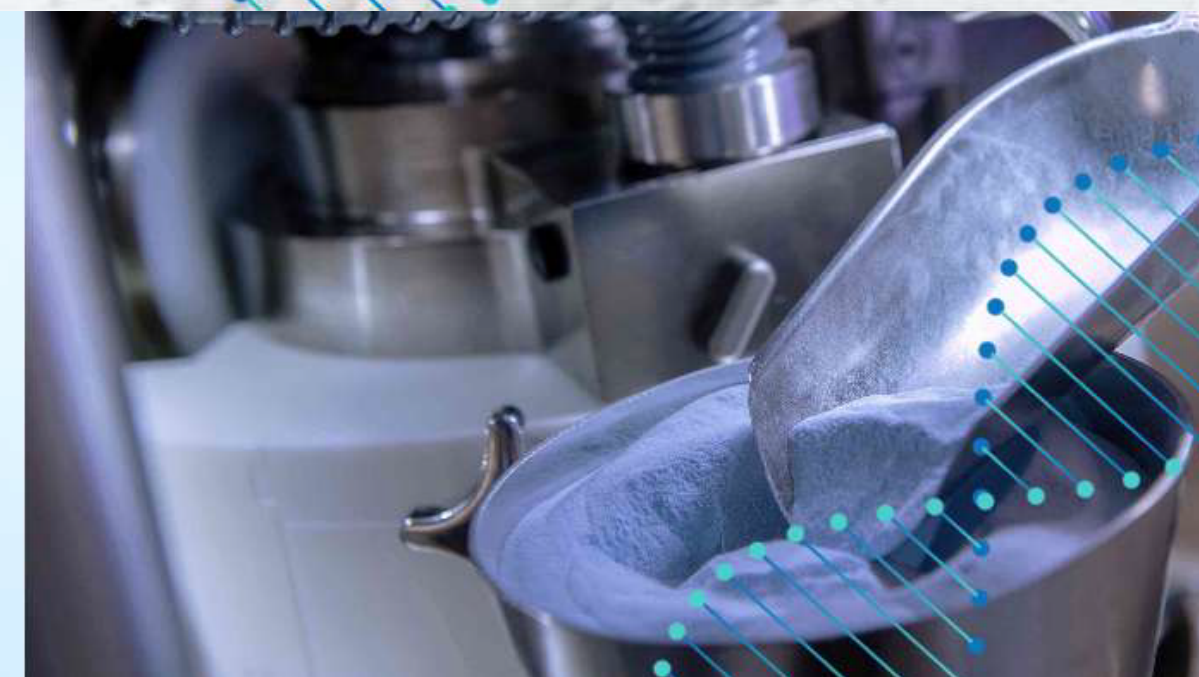




BIOALTUS LABS
APPLICATION. INNOVATION. INTEGRATION



BIOALTUS LABORATORIES



www.bioaltuslabs.com



WE AT BIOALTUS LABS FIRMLY

Believe in putting people first.

Our Journey started with the aspiration for providing Quality and Affordable Lifecare through Application, Innovation and the Integration of the resources.

We have evolved from the modest start to emerge as a strong and the established player in the market with more than 10 years standing as an hard core APIs (Active Pharmaceuticals Ingredients) and Pharmaceutical Intermediates manufacturing player.

We have scaled up to developing 30 key APIs (Active Pharmaceutical Ingredients) through our consistent efforts which has helped us to achieve a sizable business volume catering our products to all the leading companies in India and overseas, virtual manufactured at various sites while in another couple of years, we plan to develop and commercialize another 25 new molecules.





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VISION

“We aspire to be a Global Leader in providing the Quality and Affordable Lifecare through Application, Innovation and the Integration of the resources.”

MISSION

“To deliver best Pharmaceutical Products by listening and understanding the customers’ requirement and turning ideas into reality, confidentiality, knowledge, and expertise in the fields of the Product Development, Marketing, Industrial Manufacturing, Supply Chain and Regulatory Compliance”.

1

Strengths

2

Integrity

3

Transparency

4

Safety

5

Quality

6

Productivity



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LEADERSHIP

MEET OUR TEAM



Mr. Sanket Patil

Managing Director



Ms. Siya Patil

Director

TRUSTED BY OVER 5K+ ESTABLISHED BRANDS ACROSS THE WORLD.



What We Do

Products we offer

A leader into API manufacturing, Bioaltus Labs/We serves more than 500 Happy Customers all over the world with an assurance of supply continuity with commitment to Quality and yet cost effective manufacturing. Our Product portfolio includes a wide range of chemical compounds and substances that serve as the essential components in the production of Pharmaceutical drugs / Finished Formulations.

Intermediates

Bioaltus Labs manufactures basic building blocks, Key Starting Materials (KSMs) and advanced intermediates required to manufacture various drug products. High purity and Quality Pharmaceutical Intermediates are manufactured with controlled impurity profiles



Active Pharmaceutical Ingredients

Exemplify the quality of medicines, work their magic. It is a biologically active components which gives efficacy to the finished formulations. Bioaltus Labs specializes in manufacturing the APIs which gives best results for the Finished Formulations



Active Pharmaceutical Ingredients



• APIs Commercialized

- Doxofylline (Hydrophilic)
- **Levosulpiride**
- Bilastine
- **Doxofylline Injectable Grade**
- Levosulpiride Injectable Grade
- **Teneligliptin**
- Flavoxate HCl
- **Febuxostat**
- Sertaconazole
- **Acebrophylline Plain/ Microparticles**
- Sevelamer HCl
- **Eberconazole**

- Fenofibrate Micronized
- **Sevelamer Carbonate**
- Amorolfine
- **Fenofibrate Nanoparticles**
- Luliconazole
- **Tadalafil**
- Olopatadine
- **Dapagliflozin**
- Dapoxetine HCl
- **Sitagliptin**
- Vildagliptin
- **Praziquantel HCl**

• APIs Under Development

- Empagliflozin
- **Glimepiride**
- Cilnidipine
- **Topiroxostat**
- Itopiride
- **Ursodeoxycholic Acid**
- Benfotiamine

Intermediates And Fine Chemicals



Isoxepac

CAS No : 55453-87-7
Application : Olopatadine

Dioctyl Sodium Sulfosuccinate

CAS No : 577-11-7
Application : Docusate Sodium

N, N Dimethyl Formamide Dimethyl Acetal

CAS No : 4637-24-5
Application : Ofloxacin , Imatinib, Olanzapine

(1R, 3r, 5S, 8r) -3-[[[(2RS)-3-Hydroxy-2-phenylpropanoyl] oxy]-8-methyl-8-(1-methylethyl)-8-azoniabicyclo [3.2.1] octane bromide monohydrate

CAS No : 66985-17-9
Application : Ipratropium Bromide

Glimepiride Sulfonamide

CAS No : 119018-29-0
Application : Glimepiride

1,4 - Methoxyl Phenyl Piperazine

CAS No : 38212-30-5
Application : Lapatinib , Naftopidil , Urapidil

1,3 - Chlorophenyl piperazine

CAS No : 6640-24-0
Application : Trazodone

3- (Cyclopropylmethoxy)- N-(3,5- Dichloropyridin-4-yl)- 4(difluoromethoxy) Benzamide

CAS No : 162401-32-3
Application : Roflumilast

Ethyl 3-(1R) Phenyl ethyl} imidazole -4- carboxylate.

CAS No : 33125-97-2
Application : Etomidate

Adenosine

CAS No : 58-61-7
Application : Adenosine

3 - Aminoacetophenone

CAS No : 99-03-6
Application : Phenylephrine Hydrochloride

(+)- (S)-4- {1-(2,3, Dimethyl phenyl) ethyl 1H-Imidazole monohydrochloride

CAS No : 145108-58-3 (HCL) 113775-47-6 (Dexmedetomidine Base)
Application : Dexmedetomidine HCL

3 - Hydroxy Acetophenone

CAS No : 121-71-1
Application : Fenopropfen Calcium,Rivastigmine

3 - Nitrobenzaldehyde

CAS No : 99-61-6
Application : Lercanidipine

Sodium Saccharine (Technical Grade)

CAS No : 6155-57-3
Application : Artifical Sweeting Agent

Pregn-4-ene 7,21, Dicarboxylic Acid, 9, 11, epoxy -17-hydroxyl -3-oxo y lactone methyl ester (7 alpha, 11 alpha, 17 alpha) free base

CAS No : 107724-20-9 (HCL)
Application : Eplerenone HCL

A LEADER IN MANUFACTURING OF PHARMACEUTICAL INGREDIENTS



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- Bioaltus Labs has a state-of-the-art API manufacturing facility at Paithan, Aurangabad, Maharashtra. The plant shall be spread over a plot area of 45000 sq.ft.

GMP/ Production Block

Utility Block

Quality Assurance

Warehouse Block

Microbiology Lab

Administrative Block

Pilot Plant Block

Intermediate Manufacturing Block

Effluent Treatment Plant



GMP / API PRODUCTION BLOCK



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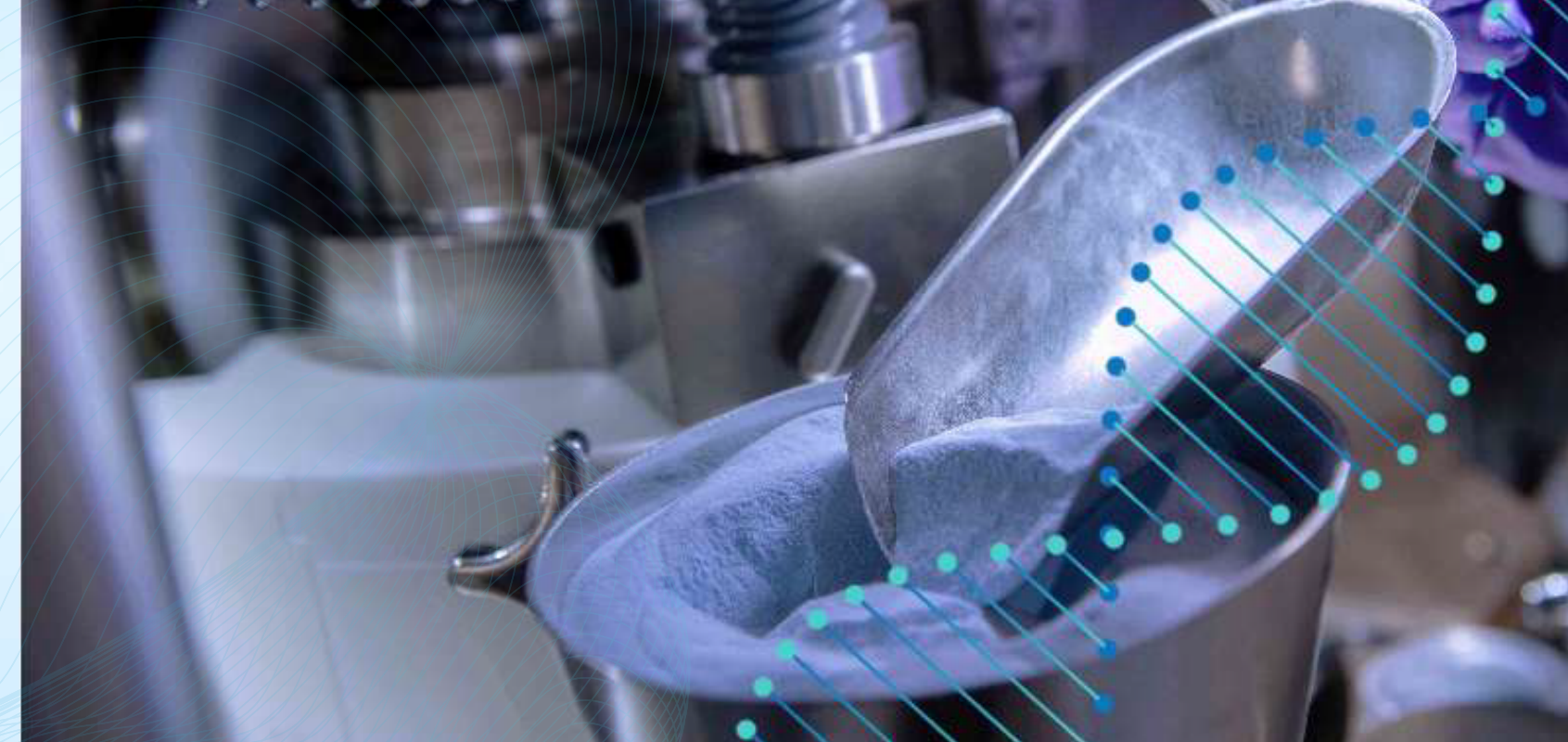
- The GMP Block shall be built with three key points in mind: Efficiency, Safety and Environment. Our compact, yet robust factory complex shall have all the key ingredients for a successful manufacturing unit. Our API manufacturing facilities shall be operated in accordance with cGMP guidelines as well as requirements of International Regulatory authorities such as the USFDA, EMEA, ANVISA, PMDA, KFDA, COFEPRIS.
- The Flexible manufacturing infrastructure and multipurpose facilities will allow the expansion of product range and change in product mix in response to changes in the customer demand. It shall enable us catering to customer requirements ranging from Gram, Kilo level to Commercial production in multi tons.
- Built to GMP requirements, our production lines uses the best of breed equipment including a fully qualified HVAC system including full control of temperature, humidity and room pressure which ensures the right environment for quality manufacturing.





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THE FACILITIES AT THE PLANT INCLUDES



Containment class OEB3

Capabilities to handle pressurized reaction up to 25 kg/cm²

Capability to handle reactions from -20°C to +120°C

Glass Lined Reactors

Stainless Steel Reactors

Hydrogenator

High Vacuum Pumps

Different type of filtration systems such as Centrifuge Machines, Nutsche Filter, Leaf Filter

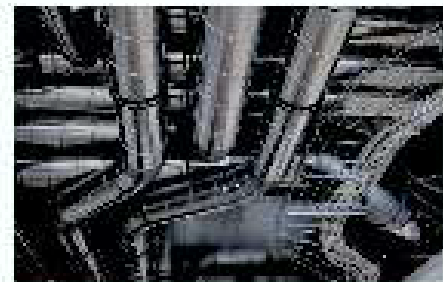
Different type of Drying systems such as FBD, VTD, ATD, ANFD

Multimill, Vibro Shifter, Blenders



UTILITY BLOCK

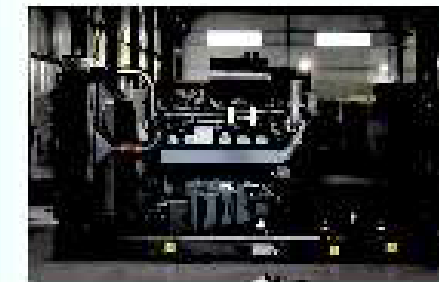
Our utilities shall be housed in a separate building –Utility Block to ensure that these critical aspects of the facility can be effectively maintained and serviced by our dedicated staff.



HVAC System
comprising of 10 AHUs



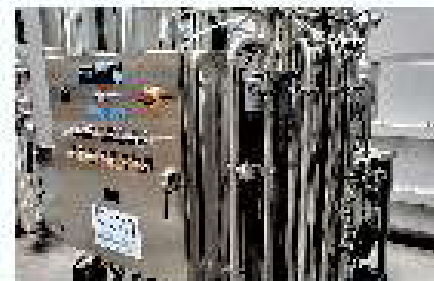
Water Purification
System



Generator system



Chilling Unit



PLC controlled Purified
Water System



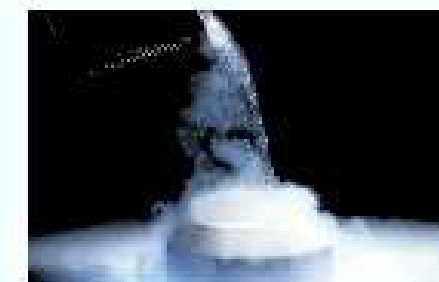
Thermic fluid system



Boiler



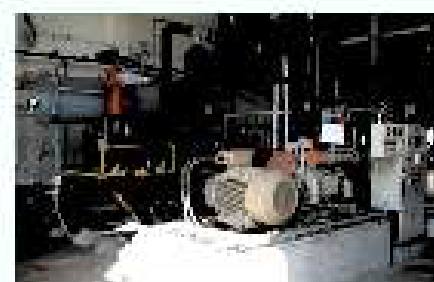
HVAC System
comprising with HEPA
filters



Nitrogen distribution
system for interstation



Compressor (oil free)



Brine plant (-25°C)

QUALITY CONTROL / QUALITY ASSURANCE LAB



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Our Quality Control Laboratory will be our advanced, accredited research facility, delivering end to end testing solutions of raw and processed material. Our facility will be geared to conduct high intensity quality control testing in both a Wet and Dry Analytical conditions.

Our array of essential equipment for Chemical Analysis, Laboratory testing, Microbiology Laboratory, and Instrumental Analysis Laboratory include:

- **HPLCs with Auto Sampler (UV & PDA detectors)**
- **GC head space with auto Sampler**
- **FTIR**
- **UV Spectrometer**
- **Stability chambers as per ICH guidelines**





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MICROBIOLOGY LAB

Our lab is staffed with trained and qualified analysts to oversee products in accordance with GLP and GMP standards and it is facilitated with:

- **TOC Analyzer**
- **Auto Titrators**
- **Dedicated AHUs**
- **Digital Polarymeter with Temperature controller**
- **Laminar Flow station**
- **ISO Class areas with Incubators**
- **Autoclave & Bio safety cabinet**



EFFLUENT TREATMENT PLANT

It includes physical, chemical, and biological processes to remove physical, chemical and biological contaminants. Its objective is to produce a waste stream including solid waste suitable for discharge or reuse back into the environment. This includes below:

- **ETP setup with complying with the ZLD requirements**
- **2 ATFD Unit**
- **MEE Unit**
- **Reverse Osmosis**

CMO-CDMO

YOUR COST-EFFECTIVE & INNOVATIVE MANUFACTURING PARTNERS



- We provide Active Pharmaceutical Ingredients (APIs) and drug substance development services with pharmaceutical and biotechnology applications for complex, niche, small molecule programs from preclinical to Phase III and commercial manufacturing.
- Bioaltus Labs provides a seamless transition for API and drug substances from the initial discovery stages of the program to commercialization. We ensure that Expertise and support at each phase of the drug program is available from development, analytical services, cGMP manufacturing and later stage development and commercialization.
- Our facilities are operated with sustainability as one of the focus areas with principles around environmental and social governance intact. Operations of our sites are linked with processes around waste minimization, waste management, water neutrality, emission control and usage of renewable power, people practice, community development activities and a strong focus on ethics compliance and transparency.



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BIOALTUS AT CPHI INDIA 2023






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**LET'S
CONNECT
THANK YOU**

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