

Pharmaceutical Research and Development Facility at RPCP, CHARUSAT

RAMANBHAI PATEL COLLEGE OF PHARMACY CHAROTAR UNIVERSITY OF SCIENCE AND TECHNOLOGY

Chemical Analysis, Pharmaceutical Formulations & Processing,
Ayurveda & Herbal Formulations, Nutraceuticals, Regulatory
Submission, Microbiology & Pharmacology Testing Facility



Charotar University of Science & Technology

(Accredited with “A” Grade by NAAC, Government of India)

[Constituted under Gujarat Private University Act No. 8 of 2009]

Aegis: Shri Charotar Moti Sattavis Patidar Kelavani Mandal

About Charotar University of Science and Technology (CHARUSAT)

Charotar University of Science and Technology (CHARUSAT) is promoted by Shri Charotar Moti Sattavis Patidar Kelavani Mandal. It is established under Gujarat Private University Act No. 8 of 2009, Govt. of Gujarat. CHARUSAT is sprawling over 105 acres of land with ultramodern facilities for teaching, learning and research. CHARUSAT has been conceived to make Charotar – the Land of Sardar Patel the Global Education Hub. It has become the First State Private University getting “A” Grade in Gujarat in the first cycle by NAAC, Bangalore. Further, it has also been one of 3 (three) Private Universities of Gujarat to appear in the NIRF Ranking.



About Ramanbhai Patel College of Pharmacy (RPCP)

Ramanbhai Patel College of Pharmacy (RPCP) was established in the year 2004 under the management aegis of Shri Charotar Moti Sattavis Patidar Kelavani Mandal. RPCP is patronized by Shri Pankaj Patel, Chairman and MD, Zydus Cadila Healthcare Ltd. M.Pharm Programmes are offered under auspices of T.P.Patel Center for PG Studies in Pharmacy at RPCP.

RPCP is established with a view to promote excellence in pharmacy education and to prepare young talent to meet the challenges of Industrial Pharmacy and Pharmacy Practice. RPCP offers B.Pharm, M.Pharm [with specialization in Pharmaceutical Technology, Pharmaceutical Quality Assurance, Pharmacy Practice, Pharmacology and Regulatory Affairs] and Ph.D. program.

The institute is fully equipped with the modern day facilities and instruments, further strengthen with advanced sophisticated instruments in the adjoining department on the campus. They include HPLC (with PDA, Fluorescence and ELSD detectors), HPTLC, Flash Chromatography, Spectrofluorimeter, Gel Electrophoresis, Fluidized bed dryer, Lyophilizer, Extruder Spheronizer, Probe Sonicator, High Speed Homogeniser, Stability Chamber, BIOPAC system for CVS/CNS/Pre Clinical & Clinical experiments, Non Invasive Blood Pressure (NIBP) measurement and state of art Aseptic Lab (Class 100) complying with industry norms.

Research Team of RPCP

The staff is composed of experienced academicians having proven record of handling research projects, laboratory technicians as well as researchers perusing a M. Pharm and Ph.D. degree in areas such as Quality Assurance, Pharmaceutical Technology, Pharmacology, Regulatory Affairs, Pharmaceutical Chemistry, Pharmacognosy and Analytical Chemistry. We use this wide range of experience and expertise to find the optimal and professional solutions. As a well-established pharmaceutical educational organisation, we consider ourselves fast, flexible, and competent in execution of scientific projects.

Response time

Delivery times are all-important to our collaborators and, consequently, of highest priority to RPCP Lab. Procedures to fulfil customer requirements are continuously being optimised. We strive hard to deliver the result of studies within the set timeline.

Competency in Executing Projects

Faculty members of RPCP has implemented many government funded research projects successfully. Faculties along with the research scholars have been involved in industry-sponsored projects. Following is the brief summary of government funded and industry sponsored projects taken up at RPCP.

- Clinical Assessment of Ayurveda Formulation Ashwagandhadi Lehya as Aphrodisiac and in Treatment of Oligospermia
- Pre-clinical pharmacokinetic study on aphrodisiac phytoconstituent
- Preparation and evaluation of biodegradable in-situ gel forming injectable controlled drug delivery system based on thermoresponsive methylcellulose hydrogel.
- Development and validation of stability indicating chromatographic methods (Accelerated and Real time stability study) for identification of some herbal formulations used in CNS disorder.
- Pre-clinical pharmacokinetic studies on aphrodisiac phytoconstituents.
- Design, synthesis and biological evaluation of flavonoids derivatives as potential Non-Steroidal Aromatase Inhibitors in Breast Cancer.
- Evaluation of multicomponent Ayurveda formulation-Ashwagandhadi Lehya.
- Development and characterization of nano-sized drug carrier microencapsulation formulations.
- Phytochemical and pharmacological studies on isolated principles of *Argyreia speciosa* for aphrodisiac and spermatogenic potential.
- Improvement of physico- chemical properties of active pharmaceutical ingredient via solid state modification
- Design, synthesis and evaluation of novel lipid lowering agent
- Pharmaceutical Product Development

- A study of Chemical Compatibility of drug with container
- Container Stability Testing
- Effect of microbial growth on various antimicrobial treated clothing materials
- Estimation and validation of the potency of Hydrus TM as an antimicrobial and disinfectant solution for various pharmaceutical and medical applications
- Development, Validation and Standardisation of Biocanine-A and CAFG in Dalbergia sissoo

RPCP is your ideal partner when it comes to,

- Development and Optimization of Pharmaceutical Formulations
- Development of Analytical Methods and Validation
- Chemical and Microbial Analysis as Per Pharmacopoeia Methods
- Stabilities Studies
- Isolation and Characterization of Phytoconstituents
- Chemical and Biological Analysis of Impurities
- Pre-Clinical Studies



List of Instruments/Equipments available in laboratories at RPCP

Equipment Name	Make (Manufacturer)	Model
Moisture Analyzer	Sartorius	MA 45
UV-Vis - Spectrophotometer	Shimadzu	UV-1700
Brookfield Dial Reading Viscometer	Brookfield	--
Homogenising Drive	Micra	D-8
Tablet Dissolution Tester	Electrolab	TDT - 08L
HPLC System	Shimadzu	
All Purpose Lab Equipment Coating Pan, Double Conmixer, Dosing Filling Liquid , Dosing Filling Ointment	Karnavati	PDA detector Bigradient SP-20AT
Tablet Punching Machine	Karnavati	Mini Press - II
High Speed Cooling Centrifuge	Remi	C24
Sterilizer System Horizontal Laboratory	Klenzaid	Klenzaid
Semi-Automatic Rotary Washing Machine	Riddhi	LRBW- 30
Incinerator	Reliable Instruments	
UV Spectrophotometer	Shimadzu	UV-1800
Tablet Dissolution & Bench Press	Elctrolab	TDT -08L
Luminescence Spectrometer	Perkin Elemer	LS55
Ultrasonic Processor (Prob Sonicator)	VIBRA CELL	VCX -500
Digital Biosignal Measurement System	Bio Pac System INC - USA	BSL BSC-W
HPTLC	CAMAG	CAMAG
Microscope with camera	Carl Zeiss Micro	Axio Lab AL"
Deep Freezer -80°C	Eppendorf	U101
Water Purification System	Milipore	Q-5 UVS
Lyophilizer - Advantage EL Freeze Dryer	Virtis	Virtis Advantage EL
NIBP - Small Animal Tail Noninvasive BP Amplifier Each NIBP 200A System Includes	Biopac	NIBP200A
Flash Chromatography	Biotage	ISOLERAONE
Radley's Carousel 6 Plus Reaction System	Radley's	RR99942
Lab Spray Drier	Labultima	LU - 222
Fluid Bed Dryer	Retech Gmbh	TG-200
Extruder-20 & Spheronizer-75	Sunsai Pharma	20 &75
Heidolph Rotary Evaporator	Heidolph	Hei Procision ML/HB/G3
Evaporative Light Scattering Detector	Softa Corporation	3008
HPLC System	Shimadzu	LC 2010CHT
UV -VIS Spectrophotometer	Shimadzu	UV-1800

Equipment Name	Make (Manufacturer)	Model
Centrifuge Multi-Purpose Refrigerated Centrifuge	Eppendorf	5804R
Bioklenz TM Bio Contamination Work Station	Klenzaid	1590B-36-24-24
Epoch Microplate Spectrophotometer (Plate Reader)	Bio Tech Instruments Inc- USA	
Inverted Trinocular Research Microscope	Carl Zeiss	AXIO Vert.A1.F.L
Auto Sampler Offline Sampling Dissolution	Electrolab	EDT-08Lx
Galaxy Incubator - CO ₂ Incubator	Eppendorf	170S
Deisient Dehumidifer	REHOBOTH	RDS100
HPLC System	Waters Alliance	Waters- e2695
Digital Tablet Hardness Tester	Vinsyst	VT -3
Diffusion Cell Apparatus	Orchid Scientifics	J-FDC-07
Shaking Water Bath	Remi Instruments	RS-B12
Chilled Water Circulator	Mediac - Equitron	EQUIBATH
Stability/ Humidity Chamber (I-Series)	Newtronics India Pvt. Ltd.	NLHC7SI
Parallel Synthesizer	Radley's	Carousel 6 Plus Reaction System
Microprocessor Based Digital PH METER	Systronics	361
KARL Fisher Titrator	Metroham	870 KF Titrino Plus

Instrument facilities available at RPCP

THE INSTITUTE IS FULLY EQUIPPED WITH THE MODERN DAY FACILITIES & INSTRUMENTS ALONG WITH SUPER ADVANCED SOPHISTICATED ANALYTICAL AND PROCESSING INSTRUMENTS



Spectrofluorimeter
(Perkin Elmer)



HPLC system
(Shimadzu)



UV VIS spectrophotometer
(Shimadzu)



HPTLC system
(Camag)



Gel Electrophoresis
(Genni)



Microscope, camera &
software (Carl Zeiss)



High Speed
Homogenizer (Micra)



Spray Dryer
(Lab Ultima)



Fluidized Bed
Dryer (ResTech)



Stability Chamber
(Thermo Lab)



Tablet Punching
Machine (Karnavati)



Extruder Spheronizer
(Sansui)



Lyophilizer
(Vertis)



Probe Sonicator
(Sonic)



Dissolution Apparatus
(Electrolab)



Deep Freezer
(Eppendorf)



BIOPAC System
(BIOPAC)

Specialized Laboratories

Pharmaceutical Microbiology & Aseptic Processing Laboratory

RPCP has it's a state of the art Aseptic laboratory. It is designed as per the standards laid down by FDCA. It includes separate area for sterility testing and microbiological work. Aseptic laboratory is designed to give best practical knowledge to students to conduct their work in the aseptic laboratory. It is equipped with essential instrument facilities like AHU (Air Handling Unit) system for sterile air supply, Centralized auto clave system, Laminar Air Flow, BOD incubator, Hot Air Oven, Colony Counter and Zone Reader. This laboratory is used for sterility testing, experiments in biotechnology, growth, isolation and identification of microorganisms, microbiological assays etc.



Cell Culture Laboratory

Cell culture is one of the major tools used in cellular and molecular biology, providing excellent model systems for studying the normal physiology and biochemistry of cells (e.g., metabolic studies, aging), the effects of drugs and toxic compounds on the cells, and mutagenesis and carcinogenesis. It is also used in drug screening and development, and large-scale manufacturing of biological compounds (e.g., vaccines, therapeutic proteins).

In recent years, there have been rapid advances in the growth and differentiation of mammalian cells in culture. This has led to increasing use of such *ex-vivo* systems in a wide variety of aspects in pharmaceutical research. With the view to promote the research using cell culture in pharmacy, RPCP has designed cell culture laboratory. It has the biosafety cabinet (i.e., cell culture hood) which is most important to prevent contamination of cell culture. It is equipped with instrumental facilities like, Cooling Centrifuge (5804R, Eppendorf, Germany), CO₂ Incubator (170R, Eppendorf, Germany), Fluorescent Microscope (Axiovert.A1, Carl Zeiss, Germany), Elisa Plate Reader (Epoch, BioTek, USA) and Deep freezer (-80°C & -20°C, U-101 Eppendorf). Cell culture

laboratory is designed to give best hands- on- training to the students. It helps the students familiarize with preparation and maintenance of areas, procedure for cell based assay i.e., MTT assays, cell uptake study etc. Cell lines are obtained from authentic sources like, NCL-Pune based on the requirement of specific studies.

Analytical Expertise in Chemistry	Expertise in Microbiology
<ul style="list-style-type: none"> • Analytical method development, validation, and transfer • Stability studies and impurity analysis • Dissolution profiles • Cleaning validation • Vitamin and mineral product analyses • Analyses of herbal medicinal products • Cosmetic analyses • Food and feed analyses • Control of packaging materials 	<ul style="list-style-type: none"> • Sterility testing • Determining microbial load • Bioassay of antibiotics • Endotoxin analyses (LAL testing) of pharmaceuticals • Water activity • Preservation studies • Method development and validation • Neutralisation of inhibition • MIC- and MBC-testing
Expertise in Formulations and Development	
<ul style="list-style-type: none"> • Pre formulation studies of drug and excipients • Development of generic formulations and controlled/extended release formulations. • Development of innovative-targeted drug delivery systems • Solubility/dissolution/bioavailability of BCS-II & IV class molecules. • Development of Cosmeceuticals, Nutraceuticals and Herbal Formulations. • Development of dissolution methods of new drug molecules • Optimization of formulations using Quality by Design (QbD) tools like, Design of Experiments (DoE) and Quality Risk Management (QRM) • Comparison of regulatory registration procedures of different countries for medicinal products • Preparation and compilation of pharmaceutical dossier in CTD format • Product development strategies as per regulatory guidance 	

Our Expertise in Pharmacological Screening

- Acute toxicities studies (OECD Guideline) using Rat and Mice
- Sub-acute toxicity studies (OECD Guideline) using Rat and Mice
- Chronic toxicity studies (OECD Guideline) using Rat and Mice
- MTT assay
- STZ induced diabetic model in Wistar rats along with diabetic complications like Neuropathy, Retinopathy and Nephropathy (Type-1 and Type-2 diabetes models)
- Preclinical models of Hyperlipidemia
- Preclinical *in vivo* model of Lung Cancer
- Preclinical models of Epilepsy (PTZ and pilocarpine based models)
- Preclinical models of Renal Stones (*in vivo* and *in vitro*) and diuretic activity
- Preclinical models of Benign Prostatic Hyperplasia
- Preclinical models of Pulmonary Fibrosis
- Preclinical models of Osteoporosis
- Preclinical models for evaluation of anti-inflammatory, anti-anxiety, anti-depressant, anti-alzheimer activity of drugs
- Preclinical models for evaluation of drugs acting on Cataract, Glaucoma
- Preclinical animal models for evaluation of Hepatoprotective, Renoprotective agents
- Preclinical animal models for evaluation of anti-ulcer agents
- *In-vitro* tissue experiments
- Preclinical models for Aphrodisiac Activity (Behavioral Studies)
- Evaluation of Spermatogenic potential of plant extracts using rats
- Histological studies
- Sperm count determination
- Biochemical studies
- *In vitro* evaluation of potential of plant extract on secretion of testosterone from TM-3 cells (Mouse leydif cell line).

Representative list of Projects/Dissertation at RPCP

1. Investigation on Role of Adenosine A2B Receptors in Chronic Nephropathy
2. Studies on Efficacy & Dynamics of *Ficus Racemosa* and *Bauhinia Variiegata* in Diabetic Neuropathy and Neurodegeneration
3. Role of Trough Mycophenoloc Acid Monitoring in Live Donor Kidney Transplant Recipients
4. Preparation and Characterization of *In-Situ* Gelling System for Solid Tumor Targeting by Intratumoral Administration
5. Formulation and Characterization of Microemulsion for Nasal Delivery of Drugs for the Treatment of CNS Disorders
6. Phytochemical Investigation on *Argyreia Speciosa* and *Hygrophila Spinosa* Used as Vajikarana in Ayurveda
7. Evaluation of Quality of Prescription Using ' Prescription quality Index' Tool - A Comparison of Primary, Secondary and Tertiary Health Care Facilities
8. Phytochemical Analysis and Preclinical Pharmacokinetic Study of Aphrodisiac Phytoconstituent
9. Development of Hepatotoxicity Model in Rats and Its Application in Evaluation of Hepatoprotective Activity of Cell Wall Contents of Probiotics
10. Oral Bioavailability Enhancement of Ganclclovir Through Polymeric Nanoparticles Development and Use of Permeation Enhancer
11. Training of Anticancer Drugs Using Ligand Conjugated Therapeutic System
12. Design, Synthesis and Biological Evaluation of Some Hetrocycles as Non-Steroidal Aromatase Inhibitors
13. Formulation and evaluation of chewable Paracetamole tablet.
14. Formulation & optimization of Non-effervescent Gastroretentive Floating Tablet of Captopril.
15. Formulation and evaluation of oral mucoadhesive tablet of anti-bacterial drug.
16. Formulation Development of Liposomal GEL of Silver Sulfadiazine for Burn Therapy.
17. Formulation and Evaluation of Liposome of Anti-HIV Drug for Brain Targeting
18. Development of Gemcitabine loaded Liposome to be use with Mild Hyperthermia for the treatment of Brain Cancer.
19. Pulmonary Delivery of Liposomal Anticancer Agent.
20. Development of Liposomal Formulation of Riluzole for Intranasal Administration.
21. Formuation and Evaluation of Nanoparticles loaded sublingual film of Raloxifene Hcl for Osteoporosis.
22. Formulation and Evaluation of Selegiline Hydrochloride Loaded Solid Lipid Nanoparticles by Intransal Route.
23. Development of Ciprofloxacin HCL loaded solid lipid Nanoparticles for Ocular Drug Delivery.
24. Formulation and evaluation of magnetic nanoparticles of 5-Fluorouracil.

25. Oral bioavailability enhancement of Agomelatine by preparing Nanoparticles.
26. Development of Levetiracetam loaded Poly-E-caprolactone nanoparticles for targeted delivery to brain.
27. Intracellular macrophage delivery of mannosylated PLGA nanoparticles Lamivudine for targeted delivery to the brain.
28. Formulation development of Quetiapine fumarate loaded nanoparticles for brain targeting.
29. Development of Ethosomal Gel for Tropical Delivery of Metronidazole.
30. Oral *in situ* Gelling Formulation of Metformin Hydrochloride.
31. Preparation and Application of Thermoresponsive In situ Hydrogel of Methyl cellulose in Wound Healing.
32. Formulation development, optimization and evaluation of colon targeted delayed release tablet containing anti-inflammatory drug.
33. Formulation development of w/o microemulsion of Didanosine for brain targeting through intranasal route.
34. Development of Aspirin and 5-Fluorouracil Loaded Pellets for Colon Cancer Targeting.
35. Preliminary *in vitro* and *in vivo* Studies on Intranasal Microemulsion of Montelukast Sodium for Brain Targeting.
36. Development and Validation of Chromatographic Method for Estimation of Berberine Chloride and Guggulsterone in Herbal Formulation.
37. To study registration guideline of herbal medicines in regulated market and to prepare dossier for phytopharmaceutical products as per CDSCO guideline.
38. Development and Validation of Stability indicating (stress) High Performance Thin Layer Chromatographic Method for *Centellaasiatica* and its Marketed Formulation.
39. Development of Stability Indicating Analytical Methods for Estimation of Tadalafil from Nano Suspension using HPCL & HPCLC & Development of analytical method for estimation of Guggulosterone-Z from Gokshuradi Guggulu using HPTLC.
40. Development of Stability Indicating RP-HPLC Method for Levothyroxine Sodium Formulation and The Application of QbD Approach in the development of A Formulation with Better Stability Profile.
41. Development and Validation of Stability Indicating HPLC method for Determination of Ospemifene and its related substances in bulk drug and tablet dosage form.
42. Development and Validation of Stability Indicating RP-HPLC method and chemometric assisted UV-Visible Spectroscopy method for simultaneous estimation of Rifampicin and Piperine in Pharmaceutical Dosage Form.
43. Development and Validation of UV Spectrophotometric, Chemometric and HPTLC methods for simultaneous estimation of Celecoxib and Diacerein from bulk drug and in combined dosage form.
44. Comparative Evaluation of Flexible Packaging Material for Protective Abilities on Dried fruit Powder of *Piper Longum*.

45. Preparation, compilation and submission of a dossier in ACTD format for marketing authorization of bi-layer tablet of Telmisartan and Hydrochlorothiazide USP in Vietnam.
46. Preparation, compilation and submission of a dossier in CTD format for marketing authorization of Erythromycin stearate tablets BP 500Mg in Kenya.
47. Dossier preparation of pharmaceutical drug project (Aspirin tablet) for Brazil.
48. Preparation, compilation and filing of ANDA dossier of Imipenem and Cilastatin sodium for injection as per USFDA guidelines.
49. A study on Preparation of Initial Marketing Authorization Application Dossier of Cisplatin Infusion by Decentralized Procedure for Europe in Common Technical Document Format as per European Guidelines.
50. Preparation, Compilation and Submission of a dossier in CTD format for marketing authorization of Sodium Chloride Injection 0.9% w/v in Australia.
51. To Study the Registration guideline of Nutraceutical Product in ASEAN Countries and to prepare a dossier of nutraceutical product.
52. Preparation, compilation and submission of a dossier in ACTD format for marketing authorization of Cetirizine tablet in Cambodia.
53. Study of post approval changes of medicinal product in three countries: US, EUROPE and SOUTH AFRICA.
54. Registration Requirements Comparison between Southeast Asian Region and Central-east African Region.
55. Study of Registration requirements of finished Pharmaceutical Generic Product (i.e. Tablet) of five selected South African Development Community (SADC) Countries.
56. Comparative Evaluation of Registration Requirements, Biopharmaceutics Classification System (BCS) Based Bio waiver for Drug Product in East African Countries and South Africa.

Ramanbhai Patel College of Pharmacy
Charotar University of Science and Technology, CHARUSAT

At & Post- Changa, Dist- Anand Ta- Petlad-388421

Phone: 02997265144, 09904132390

Email: principal.rpcp@charusat.ac.in

Web: <https://www.charusat.ac.in/RPCP/>