We Welcome Honorable Guest at

Where Life is Precious

BKJ Lifesciences Private Limited

BKJ Lifesciences Private Limited Nashik Maharashtra

Journey to BKJ Lifesciences Private Limited Nashik Maharashtra.

BKJ Lifesciences has state of art of formulation facility situated in MIDC Dindori Gat No.218, Village: Talegaon, Tal: Dindori, Dist: Nashik – 422004 State : Maharashtra which is approximately 188 km away from Mumbai .

BKJ Lifesciences,Nashik is easily accessible by road, air and by train.

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Nashik Maharashtra

Advantages of Nashik :

- Close to port and airport city of Mumbai.
- Located in air/water non-polluting zone.
- Favourable weather condition throughout the year
- Good source of water.
- Easy availability of technical staff as 8 pharmacy colleges located in the city.

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Geography of Nashik

- **Location** : 3200 feet above mean sea level.
- **Climate** : Cool and dry – therefore very much suitable for pharmaceutical industries.
- **Temperature range** : 4ºC to 37ºC (Only for few days during (May and October)
- **Rainfall** : 2600 mm (annual)
- **Sources of Energy** : Local Power Generation Plant – EKLAHARA
- **Sources of Water** : Godavari River, Kashyapi Dam, Darna Dam, Nasardi River, and Gangapur Dam.

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Industrial area in Nashik :

- Dominated by Engineering and Pharma Industries
- **Industrial Areas:** Dindori , Satpur , Ambad and Sinner.

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Location of BKJ Lifesciences Private Limited is Gat No.218, Village: Talegaon, Tal: Dindori, Dist: Nashik – 422004

Total Area : 3.5 Acre.

Size of Premises : 19300 Square Feet Ground Floor

15675 Square Feet First Floor.

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About the company

BKJ Life Sciences Pvt. Ltd starts a new business. The core activity of BKJ Life Sciences Pvt. Ltd is manufacturing of Injectable Products.

The unit is located at Gat No.218,Village Talegaon, Tal: Dindori, Dis: Nashik- 422004. The property of the business in on owned basis.

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Company Introduction

- **Management & Organization:** Dr. B.K. Jogale and Mrs. Kanchan B. Jogale are the directors of the company.
- Dr. B. K. Jogale has been in the process industry more than 25 years and gained experience in Injectable Quality control, Quality Assurance, Injectable production, Regulatory affairs, Import export management, product registrations, designing, purchase and co-ordination with reputed pharma manufacturing.

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Management Vision

- The Proposed facility will be planned as per cGMP standard & as per the WHO guidelines.
- Making the affordable Injectable Ampoule and Vials for the Indian / EU markets
- The plant is planned for closed manufacturing concept, so that the product is untouched by human hands till the time it is packed.

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Why Us?

1. Timely Deliver.
2. Quality products.
3. Fulfill Market Demand.
4. Various Discounts.
5. Easily available factors of production.
6. Proper Services.
7. Various general category injectable products like, Liquid ampoule, vial, lyophilized and Pre filled syringes.

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Plant layout Ground Floor

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Plant layout First Floor

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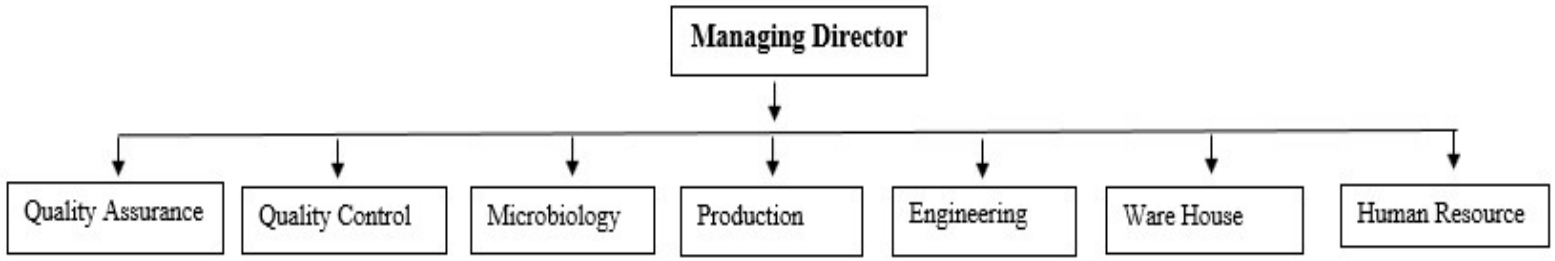
PLANT ORGANOGRAM



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DESCRIPTION OF PLANT AREA

Sr. No	Ground Floor Major Area Description
1.	Buffer Room
2.	Ampoule filling And Sealing Area
3.	Filtration Area
4.	Cool Zone
5.	Disinfectant Filtration
6.	Vial Filling Room
7.	Vial Sealing Room
8.	PFS Filling
9.	Terminal Sterilization (Loading)

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Sr. No	Ground Floor Major Area Description
10.	Terminal Sterilization (Unloading)
11.	Visual Inspection
12.	Vial Packing Room
13.	Ampoule Packing Room
14	Cold Storage
15.	Laundry & Garment Storage Room
16.	Packing Office
17.	Ware House Finish Goods Quarantine
18.	Cold Storage
19.	Recall Room

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Sr. No	Ground Floor Major Area Description
20.	Reject Room
21.	Dispatch Room
22.	Ware House Approved Finish Goods
23.	Vial Washing and Depyrogenation &Sterilization Room
24.	Manufacturing Room
25.	Autoclave Room
26.	Washing and Drying Room
27.	Manufacturing Room
28.	Ampoule Washing and Depyrogenation & Sterilization Room
29.	IPQA Production Office

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Sr. No	Ground Floor Major Area Description
30	Accessories Room
31.	De-cartoning Ampoule
32	De-cartoning Vial
33.	Filled Ampoule Colllection room
34.	Under test raw material
35.	Approved RM Store
36.	Sampling API/Excipient/Solvent
37.	Utensil Wash Area
38.	Dispensing API/Excipient/Solvent
39.	Approved Primary Packing Material

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Sr. No	Ground Floor Major Area Description
40.	PM Day Store Dispencing
41.	Approved Rubber Bung Store
42.	Admin/Hr/Purchase
43.	Director Cabin
44.	Plant Cabin
45.	PW & WFI System
46.	Engineering Store
47.	Oxygen / Nitrogen Plant Room
48.	Electrical Room

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Sr. No.	First Floor Major Area Description
1.	EHS room
2.	Male Rest Room
3.	Female Rest Room
4.	Micro Office
5.	BET Room
6.	Destruction & Washing Room
7.	Mediafill Incubation-1
8.	Mediafill Incubation-2
9.	Media Preperation
10.	Sterility Room

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Sr. No.	First Floor Major Area Description
11.	Incubation Room
12.	Cooling Zone
13.	Biosafety Room
14	MLT Room
.15.	QA Staff Documentation
16.	QA Manager Cabin
17.	QC Manager Cabin
18.	QC Staff Documentation
19.	PM Testing Room
20.	Stability Room

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Sr. No.	First Floor Major Area Description
21.	Retention sample room
22.	Hot Zone /Washing room
23.	Wet Lab
24.	Balance Room
25.	Instrument Room
26.	TOC/LPC
27	Chemical Glassware Storage
.28.	Sampling Dispensing Room
29.	AHU Service Floor
30.	Approved SPM/TPM

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PRODUCTS THERAPEUTIC CATEGORIES

- Antibiotics
- Anaesthetics
- Cardiovascular
- Psycho tropics / narcotics / controlled medicines
- Central Nervous System
- Vitamins and supplements
- Gynac / Obstetrical products
- Analgesics
- Respiratory

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PRODUCTION CAPACITY

Sr. No.	Container Strength	Capacity per Day
1.	**Liquid Injection Ampoules**	
2.	Ampoules: 1 ml to 3 ml	144000 Nos.
3.	5 ml Ampoule	100000 Nos.
4.	10 ml Ampoule	50000 Nos.
5.	20 ml Ampoule	50000 Nos.
6.	25 ml Ampoule	40000 Nos.

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PRODUCTION CAPACITY

Sr. No.	Container Strength	Capacity Per Day
1.	**Liquid Injection Vials**	
2.	2 ml Vial	115200 Nos.
3.	5 ml Vial	96000 Nos.
4.	10 ml Vial	50000 Nos.
5.	20 ml Vial	40000 Nos.
6.	30 ml Vial	40000 Nos.
7.	50 ml Vial	30000 Nos.

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PRODUCTION MAJOR EQUIPMENTS

Injection Liquid Vial Line	
Sr. No.	**Name of Equipment**
1.	Automatic High Speed Rotary Vial washing machine
2.	Automatic Four Head Liquid Filling Machine with Pick And Rubber Stoppering Machine
3.	Automatic Four Head Aluminium Cap Sealing Machine
4.	Sterilising & Depyrogenation Tunnel For Vial.
5.	Bung Processor Cum Steam Sterilizer

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Vial washing , Dry Heat Sterilizer , Vial Filling ,Vial Sealing Machine – Ambika. Bung Processer .

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Injection Liquid Ampoule Line	
Sr. No.	**Name of Equipment**
1.	Automatic High Speed Rotary Ampoule washing machine
2.	Automatic High Speed 8- Head Ampoule Filling And Sealing Machine
3.	Automatic High Speed Ampoule Sticker labelling machine
4.	Sterilizing & Depyrogenation Tunnel For Ampoule

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1. Ampoule Washing Machine ,

2. Ampoule Filing and Sealing ,

3. Ampoule Tunnel

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UTILITIES (PURIFIED WATER SYSTEM)

- **Water systems:**
- Process Water – The source water is municipal corporation water provided by MIDC.
- The feed water from MIDC is stored on terrace overhead 100,000 litres tank.
- The same water is pumped from this reservoir & distributed to various locations through GI /UPVC piping network.
- **Uses:** Day to day use-in general use, after passing through water softener, feed water to boiler.
- Sanitation: Water reservoir is emptied out, cleaned twice in a year. Records are maintained.

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Purified Water Generation System

Purified water:

- Raw water which is processed to generate purified water is passed through multi-grade sand filter, online dosing system of sodium hypochlorite, sodium metabisulphate, sodium hydroxide dosing for pH corrections as well as anti-scaling dosing and then passed through reverse osmosis membranes , electro de-ionization (EDI) unit and finally through UV lamp which produces purified water of the quality of Pharmacopeia.
- Purified water is used as pre-wash to primary packaging materials like ampoules, vials, plugs & feed water for generation of water for injection.
- Purified water which is collected in SS 316 L jacketed tank which is circulated through loop system.

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UTILITIES WATER FOR INJECTION

- **Water for Injection**
- Generation by multi column distillation unit.
- 5 columns with generation capacity of 1000 litres per hour.
- The source of water for this system is purified water, which is evaporated inter steam & then re-condensed to form distilled water.
- Water for injection at different user points are checked for chemical testing, total organic carbon (TOC) & microbiological quality as per pre-approved schedule.
- Water for injection which is collected in SS 316 L jacketed tank of 2000 lits capacity, is circulated through loop system with zero dead lags in the distribution system and the temperature is maintained between 70ºC and 80ºC.
- WFI used for manufacturing Injectables, final wash for primary packaging materials like ampoules, vials, plugs, manufacturing tanks washing etc.

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WATER FOR INJECTION GENERATION SYSTEM

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NITROGEN GENERATION AND DISTRIBUTION SYSTEM)

Nitrogen:

- Nitrogen being an inert gas is used in sampling, dispensing, manufacturing, filling process and QC lab
- Nitrogen generating plant of capacity 15N M^3 per hour is produced in- house.
- Supplied by SS 316 seamless pipes, filtered through 0.2 micron cartridge filters
- Nitrogen of purity 99.97%
- Nitrogen is generated in house with pressure swing adsorption-system (PSA).
- Air is passed through multiple columns like alumina towers, where moisture from air gets absorbed & then it passes through column of carbon molecular sieves (cms) where Oxygen gets absorbed & only pure N2 generated is passed to the collection tank.
- *Nitrogen gas quality is validated every year for :*
- Non viable particle count, dew point
- Oil mist, moisture content
- Carbon monoxide, sulphur dioxide

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Nitrogen Generation System

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UTILITIES (COMPRESSED AIR)

Compressed Air:

- Used for the ampoule /vials / rubber bungs washing process as well as for the pneumatic operations of machines .
- Compressed air is filtered through 0.2 micron

Compressed air is validated yearly for:

- 1) Non viable particle count
- 2) Dew point
- 3) Oil mist
- 4) Moisture content

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CLEAN ROOM CONDITIONS

- **Environnemental conditions :**
- Critical area/ working/filling area of class 100 under class 1000 background of surrounding area in filtration rooms and filling rooms
- All airlocks and passages of aseptic area – class 1000 to class 10,000 depending upon the activities
- Manufacturing area and washing area – class 10,000
- Airlocks of manufacturing and washing areas – class 10000 to 100000, depending on activities
- Topical ointment & creams manufacturing & filling under class 100,000
- Dispensing – under reverse laminar flow (class 100) back ground of the room: class 100,00

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HVAC SYSTEM AND CLEAN ROOMS

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QUALITY MANAGEMENT SYSTEM

Independent of manufacturing, directly reports to management

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QC Instruments

Sr. No.	Name of Instrument	Make
1.	High Performance Liquid Chromatography (HPLC)	Agilent
2.	UV /Vis Spectrophotometer	Shimazu
3.	pH meter LT-50	Labtronics
4.	Walk In Stability Chamber	Aryan Tech Solution
5.	Water Bath PID Based	Aryan Tech Solution
6.	Hot Air Ovan	Aryan Tech Solution
7.	Stability chamber	Aryan Tech Solution
8.	Potentiometer LT -32	Labtronics
9.	Digital Polarimeter	Rajdhani
10.	Abbe Refractometer	Labtronics

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Sr.No	Name of Instrument	Make
11.	Sonicator	Labtronics
12.	Analytical Balance	Wensar
13.	KF Titrator LT-63	Labtronics
14.	Muffle furnace	Labtronics
15.	Melting Point Instrument	Labtronics
16.	Heating Mental	Bio Technics India
17.	Hot Plate	Bio Technics India
18.	UV Cabinet	

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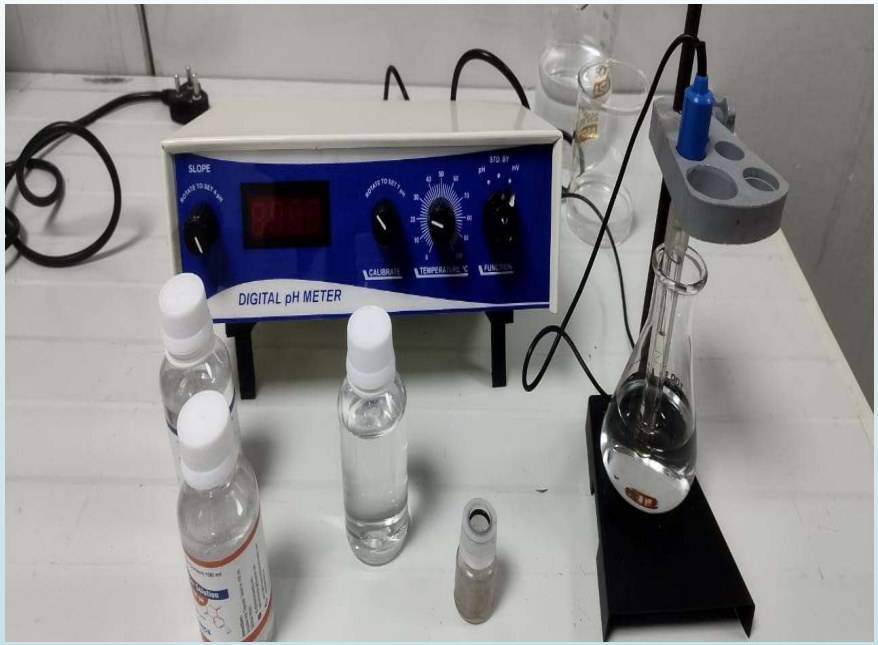
HPLC

UV Spectrophotometer



Digital pH meter

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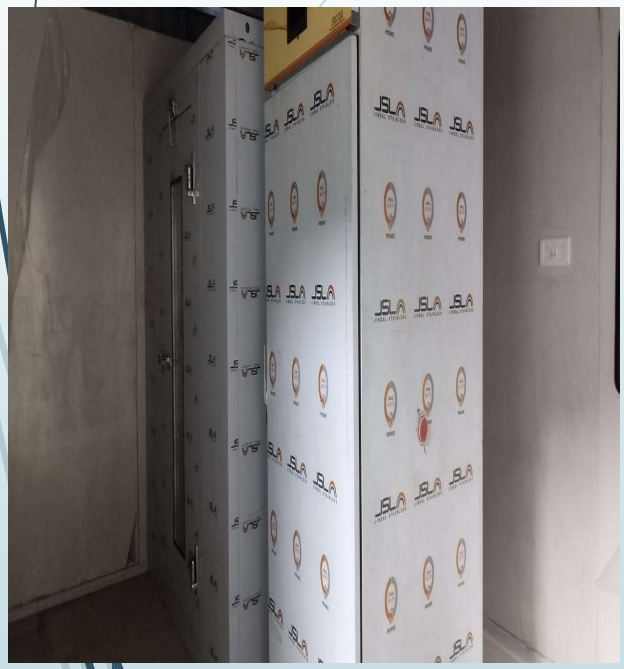

Walk In Stability Chamber

Sonicator and Water bath

Hot Air Oven

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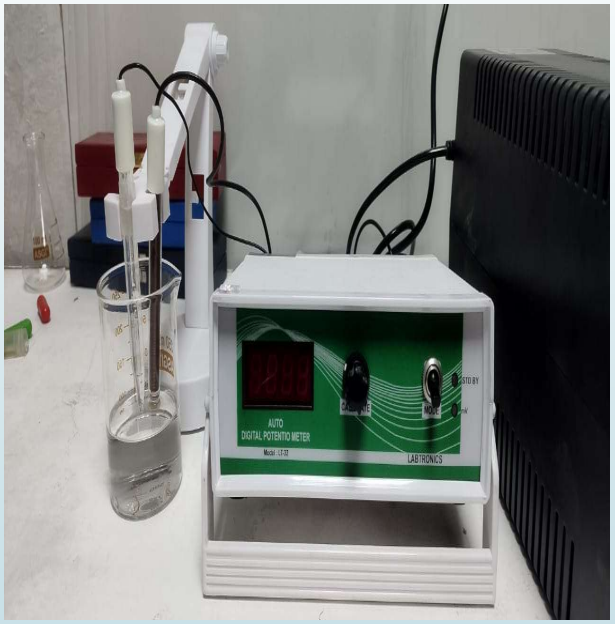
Refractometer

Digital Polarimeter



Potentiometer

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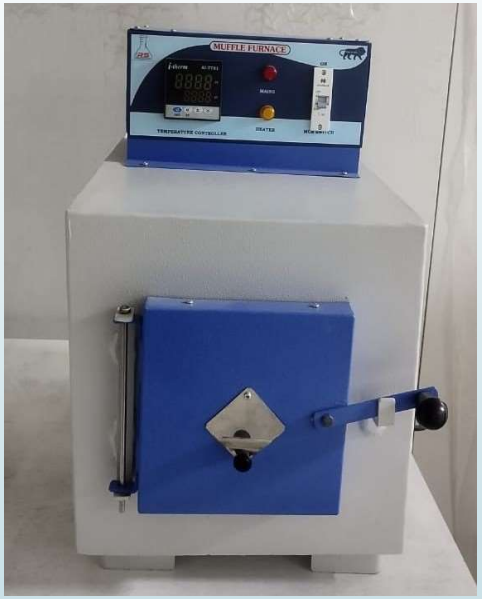
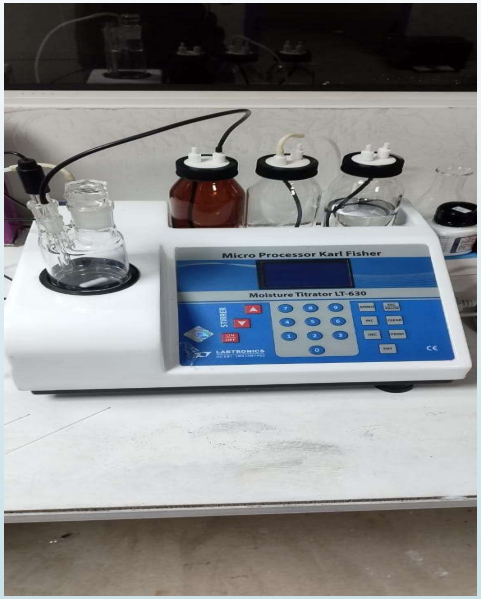
Weighing Balance



Muffle Furnace



KF Titrator

UV Cabinet

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Hot Plate

Heating Mental

Melting point Instrument

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Sr.No	Name of Instrument	Make
1.	BOD Incubator	Aryan Tech Solution
2.	Autoclave Double Door Horizontal	Map Industries
3.	Data Logger	Ambetronics
4.	Deep freezer	Aryan Tech Solution
5.	Colony Counter	Labelectronics
6.	Microscope	Orbit
7.	pH meter	Bio nexis
8.	Vortex Cyclomixer	Rawal
9.	Hygrometer	ApTechDeals

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pH Meter

Microscope

Vortex cyclomixer

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Data Logger

Colony Counter

HPHV Autoclave

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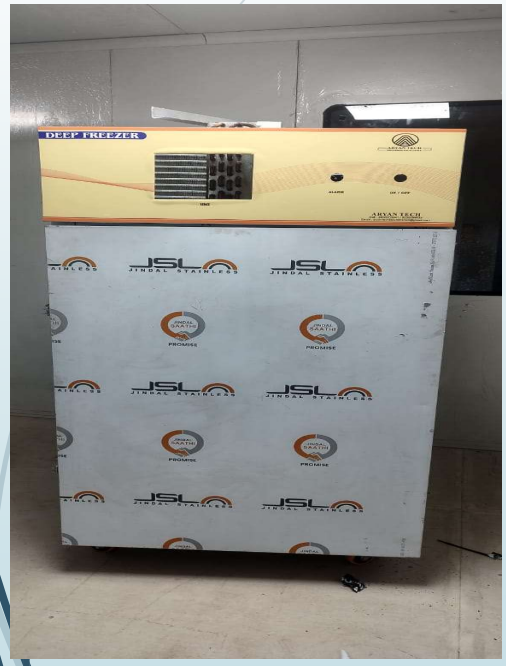

Deep Freezer

BOD Incubator

Hygrometer

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GOOD DOCUMENTATION PRACTICES

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