Part 11 and GAMP 5 compliance.

We have been working for more than 10 years as partner exhibitor in Achema (Frankfurt) and Interpack (Dusseldorf). We have established operation hub in Bergamo Italy to offer localized professional and rapid technical support and service for European customers.

For the coming years, Tofflon Technical Center and Local Competence Center will be established to further strengthen our support and service towards our customers. As your local and reliable partner, we aim to grow and work collaboratively with our customers together to achieve win-win success.



# Typical Requirements and Challenges for Probiotics Freeze Drying Manufacturing

## Product Quality

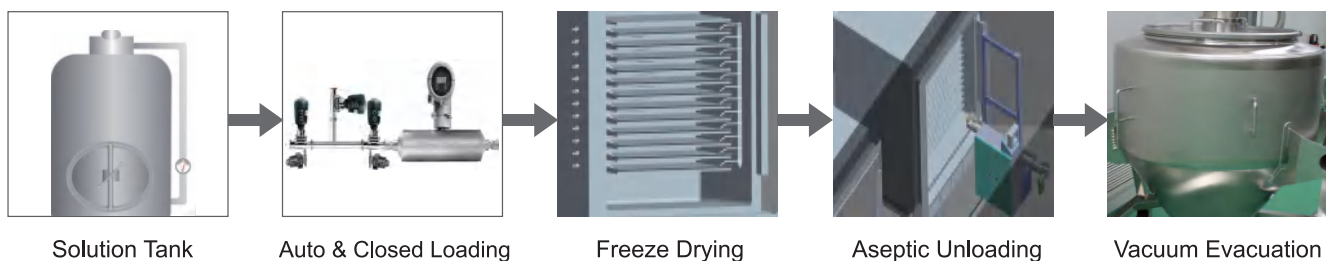
- High activity and stability

## Productivity & Automation

- Continuous processing and large-scale production
- The instantaneous sublimation of freeze-drying is immense hence the requirement for water condensation capacity is a challenge for the equipment configuration
- Sticky probiotics after freeze-drying is difficult to be discharged

## Contamination

- Aseptic material transfer process design to avoid cross-contamination
- During the freeze-drying process of probiotics, large amount of powder are generated which easily affect vacuum system



# Tofflon Innovative System Solution for Probiotics Freeze Drying Manufacturing

With Tofflon “Auto Loading + Trayless Freeze Drying + Aseptic Unloading” System, the probiotics solutions can be loaded into Tofflon Freeze Dryer with No Tray through a mass flow meter. The entire loading process is a closed system hence it minimizes the possibility of contamination. After freeze drying, the vacuum unloading system then aseptically transfers the probiotics powder into Intermediate Bulk Container. The whole process is fully automated and highly efficient.



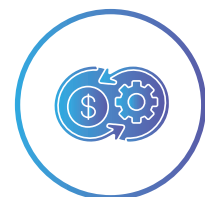
**Automation**  
Automated and isolated loading Solution



**Aseptic Process**  
Aseptic unloading by auto robot



**CIP&SIP**  
Fully automatic CIP and SIP System

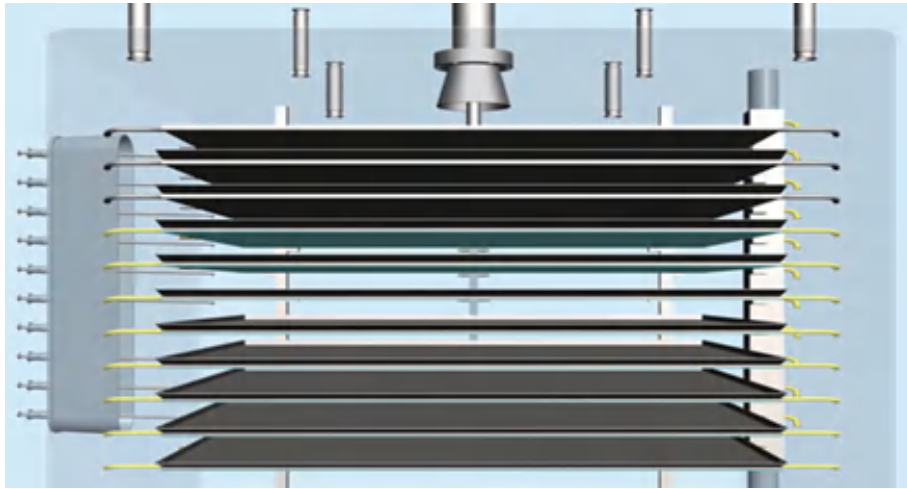


**Efficiency**  
Maintain your cost competitive and production efficiency

## Auto Loading System without Trays

For rapid and precise probiotics solution loading in the shelf of freeze dryer, the whole loading process is automatic and the door of freeze dryer keeps closed.

### Key Process 1: Automatic and Closed Loading



### Key Process 2: Aseptic Unloading



### Advantages:

- Automatic and closed loading instead of manual loading
- Precise and stable control loading
- Faster freeze drying cycle to increase productivity
- Aseptic unloading by auto robot instead of manual unloading



## Freeze Dryer (Shelf as a Tray)

As its patented technology, Tofflon Freeze Dryer (Shelf as a Tray) is developed specially for active and sensitive ingredient such as probiotics. With probiotics solution directly contacts with shelf, the freeze drying time could be reduced greatly. It is ideal for products with strict aseptic requirements during the production process.



### Advantages:

- No tray (shelf as tray) to avoid metal particle generation contamination coming from friction between shelf and tray
- Faster freeze drying cycle to increase productivity
- Guarantee aseptic unloading process
- Easy to clean and sterilize
- Sufficient ice capacity design to meet maximum sublimation demand
- Meet GMP recommendations and guidelines

## CIP & SIP

A high efficient Cleaning-In-Place (CIP) and Sterilization-In-Place (SIP) System is a critical aspect for process probiotics product which needs microbiological control and eliminate cross contamination.

The whole Tofflon system for freeze drying manufacturing is equipped with automatic cleaning and sterilizing function. It saves time, cleaning agent and water. It helps to enhance your productivity further.

## Process Support and Services



Tofflon Lyophilization Laboratory and our partners are always available to provide professional process support and service to our customers. Together we help our customers to resolve the challenges in probiotics production hence directly assisting our customers to improve their product quality, reduce production cost and increase production efficiency.

<b>Fermentation</b>	The number of viable bacteria in the fermentation broth is low
	The strain has poor freezing resistance
	Poor thermal stability of strains
<b>Centrifugation</b>	High water content of bacteria mud after centrifugation
	Strains die during centrifugation emulsification
	Decrease in pH
	Emulsion layering
	Strain death
<b>Lyophilization</b>	The survival rate of lyophilization is low
	Long freeze-drying cycle
	Poor thermal stability of bacterial powder
	The freeze-dried block has high moisture and water activity
	The lyophilized block has poor reconstitution effect and stratifies after reconstitution
	The freeze-dried block is hard and the bottom melts
	The freeze-dried block is seriously difficult to discharge
<b>Packaging</b>	Strains die during the crushing process
	Bacterial powder absorbs moisture
	Low stability of bacterial powder
<b>Finished Product</b>	There is big difference in the number of viable bacteria between different batches of bacterial powder
	Differences in other issues (moisture, solubility, etc.) between different batches of bacterial powder

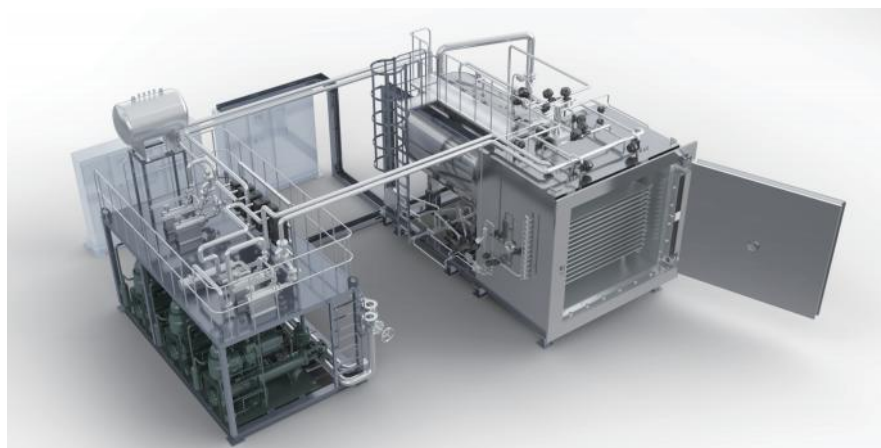
## Tofflon Service Solutions - Europe

As part of worldwide strategy, Tofflon proactively engages in all customer regions to provide rapid service support on site. We have established Regional Service Hub and develop service network in Europe to guarantee our professional and local service support towards our European customers.

With experienced local service team, the comprehensive and customized service portfolio can be offered to support our customers in achieving maximized potential output and improving production effectiveness.

### Our Service Expertise:

- Site Installation, Commissioning, SAT and Training
- Trial Batch Production Support
- On-site Repair by Local Service Organization
- Warranty Extension
- Remote Service
- Periodic Maintenance and Annual Maintenance Contract (AMC)
- Preventive Maintenance Program
- Customized Training Program
- Spare Parts Supply
- Modernization Through Upgrade and Refurbishment





## **Tofflon**

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