



***Tofflon***

**Containment OSD  
Modular Facility  
Catalogue**

EXPERTISE IN  
PHARMACEUTICAL

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## **/// Tofflon Containment OSD Modular Facility**



The pharmaceutical industry is recovering from the impact of the coronavirus epidemic. Oncology drugs remain a top focus in pharmaceutical research, leading to an increased need for high-potency solid medicines.

However, producing these high potent pills presents significant challenges for pharmaceutical companies. Normally, dedicated production equipment and facilities should be considered where high potent drugs are produced (eg. cytotoxic drugs), which takes lots of time and efforts. In addition, the whole OSD process is long and complex, involving steps like weighing, wet granulating, dry granulating, blending, tableting, capsule filling and packaging. Each step requires careful consideration of containment measures.

To address these challenges, we offer a comprehensive solution encompassing factory design and engineering, off-site construction, a modular facility specifically designed for producing high-potential OSD products, process skids, and containment equipment. Our flexible designs and innovative technology guarantee faster delivery and flawless outcomes to efficiently address the growing demands of the industry.

### **Design Concept**

Smaller area, faster construction, stand-alone facility

### **Capacity**

10~30 kg per batch or sub-lot

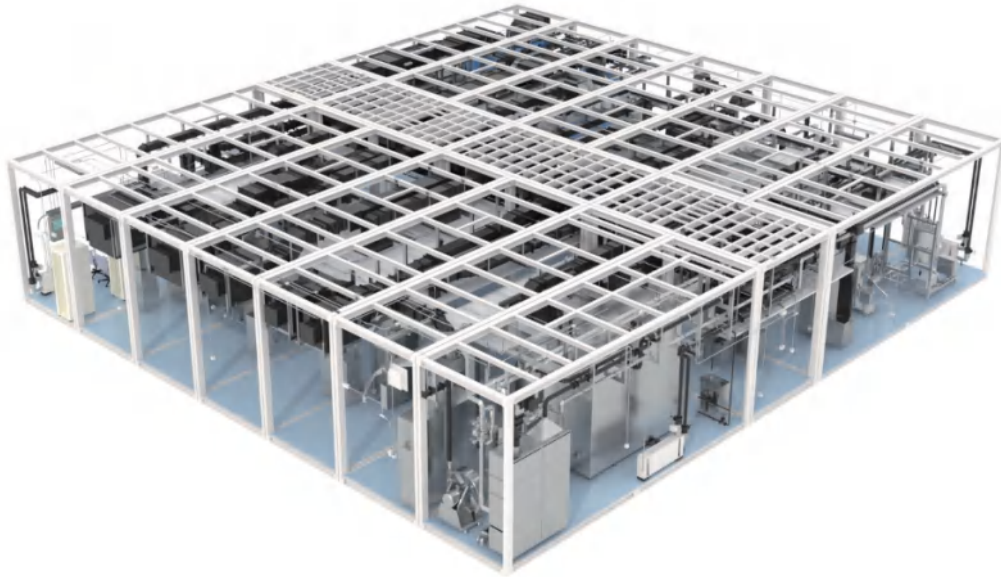
### **Applicable Scenarios**

Box-in-box, production of a high potent OSD drug

### **Total dimension( LxWxH )**

20.05 x 18.53 x 4.2(m)

## **/// Benefits of Tofflon Containment OSD Modular Facility**



### **From Project to Product**

- **Rapid deployment - Shortest delivery time**

Modular facilities are designed with a standardized design for faster construction, installation, and validation. Compared with traditional projects, it can save more than 50% of time, thus helping business units shorten the time to market and obtain higher market share and profits.

- **Process flexibility**

Modular facilities can be quickly adapted and flexibly scaled out according to demand, and can be adapted to different production needs.

- **Enhanced pre-qualification**

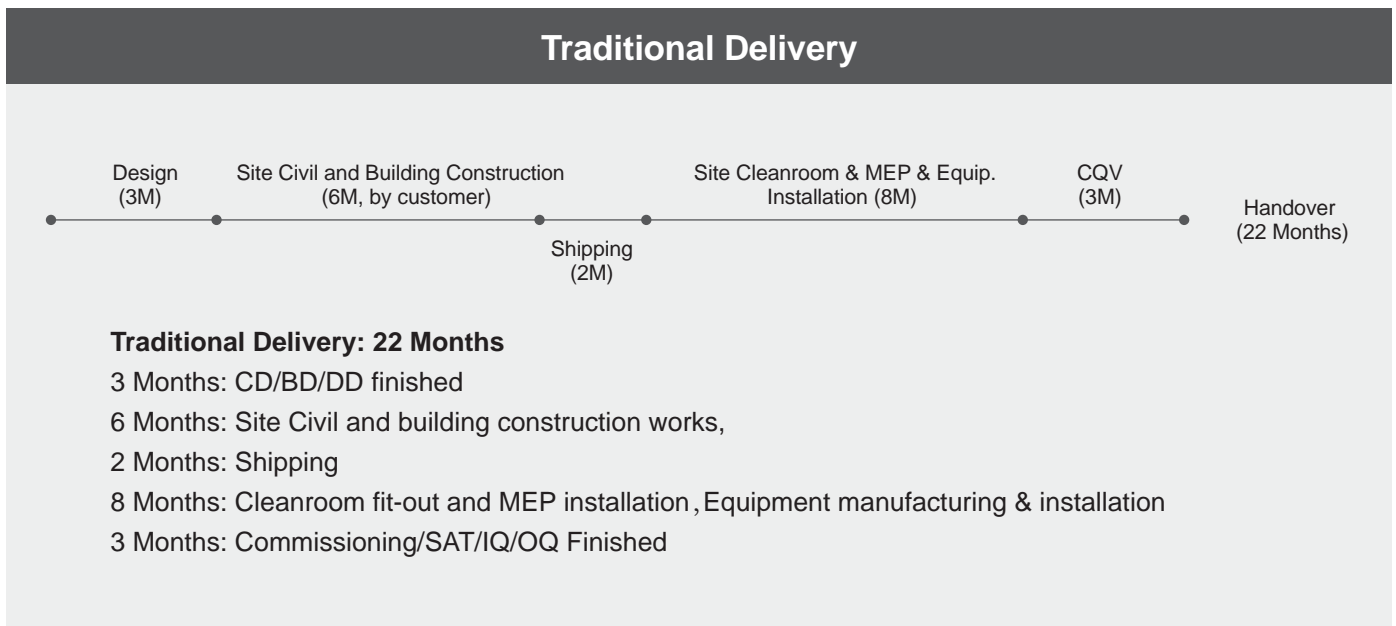
Modular facilities are built under factories' quality control system with in-house skilled labors. After assembly, the whole facility and equipment can be tested in the factory, ensure the consistency and stability of product's quality, and eliminate the extensive and time consuming qualification work at the production site.

- **Better regulation compliance**

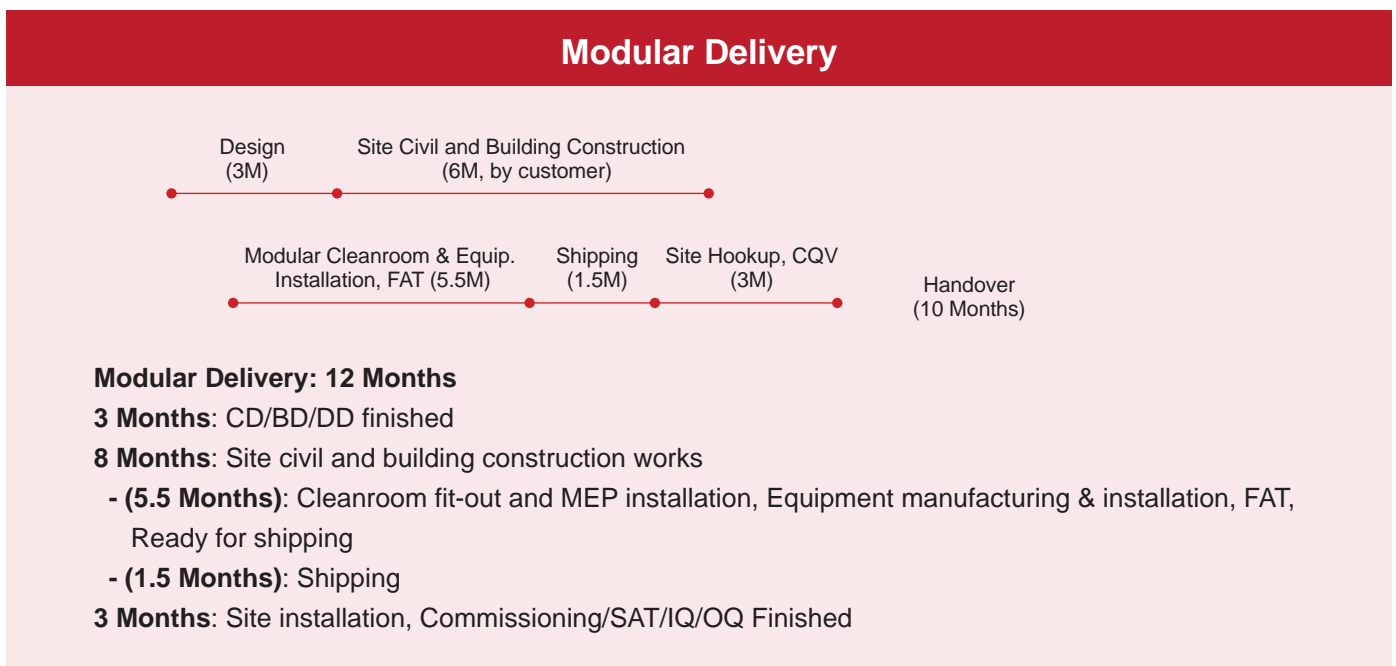
The modular facility uses advanced containment technology to reduce the impact on operators and the environment, even to meet most demanding regulatory requirement.

## Typical Project Timeline

### Modular VS Traditional



# VS

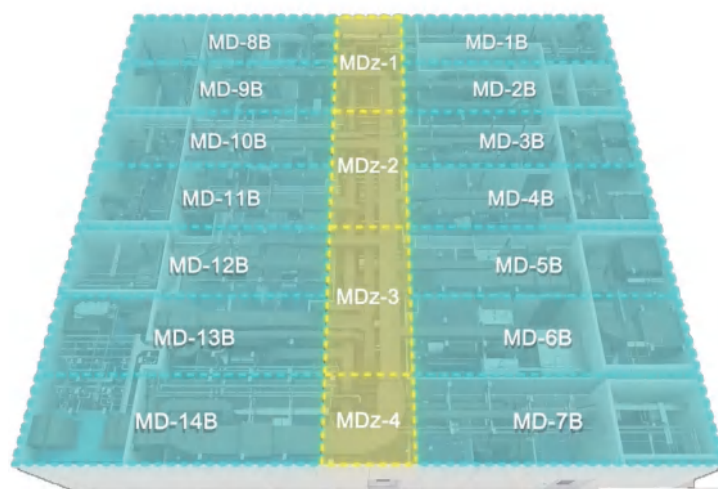


\* The time estimate is based on a typical project.

## Modular Facility Conceptual Design

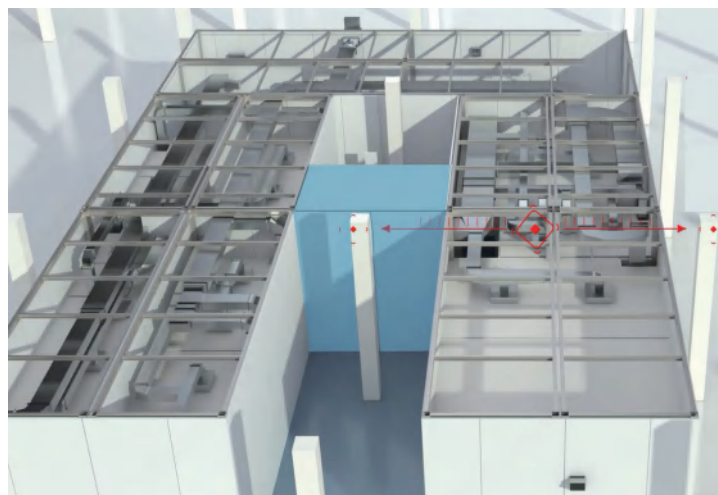
The facility typically contain 18 modules, including 4 modules for corridor area, and 14 modules for production area. Each production module will serve as dedicated function unit, which will be assembled and disassembled flexibly according to customer needs.

- Corridor Modules (4): MDz-1~MDz-4
- Production Modules (14): MD-1B-MD-14B

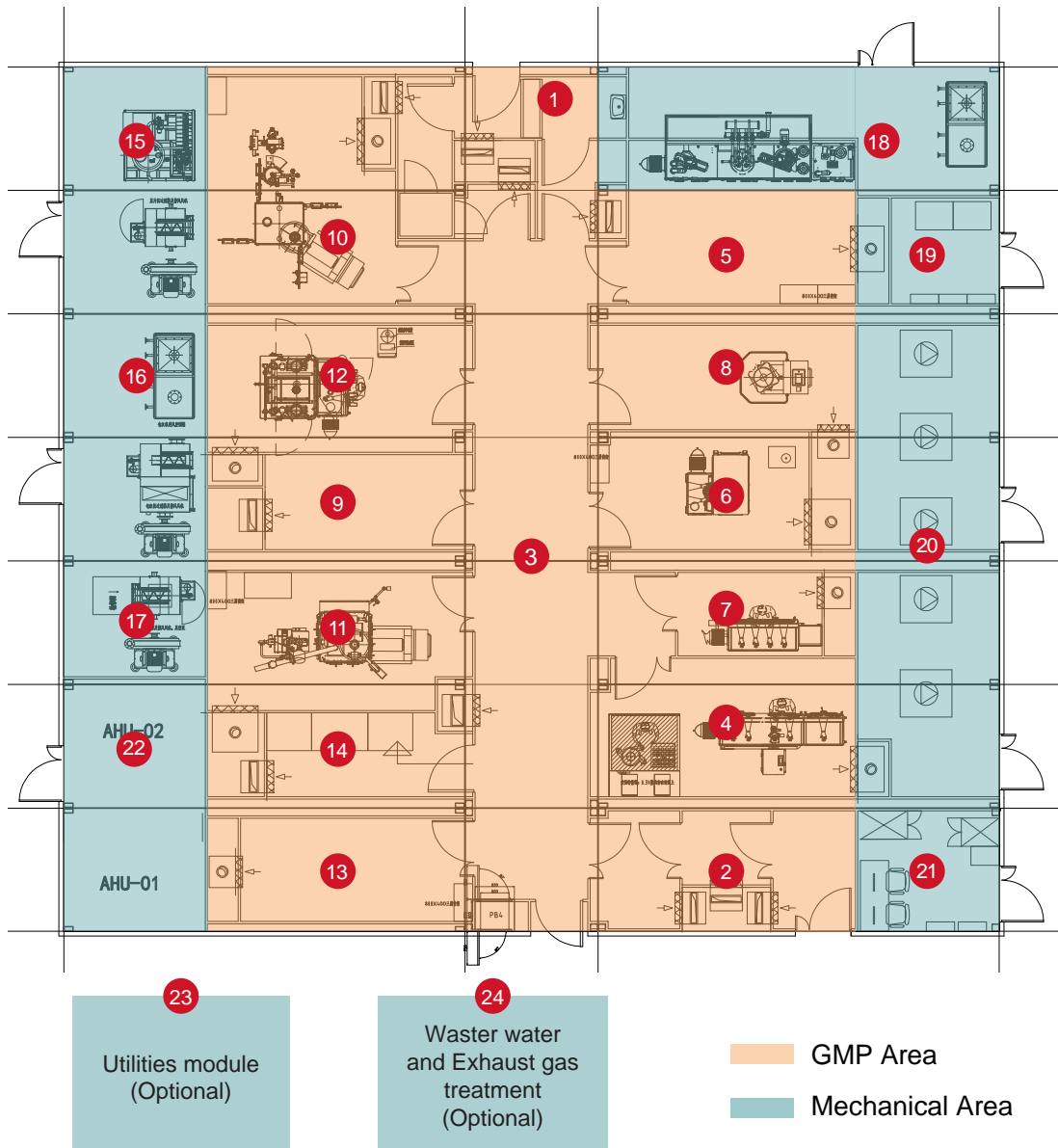


### Installation Flexibility

Modules are applicable for empty buildings without columns, and also applicable for buildings with columns, with maximum installation flexibility.



## Modular Facility Layout

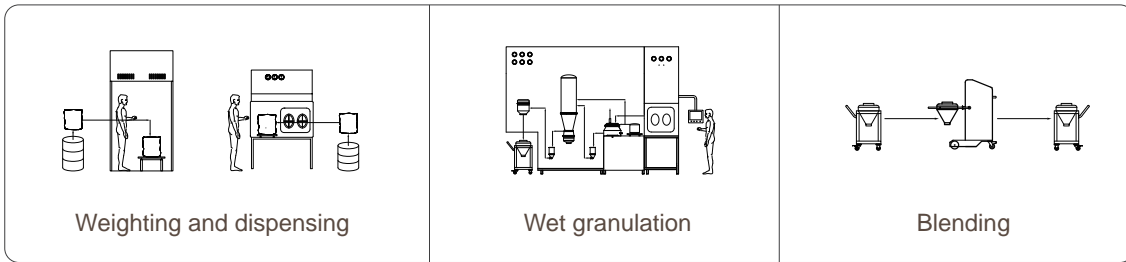


- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>1. Change room</li> <li>2. Material receiving &amp; storage</li> <li>3. Corridor</li> <li>4. Weighing room</li> <li>5. Wet granulation room</li> <li>6. Dry granulation room</li> <li>7. IPC room</li> <li>8. Blending room</li> <li>9. In process storage room</li> <li>10. Tablet compression room</li> <li>11. Capsule filling room</li> <li>12. Tablet coating room</li> </ul> | <ul style="list-style-type: none"> <li>13. Primary packaging room</li> <li>14. Washing room</li> <li>15. Technical room 1</li> <li>16. Technical room 2</li> <li>17. Technical room 3</li> <li>18. Technical room 4</li> <li>19. Electrical room</li> <li>20. Exhauster room</li> <li>21. Control room</li> <li>22. AHUs room</li> <li>23. Utilities module (Optional)</li> <li>24. Waster water and Exhaust gas treatment (Optional)</li> </ul> |
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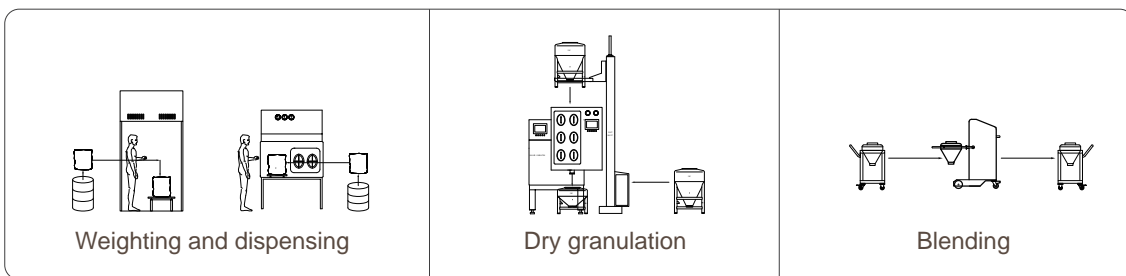
# Flexible to Your Process

**Tofflon**

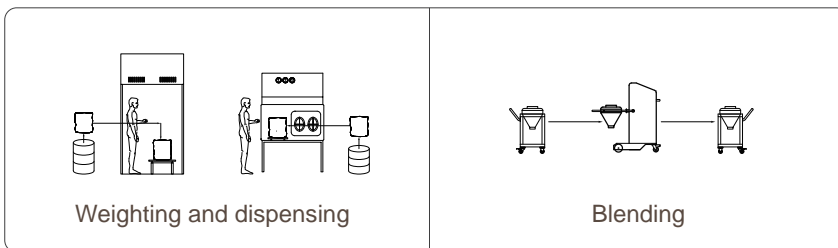
- **Wet granulation**



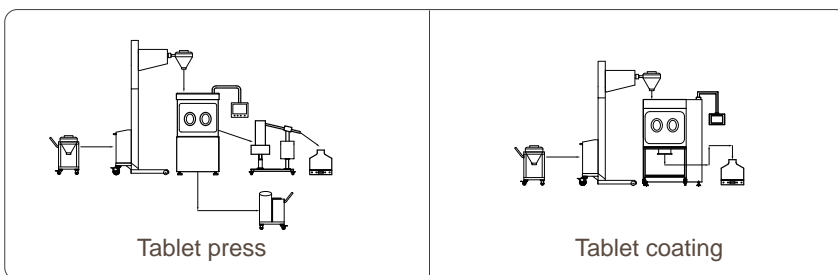
- **Dry granulation**



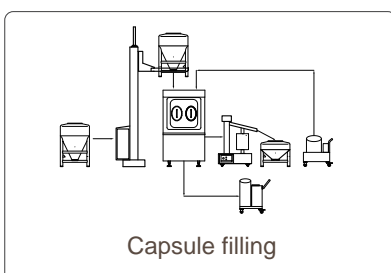
- **Direct mixing**



- **Tableting**



- **Capsule filling**

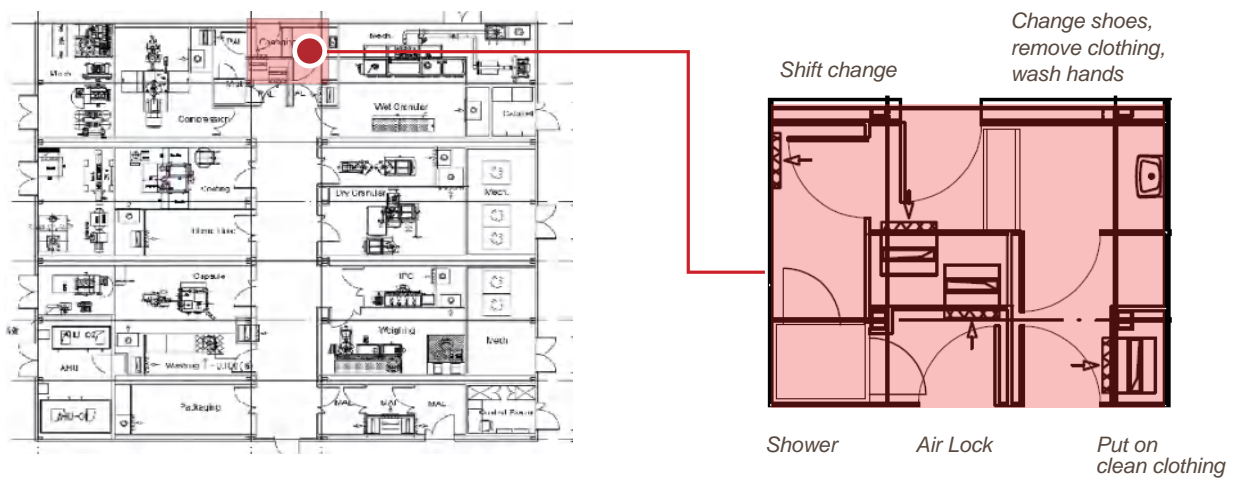


## Change Room

### Description

The meticulous design and stringent protocols play a vital role in safeguarding the integrity of potent pharmaceuticals and the health of personnel.

Change rooms stand as critical contamination control checkpoints. These specialized spaces ensure the safe transition of personnel or operators, safeguarding product sterility and personnel health.



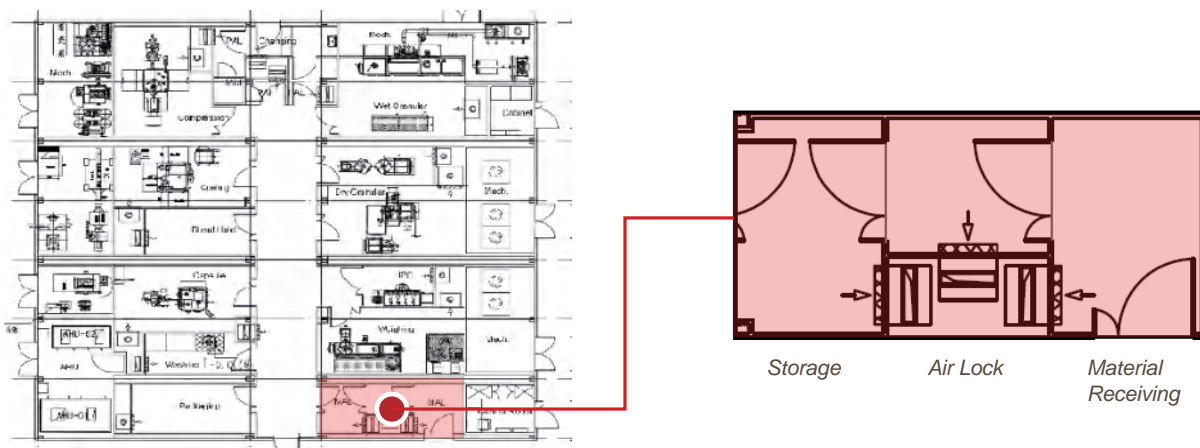
### Key Features

- Changing room's walls, floors, and ceilings are hermetically sealed, with interlocking doors, preventing even microscopic particle escape.
- Dedicated facility, separate from the other parts of the workplace, and big enough for workers to change and store their clothes.
- De-gowning room provided with mist shower to encapsulate and hold dusty contaminants to external uniforms and room/equipment surfaces.

## Material Receiving & Storage

### Description

This room is to handle incoming materials crucial for pharmaceutical production while maintaining the stringent containment requirements. Finding temporary storage space can be an incredibly beneficial solution for production preparation.



### Key Features

- Separate zones for receiving, unpacking materials reduce contamination risks.
- Interlocking Pass-Through Hatches and Airlocks helps to control material transfer while maintaining pressure differentials.
- Monitoring of environmental parameters such as air pressure, temperature, and humidity are continuously monitored and maintained within specified ranges.



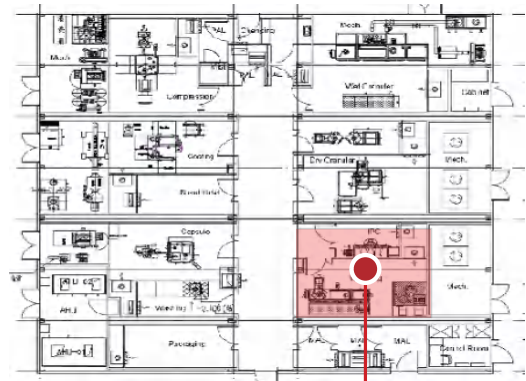
## Weighting Room

### Description

The weighing and dispensing room plays a crucial role in ensuring accurate measurement and safe transfer of these materials. It is a specialized space designed to maintain containment, prevent cross-contamination, and protect both operator and product integrity.

### Key Features

- Negative pressure isolators designed for HI-API can achieve OEB4-5 protection level.
- The isolator adopts a high-containment design with a fully welded stainless steel structure.
- High-precision balances and scales are used to ensure accurate measurement of potent ingredients.
- Equipped with PUSH-PUSH exchangeable filter.



Weighting booth for excipients



Weighting & Dispensing API and excipients (back side)

Weighting & Dispensing API and excipients (front side)



Dry mill

### Technical Data - Dry mill

Model	THSD-100
Power	2L-100L
Capacity	40-80%
Maximum speed	3-15rpm

### Technical Data - Weighting Platforms

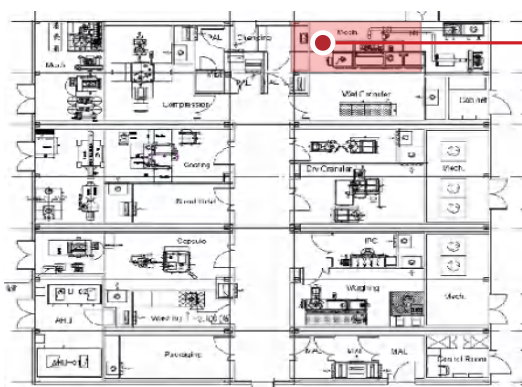
Model	PBD659-A6
Maxium Capacity	6kg
Readability /Readability (certificated)	0.1g /1g
Size (LxWxH)	300x240mmx110 mm
Model	FTBR 2430
Maxium Capacity	15kg
Readability	5g
Size (LxWxH)	240x3000mm

## Wet Granulation Room

### Description

The wet granulation room houses the process of transforming powdered ingredients into granules using a liquid binder. Strict containment measures are in place in the room.

The entire wet granulation line is housed in a dedicated isolator, including the high-shear mixer, the fluidized beds, and wet and dry mills. Fully contained and sealed systems for material transfer by using an optional AB valve for loading and unloading of materials.



### Key Features

- The containment wet granulation line for HI-API can achieve OEB4-5 protection level.
- Negative pressure isolator, preventing any cross contamination.
- Room is equipped with BIBO (bag-in-bag-out) filter to further guarantee operator's safety.
- Optional AB valves is offered for material unloading.
- Whole Line Yield > 99%.
- Impeller & Chopper Speed  $\pm 5\%$ .
- Temperature Control Accuracy 0.3%.
- Wash-In-Place Design.
- PC+PLC Real-time records.
- 21CFR Part 11 Compliant.



High Shear Mixer

### Technical Data - HSM

Model	M30
OEB	4-5
Loading	Passbox & PE bag
Unloading	SBV DN100
HSM Capacity	3.6-9.6kg (bulk density 0.4)
Pressurized air	35Nm <sup>3</sup> /h 0.6Mpa
Purified water	120L/min 3bar

## Wet Granulation Room



Fluid Bed Dryer



Dry mill

### Key Features

- Fluidized bed inlet air temperature control  $\pm 1$  °C .
- Humidity Tolerance  $\pm 1$ g.
- Air Flow tolerance  $\pm 5$ %.
- AHU equipped with 3-stage filtration cooling dehumidifier, steam heater.
- PC+PLC 21CRF Part 11 Compliant.

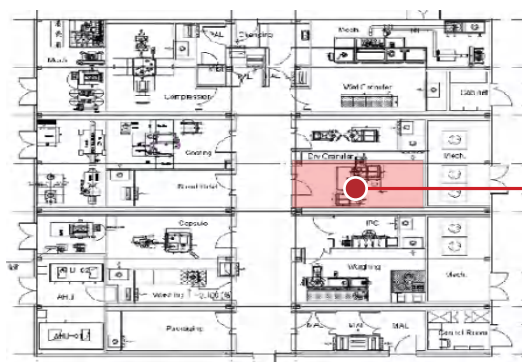
### Technical Data - FBD

Model	DG1.2
OEB	4-5
Loading	Vacuum Transfer
Unloading	SBV DN100
FBD Capacity	3.75-12.75kg(bulk density0.5) drying 4.5-12kg(bulk density 0.5) top spraying
Dry mill Capacity	200kg/h
Pressurized air	35Nm <sup>3</sup> /h
Purified water	120L/min 3bar

# /// Dry Granulation Room

## Description

- Dry granulation involves compacting and breaking down powders using mechanical pressure, without liquid or heat. It consists of three steps: compaction, milling, and sieving for particle size control. Dry granulation is ideal for moisture or heat-sensitive materials.
- The containment dry granulation line has been set up within the isolator, equipped with all necessary machinery including a roller compactor, and a dry mill.



## Key Features

- The containment roller compactor for HI-API can achieve OEB4-5 protection level.
- Consistent separation between process material and technical area.
- Bag-in-bag-out filters are standard.
- Optional AB containment valve for loading&unloading port for sealing of roller compactor.
- Modular design easy for installation, disassembly, and cleaning.
- Rollers in cantilever design.
- Integrated two-stage rotor fine granulators in Diagonal-Design.
- Automated PLC.

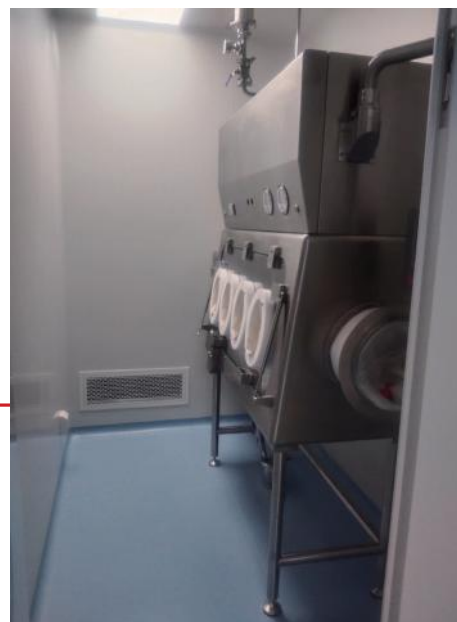
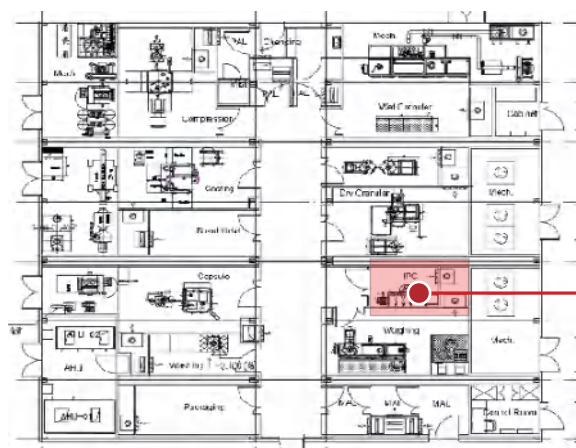
## Technical Data - Roller compactor

Model	DG1.2
Roller Diameter	120
Roller width	40
Maximum Capacity Output (kg/h)	40
Maximum Pressure(KN/cm)	20
Maximum Roller Clearance(mm)	4
Maximum Roller Speed(rpm)	15

## IPC Room

### Description

The IPC room serves as a dedicated space within our modular factory for conducting in-process control activities. It is equipped with an empty isolator, which provides a controlled environment for sampling and testing procedures after the granulation process.



### Key Features

- The IPC room features an empty isolator that ensures a controlled and sterile environment for sampling and testing processes.
- This controlled environment ensures the accuracy and reliability of the test results, enabling effective quality control during the production process.

### Technical Data - Isolator

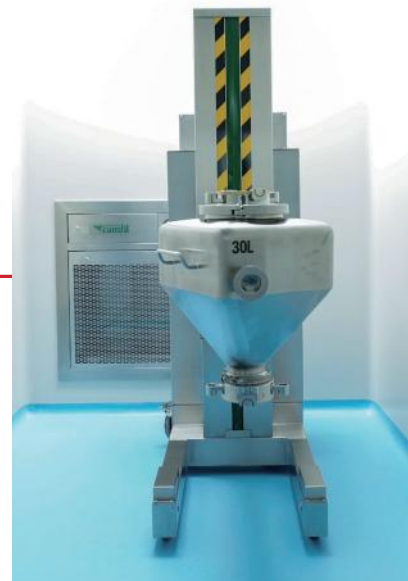
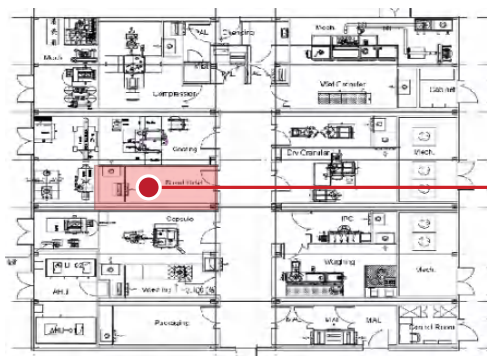
Model	Inspection Isolator
Number of glove port	4
Isolator cabinet Diemension (LxWxH)	1500 x 650 x 800
Diemension (LxWxH)	2300 x 792 x 2200
Weight (kg)	300 kg



## In Process Storage Room

### Decription

In-process storage and hoist lifter systems play vital roles in safely handling and transferring potent drugs within cleanrooms. It is crucial to hold intermediate materials and containers during different stages of the production process, minimizing manual handling and exposure risks.



### Key Features - Hoist Lifter

- The rated load of the rack and pinion is 4 times the working lifting load.
- The load will remain in the same position by the braked motor, in the event of power shutdown, without the risks of carriage slipping as hydraulic hoist lifter.
- Precise docking at low speeds and fast, efficient lifting are possible with two-speed lifting speed control.
- The electric motor driven lifter is designed for better GMP compliance, preventing the non-GMP risk with hydraulic devices.

### Technical Data - Mobile Hoist

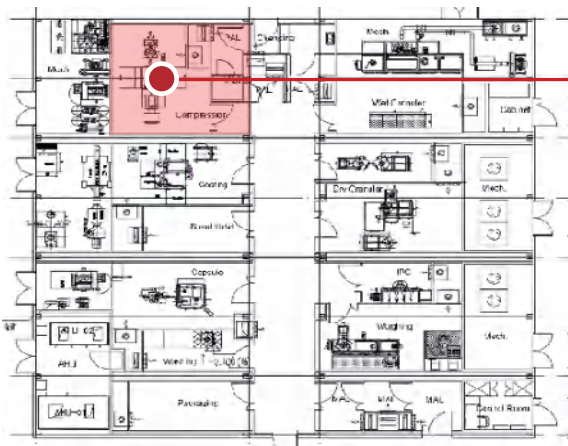
Model	TNTS-100
Rated lifting weight	100 kG
Maximum lifting height	2770 mm
Reted lifting power	0.75 kW
Input power	1 Phase 220V 50Hz
Battery usage time	60mins
Dimension (LxWxH)	1220x600x2065-2905mm
Weight	450kg

## Tablet Compression Room

### Description

Tablet compression is a process used in the pharmaceutical industry to compress powdered or granulated drug substances into tablets.

The tablet press room is equipped with a containment washable tablet press, and one integrated deduster and metal detector, which is suitable for high-potency tablet production.



Tablet Press

### Key Features

- Containment design with WIP function, upto OEB4, suitable for highly potent, oncology or hormonal drugs.
- Fully enclosed compression chamber with ergonomic glove boxes for easy accessibility.
- Tablet chamber equipped with 5 washing nozzles.
- Optional AB containment valve for sealing of loading port of tablet press.

### Technical Data - Tablet Press

Model	TC&C800C WIP	
Punch station	16	22
Tooling type	D type	BB type
Maximum tablet diameter	25 mm	13 mm
Maximum output	48,000 tab/h	66,000 tab/h
Maximum main compression	60 kN	
Maximum pre-compression	10 kN	
Filing Depth	0.5-20 mm	



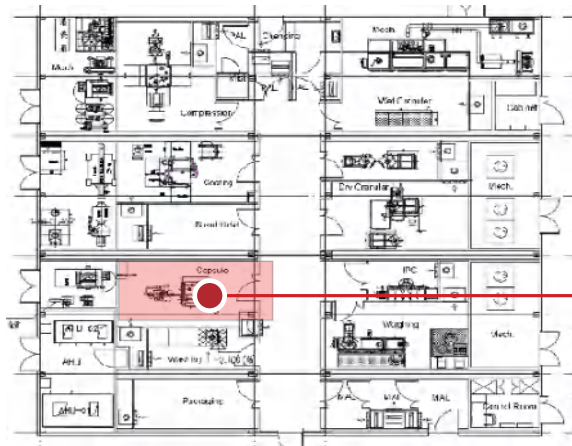
Deduster and metal detector

## /// Capsule Filling Room

### Description

Capsule filling is a pharmaceutical process used to fill empty capsules with the desired medication or active ingredients.

The capsule filling room is equipped with a containment washable capsule filling machine, and one integrated capsule polisher and metal detector, which is suitable for high-potency capsule production.



Capsule Filling Room



Capsule Filling and Capsule Polisher and Metal Detector (combi-unit)

### Key Features

- Containment design with WIP function, upto OEB4, suitable for highly potent, oncology or hormonal drugs
- The working compartment is equipped with ergonomic gloves that ensures accessibility to all parts inside without opening the windows.
- Washable capsule polisher and metal detector combi-unit.
- Optional AB containment valve for sealing of loading port of capsule filling machine.

### Technical Data - Mobile Hoist

Model	TSFK703
Output	42,000 cap/h
No. of segment bores	5
Capsule size range	00#-5#
Pressure range	-160Pa-240Pa
HEPA filter	H14
Noises	<=75dB



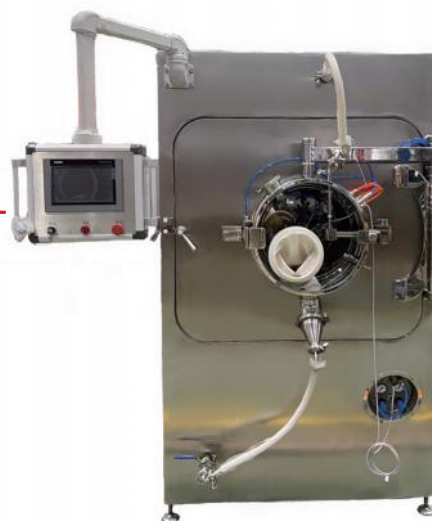
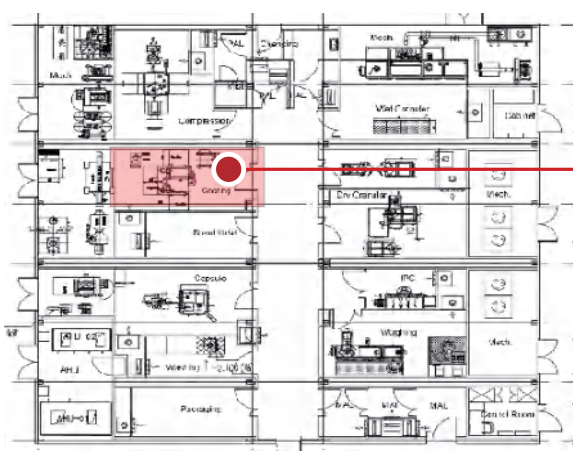
Capsule Polisher and Metal Detector

## Tablet Coating Room

### Description

Film coating is a common procedure in the pharmaceutical industry to apply a thin layer of coating onto tablets or pellets. The coating serves various purposes, including improving appearance and taste, protecting drugs, controlling release, and facilitating swallowing.

The tablet coating room is equipped with a containment washable coating machine, and related process equipments, which is suitable for high-potency capsule production.



Tablet coating machine

### Key Features

- Fully isolated working chamber, equipped with inflatable sealing, up to OEB4 protection level.
- A comprehensive WIP system without any dead corners ensures the all-embracing washing of the pan coater.
- An integrated dust collector is designed with BIBO filters to collect all dust or particles to ensure a safe production environment.
- Real-time monitoring system to control all critical parameters.
- Optional AB containment valve for sealing the loading and unloading port of the tablet coating machine.

### TECHNICAL DATA - Pan coater

Model	TBGB-40FG
Typical Capacity ( based on 1g/ml bulk density)	40 / 10 kg (Two sizes of interchangeable drum)
Speed-adjusting range of film coating drum	4-21 rpm
Temperature-regulating range of hot air	Normal temperature ~ 80 ° C
Filtration accuracy of hot air	0.5 mm (100000 grade)





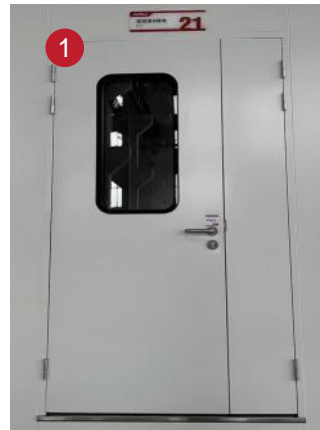
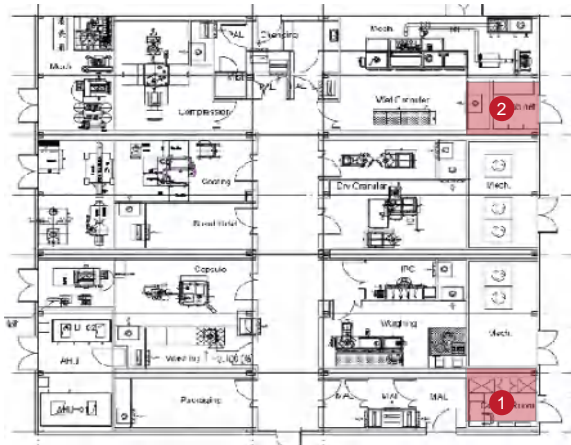


## Electrical & Control Room

### Description

The electrical room offer the power all equipment in this facility needed.

The control room works as a point of interconnection from the BMS and EMS Servers, Workstations and Networks. It will also house the other panels for services like the Fire Alarm, CCTV, IT and Access Control.



### Key Features

- BMS control and monitoring
  - >HVAC monitoring, control and alarming
  - >HVAC Third party equipment monitoring, control.
  - >Plant Utilities monitoring, control and alarming.
- Airlocks control and monitoring
  - >PAL – Personal Airlock(s)
  - >MAL – Material Airlock(s)

- Optional SCADA Function

Design the configuration screen according to the floor plan and flow chart of the production workshop, and monitor the relevant data in real time on the screen.

- >Historical data trend display, report display.
- >Alarm prompts for key data points and storage alarm records.
- >User management function, which can divide the use rights.
- >Record operator activities, audit trails, and meet GMP data integrity requirements.



### Electrical control room

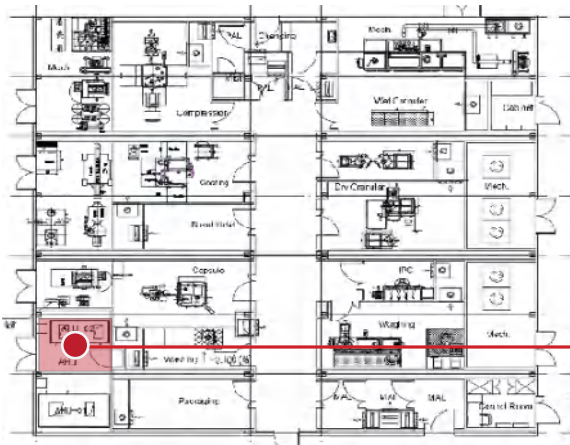
#### Key Features

- Scope: power supply/lighting/receptacles.
- Grounding/BMS/EMS/telecommunication/security/fire alarm/interlock/cabling system, etc.
- Voltage: 380V, 3 phase / 220V, 1 phase.
- Frequency: 50Hz.
- Cables between modules in mezzanine are normally installed on site to maintain rigid performance and require less maintenance.

## Electrical and Air Handling Units (AHUs) Rooms

### Description

The Modular Facility has two dedicated, separate rooms. one for the electrical control room, which serves as the central hub for monitoring and controlling various electrical systems crucial for safe and efficient operation. The second one is for the Air Handling Units (AHUs) room for the entire Modular Facility, for precise environmental, pressure, and containment control in the Modular Facility.



### Key Features

- The facility has two sets of AHUs that are integrated into a single module.
- Total fresh air strategy, BIBO designed at return for core production rooms with containment level OEB 4-5.
- All utilities tie-in interface located on the outside wall of the AHU room, with flange or tri-clamp for quick connection.

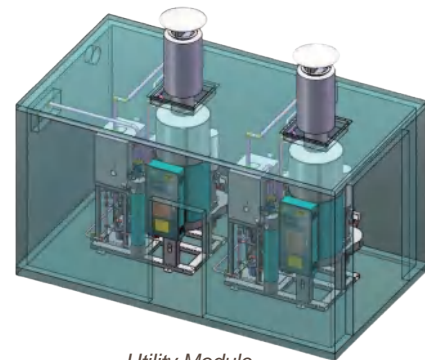
# Utility module & Wastewater and Exhaust gas treatment module

## Decription

### - Utility Module

The utility module in a pharmaceutical plant consists of systems and equipment that provide essential utilities such as purified water, steam, compressed air, HVAC (heating, ventilation, and air conditioning), and electrical power to support the manufacturing processes.

These utilities are crucial for maintaining the required environmental conditions and ensuring the quality and safety of the pharmaceutical products.



Utility Module

### - Wastewater and Exhaust gas treatment Module

The wastewater and air treatment module in a pharmaceutical plant includes systems and processes for treating and managing wastewater and air emissions generated during the manufacturing operations.

This module typically involves wastewater treatment plants, air pollution control systems, and monitoring equipment to ensure compliance with environmental regulations and minimize the impact of the plant's operations on the environment.



Wastewater and Exhaust gas treatment Module

## Technical Data - Utility Module

Utilities Name	Utilities Specifications
Solid freeze water	7/12 °C
Cooling capacity	234KW
Industrial steam	1428kg/h
Compressed air	2Nm <sup>3</sup> /min
Purified water flow rate	17m <sup>3</sup> /h
Hot water	7m <sup>3</sup> /h

## Technical Data - Wastewater and Exhaust gas treatment module

Name	Technical Data	Unit	Num	Note
Collection tank (3000L)	Diameter 1606mm Hight 3500mm	PC	1	Atmospheric tank SS304
Inactivation tank (2000L)	Diameter 1606mm Hight 3100mm	PC	1	Pressure tank SS304
Centrifugal pump	Q=5m <sup>3</sup> /h, H=15m, N=4KW/380V	PC	2	1 use, 1 spare
Mechanical mixer	N=5KW	PC	1	SS304

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