

**Clinical Trials - 2014-2019**

Sr. No.	Name of the Clinical Trial,	Name of the Principal Investigator/ Co Investigator	Name of the funding agency	Department of Pricipal Investigator/ Co-Inveatigator	Year of Award
1	A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose Level in Subjects With Type 2 Diabetes Mellitus.	Dr. Deepak Bhosle	Karmik life sciences	Pharmacology Aurangabad	2016
2	A Randomized, Double-Blind, Placebo-Controlled, Three-Arm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two Tacrolimus 0.1% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis.	Dr Ashish Deshmukh	Lambda Therapeutic Research Limited	TB & Chest Aurangabad	2016
3	Arandomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose,crossover, steady state bioequivalence study of Everolimus tablets, 10 mg of Biocon Limited, India vs. Afinitor@ (Everolimus) tablets, 10 mg of Novartis Phannaceuticals Corporation, USA in advanced renal cell carcinoma (RCC) patients	Dr Chandrashekhar Tamane	Veeda Clinical Research Pvt. Ltd,	Oncology Aurangabad	2016
4	A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And Abraxane® In Subjects With Locally Recurrent Or Metastatic Breast Cancer.	Dr Chandrashekhar Tamane	Sun Pharma Advanced Research Company Ltd (SPARC)	Oncology Aurangabad	2016
5	Real world, Non-interventional, Observational Study of Hydroxyzine hydrochloride in chronic pruritus	Dr H R Jerajani	Clinresearch Healthcare solution pvt ltd	Dermatology Navi Mumbai	2016
6	A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total Hip Replacement Surgery. Protocol Number : CV185-158	Dr Girish Gadekar	PPD Pharmaceutical Development India Pvt Ltd	Orthopaedics Aurangabad	2016
7	Real world, non-interventional, observational study of Venusia Max Cream as Moisturizer in Psoriasis	Dr H R Jerajani	Bio Quest pvt ltd	Dermatology Navi Mumbai	2017
8	To evaluate efficacy and safety of Bacillus clausii (2 billion spores/5 ml) suspension as an add on therapy to standard of care in acute viral diarrhoea in children	Dr Nimain Mohanty	Wockhardt Ltd	Paediatrics Navi Mumbai	2017
9	A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Phase II Study to Evaluate the Efficacy, Tolerability, and Safety of Topical Povidone-Iodine (PVP-I, 2% [W/W]) in Pediatric Subjects for the Treatment of MolluscumContagiosum.	Dr Ashish Deshmukh	JSS Clinical Research Limited	TB & Chest Aurangabad	2017
10	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and Not on Dialysis. Protocol Number: LRP/LNP1892/2016/007; Version No.: 1.2, Dated 15 Dec 2016	Dr Sudhir Kulkarni	LUPIN	Nephrology Aurangabad	2017

11	A ranolized, open label, parallel-group, active-comparator controlled, multi-center study to evaluate the efficacy and safety of Llipristal acetate (5 ng tablets), as compared with Leuprolide acetate (3.75 mg intramuscular injection) for 12 weeks, in the preoperative treatment of moderate to severe symptomatic uterine fibroids	Dr Lakshmi Rachkonda	Cliantha Research Limited	OBGY Aurangabad	2017
12	Title An open label, Two Arms, Comparative, Phase IV Clinical Study evaluating safety and efficacy of Oratil LZ (combination of Cefuroxime 250mg + Linezolid 600mg) versus Linezolid 600mg in patients with Diabetic Foot Infections.	Dr Anuradha Patil	Macleods Pharmaceutical Ltd	Pathology, Aurangabad	2017
13	An Open Label Prospective, comparative, randomized, clinical study evaluating efficacy and safety of treatment A (Tamsulocin 0.4 mg Modified release capsule) versus treatment B (FDC Deflazacort 30 mg plus Tamsulocin 0.4 mg Tablet) in the patients with ureteral stone.	Dr Prashant Darakh	Macleods Pharmaceutical Ltd	Urology Aurangabad	2017
14	A Two arm, Comparative, Parallel, Randomized, double-blind, double-dummy Clinical study to evaluate and compare the efficacy and safety of Cefrine (combination of cefdinir 300 mg + lactobacillus 60 million cells) Capsule versus Cefuroxime 250 mg Tablet in the treatment of patients with Upper Respiratory Tract Infections.	Dr Rajendra Bohra	Macleods Pharmaceutical Ltd	ENT Aurangabad	2017
15	A Prospective, Multicentric, Phase IV Clinical Study evaluating safety and efficacy of Leuprorelin 3.5mg Injection plus Enzomac Tablet (Trypsin 96 mg + Bromelain 180 mg + Rutoside Trihydrate 200 mg) versus Leuprorelin 3 mg Injection in the treatment of patients diagnosed with Endometriosis Protocol No.: CT-205-LEEN-2016	Dr Swati Shiradkar	Macleods Pharmaceutical Ltd	OBGY , Aurangabad	2017
16	An open label, Two arm, Comparative, Randomized Phase IV Clinical Study evaluating efficacy and safety of Alrista Forte (Epalrestat 150 Mg + Methylcobalamin 1500 Mcg + Pregabalin 150 Mg) Tablet versus Pregabalin 150 Mg Capsule in patients with Diabetic Neuropathy	Dr. Deepak Bhosle	Macleods Pharmaceutical Ltd	Pharmacology Aurangabad	2017
17	26 Week, Multicenter, randomized, placebo controlled, double blind, parallel group, phase 3 trial with a 26 week safety extension period evaluating the safety and efficacy of Dapagliflozin 5 and 10 mg and saxagliptin 2.5 and 5 mg in pediatric patients with type 2 diabetes mellitus who are between 10 and below 18 years of age	Dr Deepak Bhosale	Astrazeneca Pharma India Ltd	Pharmacology Aurangabad	2017
18	"A 24-week, randomized, double-blind, double-dummy parallel group, multicentre, active-controlled study to evaluate efficacy and safety of remogliflozin etabonate in subjects with type 2 diabetes mellitus.	Dr Deepak Bhosale	Glenmark Pharmaceutical Ltd	Pharmacology Aurangabad	2017
19	A Study to Evaluate the Effect of Dapagliflozin on Incidence of Worsening Heart Failure or Cardiovascular Death in Patients with Chronic Heart Failure with Reduced Ejection Fraction.	Dr Prashant Udgire	Astrazeneca Pharma India Ltd	Plastic Surgery Aurangabad	2017
20	Inj- TR2SERVE :A comprehensive program to train, triage, and improve services for unintended childhood injuries in India	Dr. Maninder Setia	Grand Challenges Canada	MGMHS, Navi Mumbai	2018
21	Phase 3 Multicenter Double blind study to evaluate the long term safety and efficacy of baricitinib in adult patients with atopic dermatitis	Dr H R Jerajani	Eli Lilly Company (India) Pvt Ltd Gurgaon Haryana	Dermatology, Navi Mumbai	2018

22	A Multicenter Randomized double blind placebo controlled study to evaluate the efficacy and safety of baricitinib in adult patients with moderate to severe atopic dermatitis	Dr H R Jerajani	Elli Lilly Company (India) Pvt Ltd Gurgaon Haryana	Dermatology, Navi Mumbai	2018
23	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function	Dr. Prashant Udgire	Sanofi- Synthelabo Pvt Ltd	Cardiology Aurangabad	2018
24	A Randomized, Double-Blind, Placebo-Controlled, three-arm, Parallel Design, Multiple site, Study to Evaluate the Therapeutic equivalence and Safety of Tacrolimus Ointment,0.1% (Encube Ethicals Private Limited) with Protopic® - (Tacrolimus Ointment 0.1% (Astellas Pharma US, Inc) in the treatment of Moderate to Severe Atopic Dermatitis.	Dr. Ashish Deshmukh	Accutest	Skin and VD Aurangabad	2018
25	A Multicentric, Open lable, Randomized, Comparative, clinical study evaluating safety and Efficacy of Fixed Dose combination of Trypsin 48 mg + Bromelain 90 mg + Rutoside Trihydrate 100 mg enteric coated tablet versus Serratiopeptide 10 mg enteric coated tablet in patient for heling potential in surgical wound after minor surgery.	Dr. Mahendra Surywanshi	Macleods Pharmaceutical Ltd	Surgery Aurangabad	2018
26	A Phase III Randomized, Double Blind, Parallel Group, Placebo Controlled, Multi-Centre, Multinational Study to Evaluate Efficacy and Safety of TRC150094 as an Add on to Standard of Care in Improving Cardiovascular Risk in Subjects with Diabetes, Dyslipidemia and Hypertension.	Dr. Deepak Bhosle	IQVIA HDS (India) Private Limited	Pharmacology Aurangabad	2019
27	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.	Dr. Shivaji Pole	SIRO Clinpharm Pvt. Ltd.	Interventional Radiology Aurangabad	2019
<b>Clinical Trials - 2019-2021</b>					
1	Rotasili ® vaccine intussusceptions surveillance in Kerala, Karnataka , Maharashtra and Gurjarat, India	Dr. Mohd Haseeb	Bill and Melinda Gates Foundation	Medicine , Aurangabad	2020
2	Safety and Efficacy of Lipiodol Ultra fluid in association with Surgical Glues during Vascular Embolization. (IV) Protocol No: LUF-44-001	Dr Shivaji Pole, Dr Ejaj Patel	GUERBET	Radiology, Aurangabad	2019
3	A Multicentric, Randomized, Open label, Clinical trial To Evaluate Efficacy and Safety of Tapentadol Nasal Spray in comparison to Tramadol Immediate release Capsule and Intravenous injection in patients with Post operative moderate to severe pain. PNo: CT/TAPE/PAIN/17/03	Dr Tejendersingh Chhabda, Dr Amey Chakkarwar	SIRO CRO	Surgery , Aurangabad	2019
4	Multi centre cross sectional epidemiological study to characterize the prevalence and distribution of lipoprotein (a) levels among patient with established cardiovascular diseaseP No : CTQJ23A12001	Dr Prashant Udgire	Novartis	Cardiology, Aurangabad	2019

5	A Randomized,Open label, Prospective,Comparative Multicentre, Parallel group Active controlled Phase III Study evaluate safety and efficacy of Ropivacaine readyfusor 2mg/ml versus Ropivacaine ballon pump infusor 2mg/ml as continuous surgical site infusion for treatment of post surgical Pain in lower abdominal Laprotomy. P. No:CP/04/18	Dr Vasanti Kelkar	JSS	Anaesthesiology , Aurangabad	2019
6	A Prospective, Single-center, Open-label, Randomized, Parallel group, Active-controlled Clinical Study to Evaluate the Efficacy and Safety of CefpodoximeProxetil 200 mg + Clavulanic acid 125 mg versus Amoxicillin 500 mg + Clavulanic acid 125 mg in the Treatment of Patients with Upper Respiratory Tract Infections.	Dr Rajendra Bohra	Macleods Pharmaceuticals Ltd.	ENT, Aurangabad	2019
7	A Prospective, ,Double Blind, Randomized Parallelgroup,vehicle controlled,Multicentre Clinical Study to evaluate Safety and Bioequivalence of Mupirocin Cream USP 2% (Supplied by Glasshouse Pharmaceuticals Limited Canada) using Mupirocin cream 2% (Manufactured by :Glenmark Pharmaceuticals Inc:USA) as a reference product,in subjects with secondarily Infected Traumatic Skin Lesions P.No : GH-SL-IN-01	Ashish Deshmukh	JSS	Dermatology, Aurangabad	2019
8	A randomized, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV in patients with severe pulmonary COVID-19 related disease	Dr Umar Quadri	GSK/PPD	Emergency Medicine , Aurangabad	2020
9	A Phase II, controlled clinical study designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19.	Dr Umar Quadri	Biosphere Clinical Research Pvt. Ltd.	Emergency, Aurangabad Medicine	2020
10	A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of Infimab™ in patients with moderate to severe plaque psoriasis	Dr Ashish Deshmukh	Reliance Life Sciences	Dermatology & Pharmacology, Aurangabad	2020
11	An open label, randomized, active-controlled, multi-centric phase-ii/iii study in indian toddlers and infants to assess the immunogenicity and safety of siiplhexasiilm (dtwp-hepb-ipv-hib) vaccine in comparison with siiplpentavac (dtwp-hepb-hib) + poliovac (ipv) vaccines, administered as separate injections.	Dr Deepak Tayade	Serum Institute of India	Community Medicine, Aurangabad	2020
12	A randomized double blind placebo controlled study to evaluatethe effcacy and safety of cordyceps capsules ( Food supplment) as an additional on therapy in patient with mild to modrate covid -19 infection	Dr Sagar Sinha Dr Siddharth Dubhasi, (AIIMS, Nagpur) Dr.Jayashree Ghanekar, Dr Sameer Kadam , Dr Parineeta Samant	M/S Ambosia Food Farm Co. Utrakhand	Emergecnry Medicine , Surgery, Biochemistry , Navi Mumbai and AIIMS, Nagpur	2020

13	Survey to collect voice samples of patients and age matched healthy individuals P No: VoQuest01	Dr Deepak Bhosle	Quest	Pharmacology, Aurangabad	2020
14	A Multicenter, Phase III, Double-Blind, Randomized, Placebocontrolled Study To Evaluate The Efficacy Of Recombinant Bcg Vpm1002 In Reducing Infection Incidence And Disease Severity Of Sars-Cov-2/ Covid-19 Among High-Risk Subjects P No: SII-Rbcg/COVID-19/IN-01	Dr Deepak Tayade	Serum Institute of India Pvt. Ltd	Community Medicine, Aurangabad	2020
15	A Phase III, Multicentre, Randomized, Double Blind, Parallel group, Comparative Clinical Study to evaluate Efficacy and Safety of Ropivacaine Hydrochloride 0.75% (7.5mg/ml) in Dextrose 8% (80 mg/ml) injection compared to Bupivacaine Hydrochloride 0.5% (5mg/ml) in Dextrose 8% (80mg/ml) injection for subjects undergoing lower limb orthopedic surgeries under spinal anaesthesia P No: BCR/RPD/01	Dr Vasanti Kelkar	Neon	Anaesthesiology , Aurangabad	2020
16	A Comparative, Randomized, Two arm, Double blind, Parallel Group, Multicentre, Phase III Clinical study to Evaluate the Efficacy, Safety, and Tolerability of Netarsudil Ophthalmic Solution 0.02% vs Timolol maleate Eye drops 0.5% in treatment of elevated Intraocular Pressure (IOP) in subjects with Open Angle Glaucoma or Ocular Hypertension P No: APL/CT/18/03	Dr Jyotika Mishrikotkar	Mediclin Clinical Research	Ophthalmology, Aurangabad	2020
17	A prospective, Multicentre, Randomized, Double blind, Phase 3 study to evaluate the safety and efficacy of a gel formulation of Esmolol hydrochloride (Galnobax) in treating Diabetic Foot Ulcer P No: NG-A16	Dr Deepak Bhosale	JSS	Pharmacology , Aurangabad	2020
18	A Randomized Open-Label Study To Evaluate The Efficacy And Safety Of Favipiravir And Umifenovir As Compared To Favipiravir Alone In Moderate Hospitalized Adult Indian Covid-19 Patients P No: GPL/CT/2020/004/III	Dr Anand Nikalje	Glenmark	Pharmacology , Aurangabad	2020
19	A Phase II, controlled clinical study designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19.	Dr Umar Quadri	MGC Pharma	Emergency Medicine , Aurangabad	2020
20	A Randomized, Open Label, Single Centre, Observational, Prospective, Clinical Study to Evaluate the Efficacy and Safety of GanjhuVir syrup and tablet when administered along with Standard of Care (SOC) and compared against SOC in Covid-19 positive patients.	Dr Umar Quadri	Radhika Ayurveda Research and Development	Emergency Medicine, Aurangabad	2020
21	A Randomized, Open Label, Parallel Efficacy, Active Control, Multi- Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of an Ayurvedic Formulation- II (SanshamaniVati Plus) as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19 Patients.	Dr Syed Umar Qudari	AYUSH CSIR	Emergency Medicine , Aurangabad	2020

22	A randomized, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV in patients with severe pulmonary COVID-19 related disease	Dr Umar Quadri	GSK	Emergency Medicine , Aurangabad	2020
23	Randomized, double-blind, placebo-controlled, parallel-group, multi-centre phaseII/III adaptive clinical trial to assess the safety and immunogenicity, of Gam-COVID-Vac combinedvector vaccine for SARS-CoV-2 infection in Indian Healthy Subjects	Dr. Anand Nikalje	JSS Medical Research India Pvt Ltd.,	General Medicine, Aurangabad	2020
24	Double-blind, vehicle-controlled, randomised, multi-centre study to evaluate the efficacy and safety of LH-8 cutaneous solution in children and adolescents with moderate to severe scalp Alopecia Areata.	Dr. Ashish Deshmukh	CliniExperts Research Services Private Limited	Dermatology , Aurangabad	2020
25	A Multicenter, Phase III, Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subject under	Dr. Tayade Deepak Narayan	Dignosearch	General Medicine , Aurangabad	2020
26	Promesa DES - 1: A Prospective, Multicenter, Single arm, Open label Study to Evaluate Safety and Performance of Promesa™ DES Sirolimus Eluting Self-Expandable Nitinol Peripheral Stent System for Treating Superficial Femoral Artery (SFA) and Iliac Artery Lesions.	Dr. Shivaji Pole	Meril Life Science Pvt. Ltd.	Radiology , Aurangabad	2020
27	Open label, Randomized, Active-controlled, Multi-centric phase II/III Study in Indian Toddlers and Infants to Assess the Immunogenicity and Safety of SIIPL HEXASIIIL™ (DTwP-HepB-IPV-Hib) Vaccine in Comparison to SIIPL Pentavac (DTwP-HepB-Hib) + Poliovac (IPV) vaccines Administered	Dr. Deepak Tyade	HEXA	Pediatric, Aurangabad	2020
28	A prospective, multi-centre, open lable, phase IV study to evaluate safety and efficacy profile of Infimab™ in patients with moderate to severe plaque psoriasis	Dr Ashish Deshmukh	Reliance	Skin & VD, Aurangabad	2020
29	A prospective, randomized, two-arm, active-controlled, parallel, Multicentre, non-inferiority, phase III clinical trial to assess the efficacy and safety of Amorolfine lotion 0.25% W/v as compared to Amorolfine cream 0.25% w/w in patients with superficial fungal infection of the skin	Dr Ashish Deshmukh	Zydus	Skin & VD, Aurangabad	2020
30	A prospective, Double-Blind, Randomized, Parallel- Group, Vehicle-controlled, Multicentre study to Evaluate the Safety and Bioequivalence of Mupirocin Cream USP 2 % (Supplied By: Glasshouse Pharmaceutical Limited Canada) using Mupirocin Cream USP 2% (Manufactured by: Glenmark Pharmaceuticals Ins; USA) as a Reference product, in subject, with Secondarily Infected Traumatic Skin Lesions.	Dr Ashish Deshmukh	JSS	Skin & VD, Aurangabad	2020

31	A Phase III, Multicentric, Prospective, Randomized, Parallel Study to Evaluate the Efficacy and Safety of Molnupiravir in Adult Indian Patients with Mild COVID-19.	Dr. Umar Quadri	Hetero Labs Limited	General Medicine, Aurangabad	2021
32	A Phase-III, Multicenter, Prospective, Double Blind, Randomized, Parallel Clinical Study Evaluating The Efficacy, Safety And Tolerability Of Hetero-Tocilizumab In Cytokine Storm Of Severe Coronavirus Disease (Covid-19) Pneumonia (TOCICOVID Study)	Dr. Anand Nikalje	Hetero Biopharma Limited	General Medicine, Aurangabad	2021
33	A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Noninferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations	Dr. Mohammed Haseeb	Tergene Biotech Pvt. Ltd	Pediatric, Aurangabad	2021
34	A multicentre, prospective, open label, randomized comparative clinical trial to evaluate safety and efficacy of Reliance Life Sciences' Bevacizumab (R-TPR-023) plus standard of care and standard of care alone in COVID 19 Acute Respiratory Distress Syndrome (ARDS) Patients with non-invasive ventilation.	Dr. Anand Nikalje	Reliance life Sciences Pvt. Ltd	General Medicine, Aurangabad	2021
35	AZ-C-MVL-18-101-A Prospective Randomized Double Blind Multicentric Two Arms Phase III Clinical Trial To Assess the Efficacy And safety of levobupivacaine in Dextrose injection manufactured by Neon Laboratories Ltd. Cersus that of Bupicain Heavy (Bupivacaine Hydrochloride In Dextrose Injection) Manufactured By Thmis Medicare Ltd. for Spinal Anaesthesia inb Adult Patients	Dr. Kelkar Vasanti Prabhakar	Biosphere Clinical Research Pvt. Ltd	Anaesthesiology, Aurangabad	2021