Alchemos Group of Companies – Corporate Profile

CDSCO
U.S. FOOD & DRUG ADMINISTRATION
MHRA
Regulating Medicines and Medical Devices
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

LOCATIONS

ALCHEMOS UNIT - I
Latur MIDC - 413512

ALCHEMOS UNIT - II
Plot No-D81, Supa MIDC - 414301

ALCHEMOS UNIT - III
Plot No.FS-36, Mahad Industrial Area - 402301

ALCHEMOS USA LLC – SALES OFFICE
8 East Garden Way, Dayton, NJ 08810 US

BioRadius
Therapeutic Research

Clinical Research Organization

About Us :

Alchemos Group of companies Incorporated in Yr 2021 with corporate office at Pune, Maharashtra, India.

Alchemos Private Limited is an Indian-based enterprise specializing in the manufacturing and R&D of nutraceuticals, pharmaceutical derivatives, and specialty chemicals. Established in 2021, the company has rapidly expanded its global footprint, emphasizing innovation, quality, and compliance.

Headquarters: Survey No. 4, Saraswadi Chamber, Tathawade, Pune, Maharashtra, India - 411018

Certifications: US FDA, GMP, ISO 9001:2015, GMP, HACCP, HALAL, KOSHER

Global Presence:
USA: Alchemos USA LLC, Dayton, NJ
Canada: Scarborough, Ontario

What we offer :

ALCHEMOS

Manufacturing	: Specialty Chemicals
	Nutraceuticals and Supplements
	Minerals
R & D Services	: Development of new research molecules
	Testing and analysis of product quality
	Performance analysis and process improvement
	Consultancy in manufacturing process
CRO (Bioradius)	: Bio-Availability & Bio-Equivalence
	Bio-Analytical Research
	Clinical Trials
	In vitro Assays

LATUR MIDC UNIT - I

Location: Plot No. C 49, Additional MIDC, Latur, Maharashtra, India - 413531

Specialization: Production of nutraceuticals and specialty compounds.

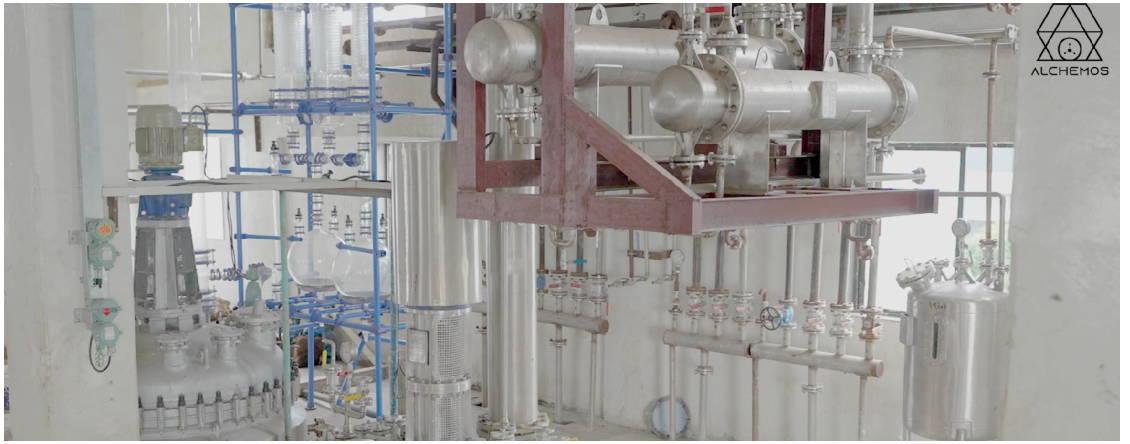
Certifications: ISO 9001:2015, GMP, HACCP, HALAL, KOSHER, FSSAI

SUPA MIDC UNIT – II

Location: SUPA MIDC, Maharashtra, India

Specialization: Manufacturing of nutraceutical and pharmaceutical derivatives.

Certifications: FDA, FSSAI, ISO 9001:2015, GMP, HACCP, HALAL, KOSHER



MAHAD MIDC UNIT – III

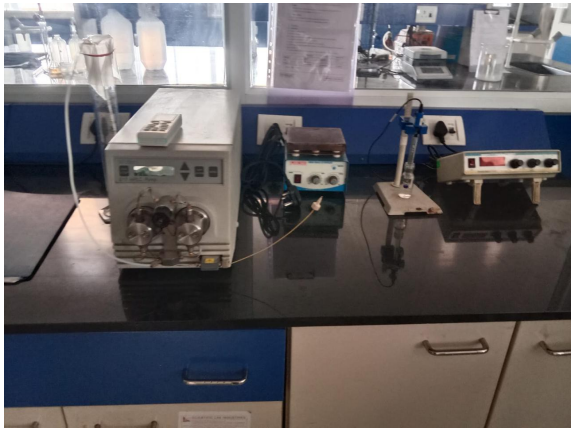
Location: Mahad MIDC, Raigad, Maharashtra, India

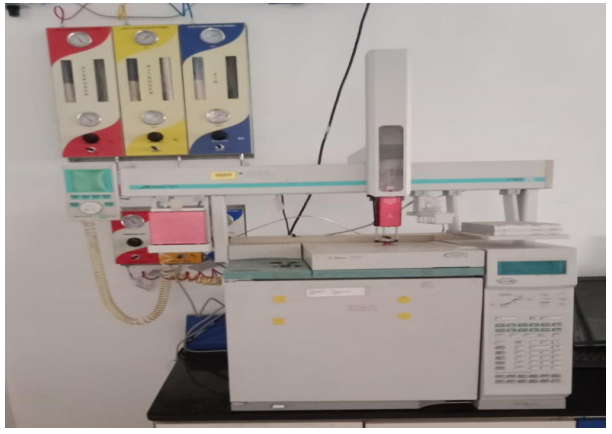
Specialization: Production of Minerals and API.

Certifications: FDA, GMP, FSSAI, ISO 9001:2015, GMP, HACCP, HALAL, KOSHER.

Research & Development Facility

- Development of new research molecules.
- Testing and analysis of product quality.
- Performance analysis and process improvement.
- Consultancy in efficiency improvement and manufacturing process establishment.



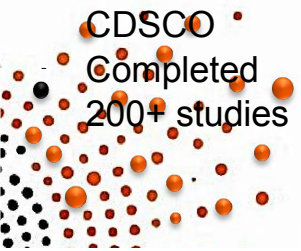


SERVICES

BioRadius
Therapeutic Research

BA / BE Studies

- Bioequivalence Studies
- Bioavailability Studies
- Approved Clinical Facility with 60 beds
- Dedicated Screening unit
- Approved by USFDA, UK MHRA and CDSCO
- Completed over 200+ studies



Clinical Trials

- Experience working with large scale clinical trials
- Phase I, II and Phase III
- Nutraceuticals
- Full Scale Support – From SEC till Market Authorization
- Extended Network of SMOs and Hospitals

Bio Analytical Service

- Completed over 44+ Studies
- LC MS/MS based assays
- BioMarker analysis
- Impurity analysis
- CDSCO approved GLP facility
- Several products approved by UK MHRA and USFDA and in market.
- Working with various National and International Pharma and Biopharmaceuticals.

Immuno-Assays

- Specialize in Invitro immunogenicity assays for Biosimilars and Peptide immunoassays
- R&D and regulated support
- IVCIA , IIRMI, T-cell Proliferation, Cytokine storm assay, MLR.
- Custom tailored assays for Biosimilars and biologics
- ELISA based assays
- Cell based assays

Biologics and Innate Adaptive

TEAM & CAPABILITIES

BioRadius
Therapeutic Research

200 + BE STUDIES COMPLETED

- ORAL DOSAGE FORMS
- NASAL SPRAYS & INHALERS
- INJECTABLES- IV, IM, SC
- INTRAVAGINAL TABS
- SUPPOSITORIES
- OINTMENTS,PATCHES,CREAMS

MULTI-REGULATORY APPROVALS

- US-FDA
- UK-MHRA
- CDSCO

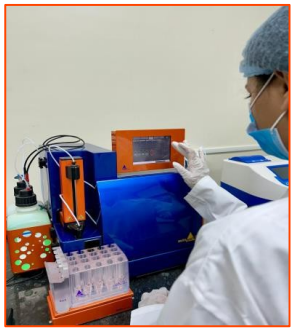
EXPERIENCE CONDUCTING COMPLEX STUDIES

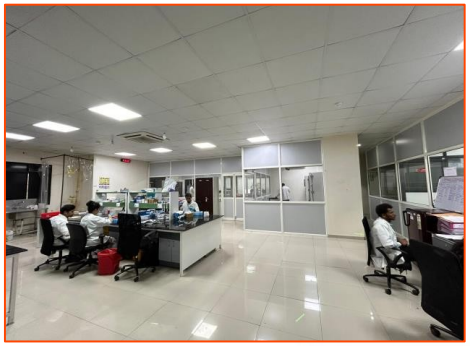
List of a few Complex Studies conducted at BioRadius:

- **DPI VS MDI studies: Indacaterol,Glycopyrronium**
- **Suspension vs oral solid Bioequivalence:** Atorvastatin (UK MHRA), Lisinopril (UK MHRA), Sildenafil (UK MHRA), Quetiapine (UK MHRA)
- **IV:** Liposomal Amphotericin Injection
- **Modified Release dosages:** including Pirfenidone, Bictegravir, Emtricitabine, Tenofovir alafenamide Tablets, Amitriptyline, Olanzapine and Rilpivirine Tablets (First to file for USFDA), Levothyroxine (US FDA), Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate tablets Siponimod (genotyped for CYP2C9to determine their CYP2C9 metaboliser status)
- **Others:** Mirabegron, Metformin and Glicazide Tablets, Aripiprazole, Dolutegravir

Bio-Analytical Laboratory

BioRadius
Therapeutic Research





Clinical Facility

- ~15000 Sq.ft single floor area of clinical site of 60 beds with two separate clinics

- State-of-the-art 3- bedded ICU unit
- Dedicated screening area of ~ 5000 sq.ft to fast track subject screening process
- Independent clinic-wise access controlled documentation physician room for study document and subject safety

- Emergency stretcher lift conveyance from clinics to Ambulance

Corporate Policy

ALCHEMOS

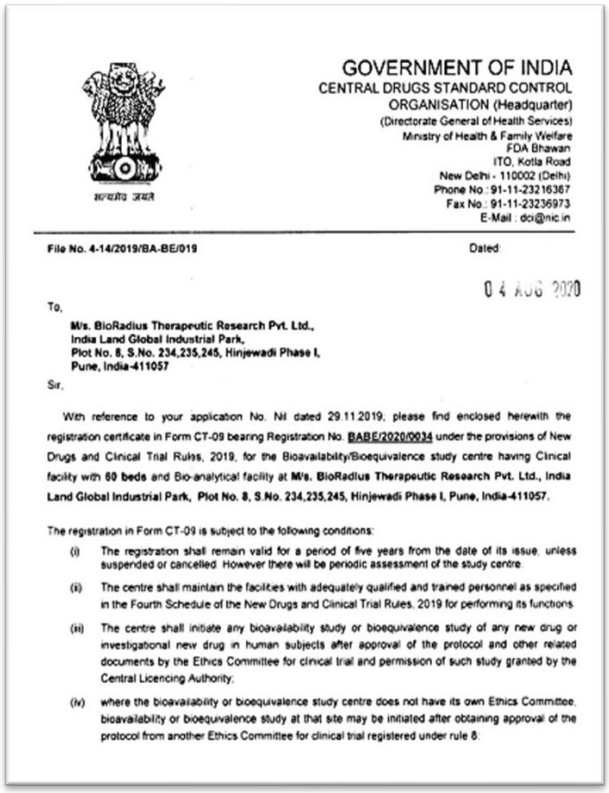
Policy of Alchemos is to provide products and services that conform to our customers requirements and deliver them on time with great service.

Our name must represent quality to our vendors, ourselves and our customers.

Group is fully committed to provide customer satisfaction and high quality products through an approach on integrity, customer dedication, focus on innovation, uncompromising business ethics and continual improvement of the quality management system.

The top management has established quality objectives for each department which are reviewed periodically to ensure continuous improvement of the quality management system.

ACCREDATIONS & APPROVALS



GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhawan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No : 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

सत्यमेव जयते

File No. 4-14/2019/BA-BE/019 Dated:

04 AUG 2020

To,

M/s. BioRadius Therapeutic Research Pvt. Ltd.,
India Land Global Industrial Park,
Plot No. 8, S.No. 234,235,245, Hinjewadi Phase I,
Pune, India-411057

Sir,

With reference to your application No. Nil dated 29.11.2019, please find enclosed herewith the registration certificate in Form CT-09 bearing Registration No. **BABE/2020/0034** under the provisions of New Drugs and Clinical Trial Rules, 2019, for the Bioavailability/Bioequivalence study centre having Clinical facility with **60 beds** and Bio-analytical facility at **M/s. BioRadius Therapeutic Research Pvt. Ltd., India Land Global Industrial Park, Plot No. 8, S.No. 234,235,245, Hinjewadi Phase I, Pune, India-411057.**

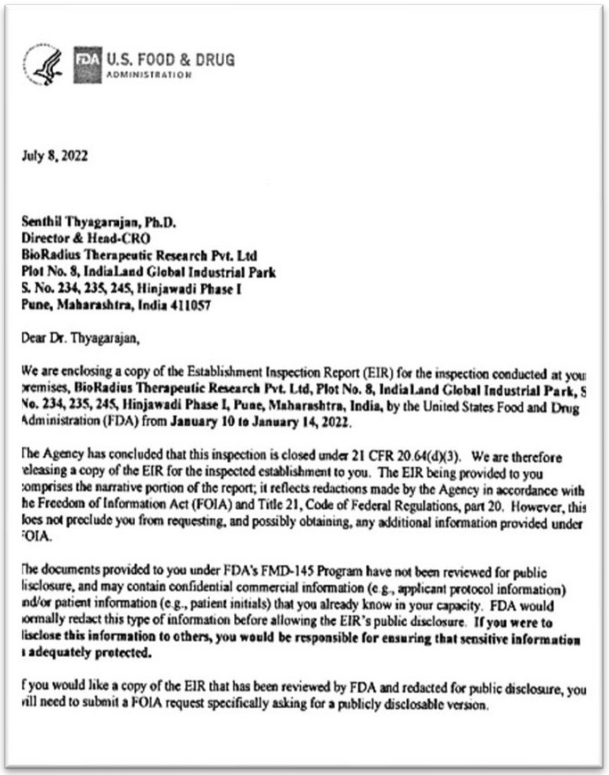
The registration in Form CT-09 is subject to the following conditions:

(i) The registration shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled. However there will be periodic assessment of the study centre.

(ii) The centre shall maintain the facilities with adequately qualified and trained personnel as specified in the Fourth Schedule of the New Drugs and Clinical Trial Rules, 2019 for performing its functions.

(iii) The centre shall initiate any bioavailability study or bioequivalence study of any new drug or investigational new drug in human subjects after approval of the protocol and other related documents by the Ethics Committee for clinical trial and permission of such study granted by the Central Licencing Authority.

(iv) where the bioavailability or bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from another Ethics Committee for clinical trial registered under rule 8.



U.S. FOOD & DRUG ADMINISTRATION

July 8, 2022

Senthil Thyagarajan, Ph.D.
Director & Head-CRO
BioRadius Therapeutic Research Pvt. Ltd
Plot No. 8, IndiaLand Global Industrial Park
S. No. 234, 235, 245, Hinjawadi Phase I
Pune, Maharashtra, India 411057

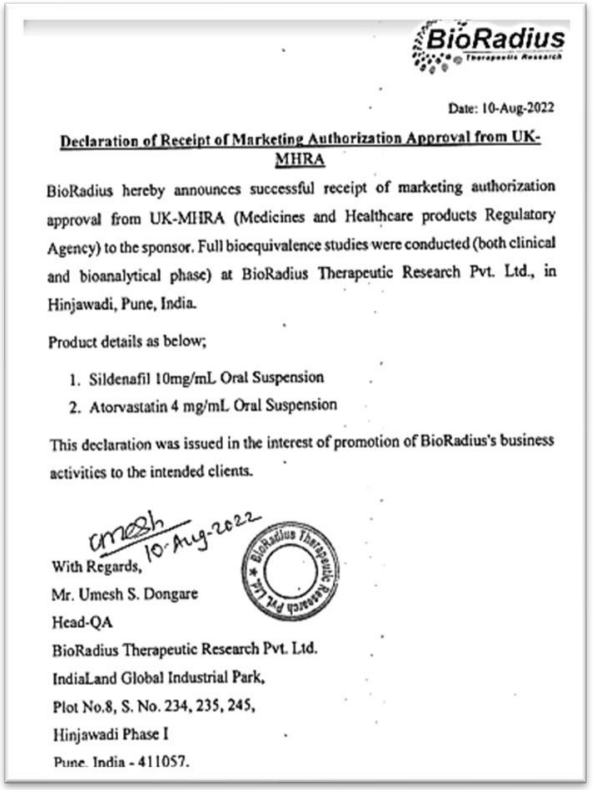
Dear Dr. Thyagarajan,

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your premises, **BioRadius Therapeutic Research Pvt. Ltd, Plot No. 8, IndiaLand Global Industrial Park, S No. 234, 235, 245, Hinjawadi Phase I, Pune, Maharashtra, India,** by the United States Food and Drug Administration (FDA) from **January 10 to January 14, 2022.**

The Agency has concluded that this inspection is closed under 21 CFR 20.64(d)(3). We are therefore releasing a copy of the EIR for the inspected establishment to you. The EIR being provided to you comprises the narrative portion of the report; it reflects redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and Title 21, Code of Federal Regulations, part 20. However, this does not preclude you from requesting, and possibly obtaining, any additional information provided under FOIA.

The documents provided to you under FDA's FMD-145 Program have not been reviewed for public disclosure, and may contain confidential commercial information (e.g., applicant protocol information) and/or patient information (e.g., patient initials) that you already know in your capacity. FDA would normally redact this type of information before allowing the EIR's public disclosure. **If you were to disclose this information to others, you would be responsible for ensuring that sensitive information is adequately protected.**

If you would like a copy of the EIR that has been reviewed by FDA and redacted for public disclosure, you will need to submit a FOIA request specifically asking for a publicly disclosable version.



BioRadius Therapeutic Research

Date: 10-Aug-2022

Declaration of Receipt of Marketing Authorization Approval from UK-MHRA

BioRadius hereby announces successful receipt of marketing authorization approval from UK-MHRA (Medicines and Healthcare products Regulatory Agency) to the sponsor. Full bioequivalence studies were conducted (both clinical and bioanalytical phase) at BioRadius Therapeutic Research Pvt. Ltd., in Hinjawadi, Pune, India.

Product details as below;

1. Sildenafil 10mg/mL Oral Suspension
2. Atorvastatin 4 mg/mL Oral Suspension

This declaration was issued in the interest of promotion of BioRadius's business activities to the intended clients.

umesh 10-Aug-2022

With Regards,
Mr. Umesh S. Dongare
Head-QA
BioRadius Therapeutic Research Pvt. Ltd.
IndiaLand Global Industrial Park,
Plot No.8, S. No. 234, 235, 245,
Hinjawadi Phase I
Pune, India - 411057.

BioRadius Therapeutic Research Pvt. Ltd.

Additional Certifications:

ISO 9001:2015, GMP, HACCP, HALAL, KOSHER, FSSAI

ALCHEMOS

Let's discuss
Thank You