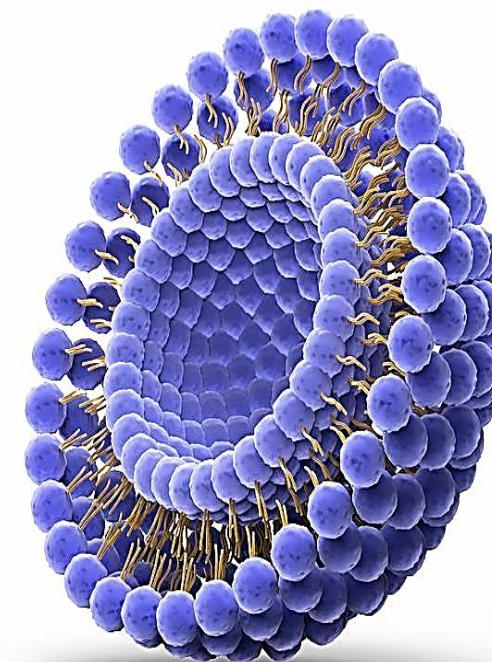


bioneemtec | 

# BIONEEMTEC INDIA

An unique Place for active molecules ..

**CENTER OF INNOVATION AND TECHNOLOGY**  
**(CRAMS &CDMO)**

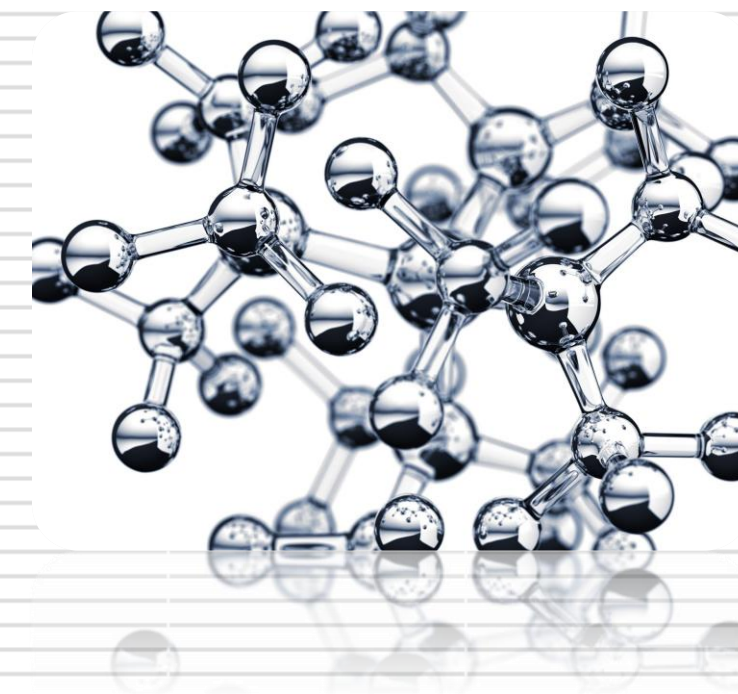




- At Bioneemtec India Private limited , we operate at the intersection of innovative natural products ,Pharmaceutical and biotechnology , delivering innovative solutions that cater to the diverse needs of our clients across India .
- Over the years , we have evolved our services to include custom research and development , biotechnology training programs , contract manufacturing services for Pharmaceuticals and Cosmaceutical companies .
- Each services is designed to address the unique challenges faced by our clients , ensuring that we remain at the fore front of industry advancements while fostering a culture of Innovation and Excellence.
- We focus on delivering high –quality Custom research and development services tailored to our clients need ..

## WHAT WE DO...

- **Identifying New and Unique Routes for the synthesis of KSM, INTERMEDIATES , APIs and Impurity**
- **Alternative ROS synthesis and development**
- **Small Molecule Synthesis**
- **Low Volume High Value Products**
- **Patentable Process**



## OUR SERVICES...

- **Research & Development/CRO/CMO**
- **Product / Process Development and Tech-Transfer**
- **Molecules Synthesized as per Pharmacopeia-US/EP/JP/CP/ICH Guidelines**
- **Innovations & Patents**
- **Stability studies**
- **Drug Master Filing (DMF 360)**

# We Are In CRAMS & CDMO

## Current Customers Base

- Bioneemtec Pilot Plant Facility
- USFDA-GMP site for commercial production

- Small Scale Organization
- 25 Employees, 6 Consultants / Experts
- 4500 Sft. Builtup area of pilot plant

- Contract Research & Manufacturing
- Lab, Pilot Plant and Production block

- Stainless Steel Reactors **300L, 1KL, 2KL and 3KL**
- Glass Lined Reactors **300L, 1KL, 2KL and 3KL**
- Vapor phase Reactors **20L**
- Continuous Flow Chemistry Reactors **5L**
- Fermenter – **10L, 1KL and 2KL**
- Hydrogenator **5L, 100L and 1KL**
- Industrial Centrifuge **36 and 42inch**
- Tray Dryer: **30trays**
- Spray Dryer ; **20L/hr**
- Lyophilizer under installation



**Pharmaceutical  
and  
Biopharmaceutical**

China

Chennai,  
India

United States of America

Bengaluru, India

Italy

Germany

Hyderabad,  
India

Spain



Ministry of MSME, Govt. of India

# PROCESS CHEMISTRY

## INTERMEDIATES AND APIs

- We focus on the imported key start materials , Intermediates , Active Pharmaceutical Ingredients .
- We are supporting for manufacturing Key start Raw materials , Intermediates and APIs with their safety and Quality in the International markets to meet United states ,Japan , Chinese and European Pharmacopeia .
- Technology development / Technology transfer to the API manufacturers
- Impurity Profiling Studies
- Method /Process development
- **DRUG DISCOVERY & SYNTHESIS**

API

INTERMEDIATES

NEW CHEMICAL  
ENTITIES



# FLOWTECHNOLOGY-GREEN CHEMISTRY

## *THE SMART MANUFACTURING OF PHARMACEUTICAL PRODUCTS*

- It is an area of chemistry and chemical engineering focused on the design of products and processes that minimize or eliminate the use and generation of hazardous substances.
- Flow chemistry is well-suited for automation, where automated systems can control and monitor the entire production process.
- APIs can be manufactured with minimal human intervention, making the process safer and more reliable.
- Flow technology – Pilot plant facility with 100 to 400ml/min
- Technology development -**CENTER OF INNOVATION & TECHNOLOGY – CUSTOM RESESARCH, DEVELOPMENT &SCALEUP...**

ANTI  
BACTERIALS

ANTI  
INFLAMMATORY

ONCOLOGY MOLECULES



# **FERMENTATION & rDNA TECHNOLOGY**

**1. VITAMINS**

**2. AMINOACIDS**

**3. STEROIDS BIOSYNTHESIS**

**4. MACROLIDS**

**5. MYCIN DERIVATIVES**

**6. INDUSTRIAL ENZYMES -BIOTRANSFORMATION – ENZYME APPLICATION IN PHARMA PRODUCTS**

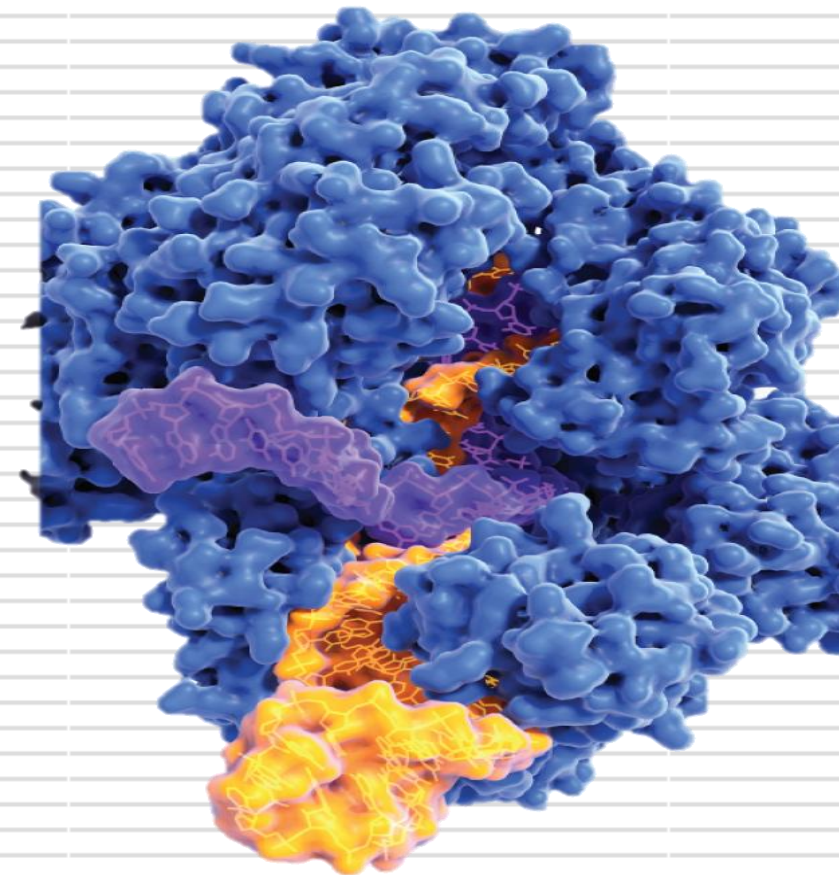
**7. BIOSIMILARS**

**CUSTOM RESEARCH & CUSTOM MANUFACTURING FACILITY**



# PLANT/MICROBIAL BIOACTIVE MOLECULES

1. BIOSURFACTANTS
2. BIOLEACHING
3. BIOENZYMES
4. BIOFLOCCULANTS
5. BIOPIGMENTS





# BIOLOGICAL STUDIES

- 1.ANTIBACTERIAL ASSAY .
- 2.ANTIFUNGAL ASSAY
- 3.CAM ASSAY
- 4.DRUG SCREENING – NUTRITIONAL PARAMETERS
- 5.ANIMAL CELL LINE BIOLOGICAL STUDIES
- 6.STABILITY STUDIES – EXTRACTS & FORMULATIONS
- 7.BIOINFORMATICS
- 8.NUTRITIONAL PARAMETERS- QUANTIFICATIONS STUDY
- 9.SUPPPORTIVE WORK FOR DRUG MASTER FILING



# ANALYTICAL STUDIES

- 1.ULTRA VIOLET SPECTROSCOPY .
- 2.ELECTRPHORESIS
- 3.POLYMERASE CHAIN REACTOR
- 4.METHOD DEVELOPMENT ON CHROMATOGRAPHY
- 5.HIGH PERFORMANCE THIN LAYER CHROMATOGRAPHY
- 6.HIGH PERFORMANCE LIQUID CHROMATOGRAPHY
- 7.POLARIMETER
- 8.GAS CHROMATOGRAPHY / GC-MS/LC-MS
- 9.NMR SPECTROSCOPY



# NON-GMP /GMP SUPPORT- ANALYTICAL METHOD VALIDATION STUDIES

ANALYTICAL –HPLC (WATERS)  ANALYTICAL –GC ( BRUKER)  STABILITY STUDIES



## DRUG MASTER FILING

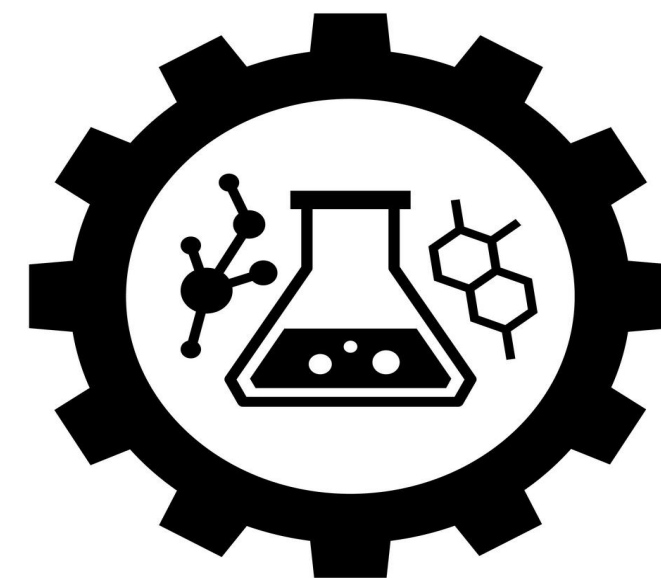
- United states drug master filing –USD MF
- European drug master filing- EUDMF
- China drug master filing – CP
- Japanese drug master filing – JP
- International council for harmonization of technical requirements for pharmaceuticals for human use -ICH

## METHOD DEVELOPMENT & VALIDATION STUDIES

- ❖ Analytical method development using High performance liquid chromatography, Gas chromatography
- ❖ Impurity study using LC-MS and GC –MS along with **PXRD, TGA, DSC and RC techniques..**
- ❖ Impurity profiling and quantification using chromatography and do structural interpretation of isolated impurities and deploying process improvement strategies.
- ❖ Working in Chem.Office and SciFinder, Scopus, Reaxys and Statgraphics (DOE software).
- ❖ Expertise in QbD Based Products Development (**DOE, FMEA, PAT, PGI Control Strategy**)

## PRODUCTION ACTIVITIES

- ❖ Functioning with R&D, AR&D, IP, Engineering and RA, QA, QC and production.
- ❖ Expertise in **US-FDA/GMP, GLP, AALACC, OHSAS 18001-7000 certification audits .**
- ❖ Stability studies
- ❖ GMP & NON –GMP production site
- ❖ SUPPORTING **360 DEGREE DRUG MASTER FILING**



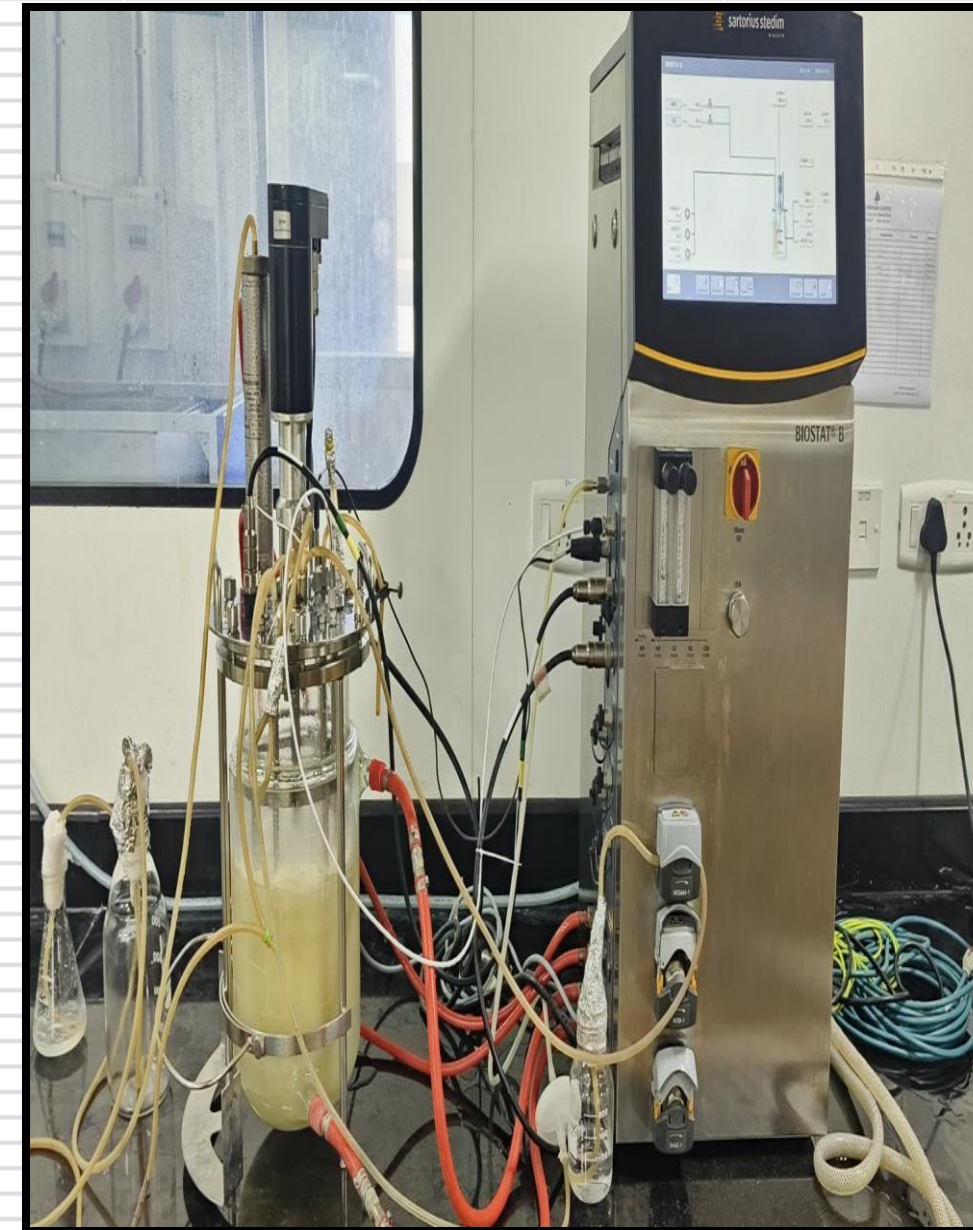
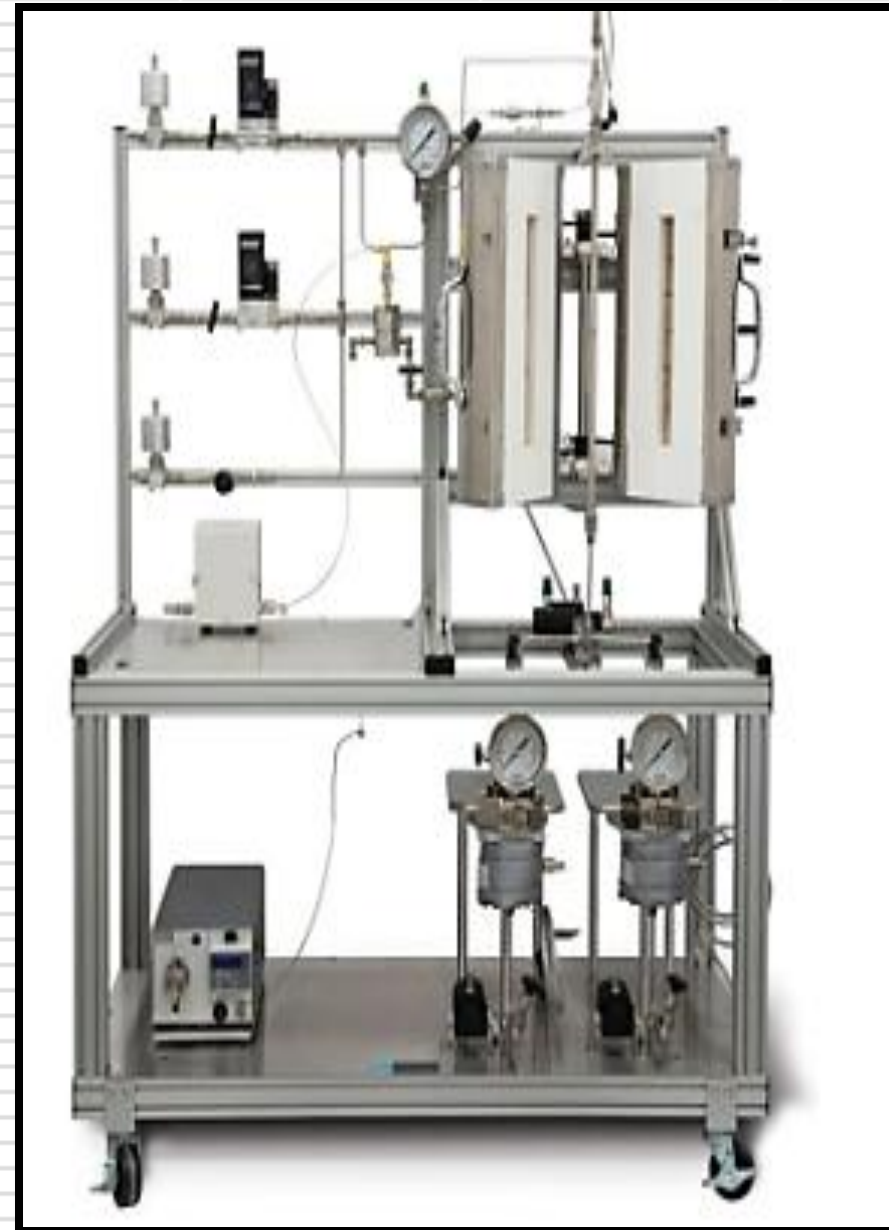
# RESEARCH, DEVELOPMENT & SCALEUP/PILOT PLANT STUDIES

CHEMICAL REACTIONS

FLOWCHEMISTRY REACTIONS

FERMENTATION REACTIONS

SPRAY DRY TECHNOLOGY



**BIOREACTORS**



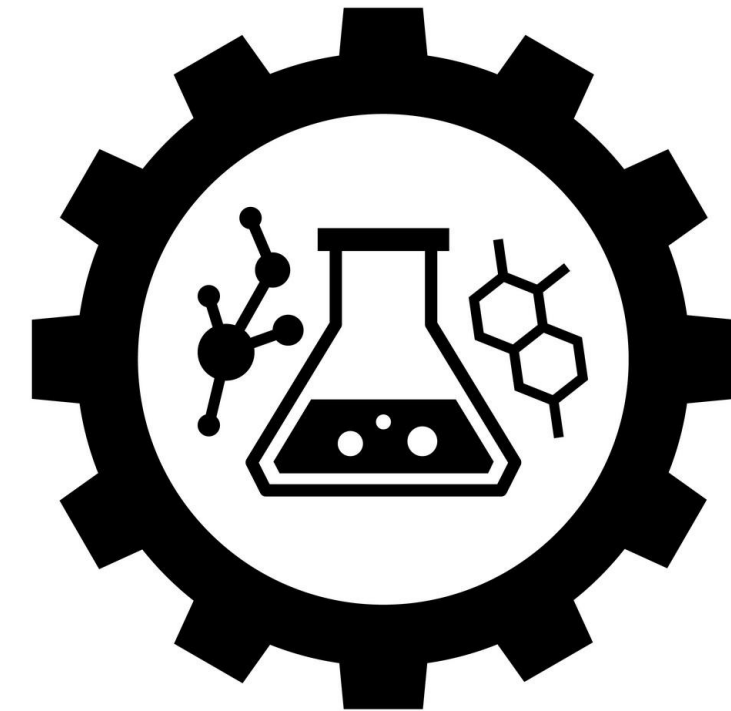
**REACTORS**



# **BIONEEMTEC – SAFETY AND CONFIDENTIALITY FOR CUSTOMERS**

- BIONEEMTEC agrees to maintain in confidence all information as will be disclosed or has been disclosed to the Company or as will be generated by the Company in connection with the Services.
- The Company shall take all necessary and reasonable precautions to prevent information from being disclosed to any other person, firm, corporation or entity not a party to our relationship.
- The Company agrees to require all subcontractors and consultants, if any, engaged by the Company in connection to the Services to maintain such information in confidence as a condition of such engagement.
- The Company shall indemnify Owner, its employees, affiliates and agents against all losses or damages incurred as a result of a violation of this agreement.
- BIONEEMTEC maintains all safety precautions in the Lab.

14



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