SUMANDEEP VIDYAPEETH

(Declared as Deemed to be University under Section 3 of the UGC Act 1956)

Accredited by NAAC with a CGPA of 3.53 out of four-point scale at 'A' Grade

Category – I deemed to be university under UGC Act - 2018

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CURRICULUM
Bachelor of Science
(B.Sc)
CLINICAL RESEARCH

Attested CTC

15/2/2021

Vice-Chancellor
Sumandeep Vidyapeeth
An Institution Deemed to be University
Vill. Piparia, Taluka: Waghodia.
Dist. Vadodara-391 760. (Gujarat)

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Smt. B. K. Shah Med. Instt. & Rese. Centre
Dean

AMENDED UP TO DECEMBER -2020

INTRODUCTION

Scope

The quality of paramedical care has improved tremendously in the last few decades due to the advances in technology, thus creating fresh challenges in the field of healthcare. It is now widely recognized that health service delivery is a team effort involving both clinicians and non-clinicians, and is not the sole duty of physicians and nurses. Professionals that can competently handle sophisticated machinery and advanced protocols are now in high demand. In fact, diagnosis is now so dependent on technology, that paramedical and healthcare professionals are vital to successful treatment delivery.

Effective delivery of healthcare services depends largely on the nature of education, training and appropriate orientation towards community health of all categories of health personnel, and their capacity to function as an integrated team, with a range of skills and expertise, play key roles within the National Health Service, working autonomously, in multi-professional teams in various settings. All of them are first-contact practitioners and work across a wide range of locations and sectors within acute, primary and community care.

Learning goals and objectives for paramedical healthcare professionals

The learning goals and objectives of the undergraduate and graduate education program will be based on the performance expectations. They will be articulated as learning goals (why we teach this) and learning objectives (what the students will learn). Using the framework, students will learn to integrate their knowledge, skills and abilities in a hands-on manner in a professional healthcare setting. These learning goals are divided into nine key areas, though the degree of required involvement may differ across various levels of qualification and professional cadres.

Program outcomes

Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

Ethics and accountability

Students will understand core concepts of clinical ethics and law so that they may apply these to their practice as healthcare service providers. Program objectives should enable the students to:

- Describe and apply the basic concepts of clinical ethics to actual cases and situations
- Recognize the need to make health care resources available to patients fairly, equitably and without bias, discrimination or undue influence
- Demonstrate an understanding and application of basic legal concepts to the practice
- Employ professional accountability for the initiation, maintenance and termination of patient-provider relationships

- Demonstrate respect for each patient's individual rights of autonomy, privacy, and confidentiality

Commitment to professional excellence

The student will execute professionalism to reflect in his/her thought and action a range of attributes and characteristics that include technical competence, appearance, image, confidence level, empathy, compassion, understanding, patience, manners, verbal and non-verbal communication, an anti-discriminatory and non-judgmental attitude, and appropriate physical contact to ensure safe, effective and expected delivery of healthcare.

Eligibility for admission:

1. He/she has passed the Higher Secondary (10+2) Science or a duly constituted Board with pass marks in Physics, Chemistry, Biology
2. Diploma in Radiology Imaging Technology with minimum aggregate of 50% marks.

Duration of the course:

Duration of the course is 4 years including 1 year internship.

Attendance:

A candidate has to secure minimum 80% attendance in overall with at least-
1. 75% attendance in theoretical
2. 80% in Skills training (practical) for qualifying to appear for the final examination.
No relaxation, whatsoever, will be permissible to this rule under any ground including indisposition etc.

Medium of instruction:

English shall be the medium of instruction for all the subjects of study and for examination of the course.

Assessment:

Assessments should be completed by the academic staff, based on the compilation of the student's theoretical & clinical performance throughout the training programme. To achieve this, all assessment forms and feedback should be included and evaluated. Student must attain at least 50% marks in each Theory, Internal assessment and Practical independently / separately for each individual subject.

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COURSE OF INSTRUCTION

Course Name	Course code	Theory (In hrs.) (Class and lab)	Practical (In hrs.) (Clinical)
First Year – total hours-400			
Pharmacology	BCR101	60	40
Clinical Research	BRC102	60	40
Medicine	BRC103	60	40
Biostatistics	BRC104	60	40
Total		**240**	**160**
Second Year –total hours-400			
Pharmacology	BRC201	60	**40**
Clinical Research	BRC202	**60**	40
Medicine	BRC203	60	40
Biostatistics	BRC204	60	40
Total		**160**	**100**
Third Year – total hours 600			
Pharmacology	BRC301	160	40
Clinical Research-I	BRC302	120	80
Clinical Research-II	BRC303	120	80
Total		**400**	**200**

SCHEME OF EXAMINATION

Course	Course Code	Assessment			
		Hours	Internal	External	Total
First Year					
Pharmacology	BCR101	3	20	80	100
Clinical Research	BRC102	3	20	80	100
Medicine	BRC103	3	20	80	100
Biostatistics	BRC104	3	20	80	100
Total			**80**	**320**	**400**
Second Year -					
Pharmacology	BRC201	3	20	80	100
Clinical Research	BRC202	**3**	20	80	100
Medicine	BRC203	3	20	80	100
Biostatistics	BRC204	3	20	80	100
Total			**80**	**320**	**400**
Third Year -					
Pharmacology	BRC301	3	20	80	100
Clinical Research-I	BRC302	3	20	80	100
Clinical Research-II	BRC303	3	20	80	100
Total			**60**	**240**	**300**

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FIRST YEAR B.SC IN CLINICAL RESEARCH

BCR101-PHARMACOLOGY 60 HOURS

Introduction to Pharmacology
Definitions and brief – (pharmacology, pharmacokinetics, pharmacodynamics, drug, pharmacotherapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts

Routes of Drug Administration
Local routes (topical, deeper tissues and arterial supply etc.), systemic routes (Oral, sublingual, rectal, coetaneous, inhalation, nasal, parenteral etc.)

Dosage Forms of Drug –
Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nano some, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices)

Sources of Drugs –
Natural sources and synthetic sources

Pharmacodynamics:
Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction

Factors Modifying Drug Action
Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cumulation, tolerance,etc.

Pharmacokinetics – brief of absorption, distribution, metabolism and excretion

Autonomic nervous system - Introduction, cholinergic system, anti-cholinesterase,

BCR102-CLINICAL RESEARCH 60 HOURS

Introduction to Clinical Trials
Glossary of terms in clinical trials, history, requirements, new drug development process, need for new drug, selection of a chemical compound as a potential drug, screening of

chemical compounds, translation medicine, assessment of preclinical data **Phases of clinical trials.**

Principles of controlled clinical trials-
Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials- Requirements, regulations and feasibility. Improving patient enrolment and retention in Clinical Trials

Other Clinical Studies
Pharmacoepidemiology, pharmacovigilance, ADR monitoring, pharmacokinetic trials, quality of life studies

Legal issues in clinical trials

Drug regulations
National- good clinical practice and schedule Y
Critical evaluation of literature- Systematic review and meta-analysis, evidence-based medicine

BCR103-MEDICINE **60 HOURS**

Note: brief study of the following topics with their relevant applications

Introduction to clinical medicine

Science and art of medicine, global issues in medicine, screening and prevention of diseases

Basic climatic and environmental diseases

Diabetes mellitus

Functional anatomy, physiology, presenting problems in Diabetes mellitus, management, drugs-class effect and side effects, dietary management, long term complications in brief

Hypertension
Definition, types of hypertension, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects

Coronary artery diseases
Ischemic heart disease ; definition , types, causative factors, path physiology, life style modifications, treatment (different classes) ,class effect and side effects in brief

Cerebrovascular diseases
Stroke: etiology, management; life style modifications, treatment (different classes), class effect and side effects in brief

BCR104-BIOSTATISTICS **60 HOURS**

Introduction- Biostatistics and standard terminology

Basic knowledge about presentation of data

Type of diagram, one dimensional diagram, two-dimension diagram, three-dimensional, pie diagram and pictogram

Graphic representation of data

Histogram, frequency, polygon and frequency curve.

Sampling - Definition, selection of samples, merit and limitation of sampling, methods of sampling.

Measures of central tendency

Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean.

Measures of dispersion
Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation.

Definition and application

Correlation, regression, Chi-square test and t-test.

Communication
Types of communication, pronunciation, consonants and vowel sounds, grammar, noun, adjectives, use of definite and indefinite articles, tenses. Vocabulary; antonyms, synonyms, homonyms, one word substitution, common phrases and idiomatic expressions

Each student shall undergo training in Skill Simulation Laboratory for learning certain basic clinical skills like IV/IM injection, setting IV-line, Cardio-pulmonary resuscitation (CPR), and Life support skills in the beginning of second year, for duration of continuous four days. (Board of Studies letter No.:FPMS/SV/BOS-MIN/0006/2016-17, dated 19/04/2017, and vide notification of Board of Management resolution Ref.:No. SVDU/R/2017-18/5056, dated 09/01/2018).

SECOND YEAR B.SC IN CLINICAL RESEARCH

BRC201-PHARMACOLOGY **60 HOURS**

Histamine

Classification of drugs, prototype drug- actions, prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Antihistamine
Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Drugs acting on kidneys and GIT:
Diuretics
Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Antidiuretics

Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Drugs for peptic ulcer

Introduction to disease in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Cardiovascular Pharmacology:

Hypertension
Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

CHF: Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Coronary Artery Disease

Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Arrhythmia

Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Endocrine Pharmacology:
Diabetes Mellitus

Introduction to disease in brief, insulin – types of insulin, class effect and side effect, methods to deliver insulin, management of acute complication of diabetes, oral hypoglycemic drugs- classification of drugs, class effect and side effect, peculiar effect and side effect of some important drugs

Thyroid hormone and Thyroid inhibitors

Anatomy &physiology of thyroid in brief, classification of drugs, prototype drug- actions,

Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Corticosteroids- Anatomy &physiology of adrenal gland in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Estrogen, Progestins and Contraceptives- Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Oxytocin and other drugs acting on uterus- Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs**,**

Drug affecting calcium balance- Physiology of calcium balance in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

BRC202-Clinical Research 60 HOURS

Toxicity studies – Acute, sub-acute and chronic toxicity studies, Detail of Acute, sub acute and chronic toxicity studies, Mutagenicity, Carcinogenicity and Teratogenicity

Quality Assurance/Quality Control studies: Guidelines and operational techniques

Drug regulations:
International: Food and Drug Administration and European Medicine Agency.

- Introduction of FDA
- History of FDA and Departments in FDA
- Regulations in FDA
- Regulations in FDA
- How FDA works
- introduction of European Medicine Agency

Clinical Data Management- Introduction, planning of trial, database, flow of data, creating database, Data Validation, system validation, data entry, E- data capture.

Therapeutic drug monitoring - Efficacy and safety measurement, endpoints

Auditing: Research Auditing & Inspections

Preparing Clinical Trial Report: Interim study report, close out report

Case Record Form: Introduction to CRF, Format and Sponsor Needs, guidelines related to CRF filling

Research ethics and research audits: Declaration of Helsinki

Ethical issues in Genetic Research: Genetic engineering, Gene mapping, cloning and ethical issues

Research methodology (laboratory and clinical) - Definition, objectives, concept, variable

Research process, research question – Hypothesis, features of a good research design.

Experimental Design- Concept of independent & dependent variables

Exploratory Research Design – Descriptive vs analytical Research, applied vs fundamental research, qualitative vs quantitative research

Use of tools / techniques for research- Methods to search required information effectively and teaching of latest software to search data and facilitate writing for publications e.g. Endnote

Funding Medical Research – Budgeting of a clinical trial in detail

Business Process Outsourcing and Contract Research Organization- Organizational structure, Types, Relationships with various stakeholders in the Clinical trial process

Overview of Pharma. Business- India and worldwide: Introduction, Major Pharma players: global & Indian, their area of research market scenario of health care products

Business Development- Introduction, methodology and importance
Translational medicine- Introduction, methodology and importance
Conflicts of Interest- Investigator, sponsor, publisher

Community based Qualitative Research and Research Ethics- Ethical Principles, informed consent, confidentiality of information shared and anonymity of research participants, no harm to participants, beneficence and reciprocity

Facilitating Best Practices

- Introduction to Standard operating procedures (SOP's) & need forSOP
- Training and decision-making

BRC203-MEDICINE 60 HOURS

Arthritis- Rheumatoid arthritis, osteoarthritis- Definition, pathophysiology, treatment - different classes of drugs, class effect and class side effect, pharmacological- classification of drugs, class effect & class side effect & non-pharmacological treatment

Shock - Definition, pathophysiology, types of shock, presenting features, diagnostic investigation in brief, pharmacological- classification of drugs, class effect & class side effect and non-pharmacological treatment

Inflammatory Bowel Disease and Irritable Bowel Syndrome- Definition, pathophysiology, presenting features, management, investigation, pharmacological-classification of drugs, class effect & class side effect & non-pharmacological treatment

Heart failure, Coronary artery diseases: drugs, surgical treatment in brief & stents

Common infections:

- **Tuberculosis –** causative agents, diagnostic criteria, etiological agents in brief, categories of tuberculosis, classification of drugs, first line drugs in detail different classes of drugs, class effect and class side effect , DOTS therapy, multidrug resistant tuberculosis
- **AIDS -** Etiological agents in brief, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment regimes, prophylactic therapy, therapy in pregnancy
- **Malaria-** Life cycle of causative agent, types of malaria, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment of relapsing malaria, treatment of cerebral malaria, multi drug resistant malari

BRC204-BIOSTATISTICS
60 HOURS

Probability: Definition and Application

Parametric Tests: Definition and Application
Analysis of variance-One Way and Two Way

- McNamara's test
- Exact probability test

Rank score tests – Definition and Application

- Wilcoxon signed ranktest,
- Wilcoxon two sample ranktest,
- The Mann Whitney Test,
- The Spearman Test,
- The Friedman Test.

F-test – testing of two population variances

Study design and choosing a statistical test Design-Assignments

Practical Lab (Part I-IT & Part- II Communication and management)

MS- Excel – Introduction to excel and RDBMS

Clinical Data Management – Overview, regulation, data management plan, data aquacition and CRF designing, database designing and implementation, data entry and verification and data analysis.

Soft Skills - Introduction and definition, motivation, SWOT analysis, goal setting, business

etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.

- Introduction
- Working with SAS Data Sets
- Working with Raw Data Files
- Creating Variables
- Manipulating Data
- Generating Reports
- Getting started with SAS
- Getting familiar with SAS Data Sets
- Producing List Reports
- Enhancing out put
- Creating SAS Data Sets
- Data step Programming
- Combining SAS Datasets
- Producing Summary Reports

MANAGEMENT

ACCOUNTING - Basic accounting, Accounting principles & conventions, Accounting Terms, Types of accounts, Accounting Rules , Double Entry, Ledger Posting, Trial Balance, Final Accounts

MARKETING - Marketing Concept, Marketing environment, Marketing mix, Market Segmentation, Consumer behavior, Advertisement, Pricing policy, Ethical and social

Communication English

- **Grammar usage –** Pronoun, Problems in grammar usage, Transitive and Intransitive Verb,
- Singular and plural verbs, Adverb
- **Vocabulary usage-** How to Keep Your Sanity with transitive and intransitive verbs
- Interview Skills
- **Reading Assignments**
- **Writing Assignments**

THIRD YEAR B.SC IN CLINICAL RESEARCH

BRC301-PHARMACOLOGY HOURS	**60**

Introduction, classification, mechanism of action and side effect of the following

categories of drugs:

- General Anesthetics
- Sedative and Hypnotics
- Antiparkinsonian
- Antipsychotic
- Antidepressant

Opioid analgesic and antagonist - introduction to pain pathway in brief and classification of drugs, prototype drug- actions, side effect of some important drugs

Antimicrobials — introduction, classification, mechanism of action and side effect of the following categories of drugs:

- Sulfonamides
- Cotrimoxazole and Quinolones
- Beta-Lactam Antibiotics
- Tetracycline & Chloramphenicol
- Amino glycosides antibiotics
- Macrolide, lincosamide, glycopeptides, & other Antibacterial Antibiotics
- Antitubercular drugs
- Antileprotic drugs
- Antiviral drugs
- Antimalarial drugs
- Antiamoebic drugs
- Antiprotozoal
- Antihelmenthic drugs

Immunomodulatory drugs- introduction, classification, mechanism of action and side effect of Immunomodulatory drugs

Anti-cancer drugs - introduction, classification, mechanism of action and side effects of anti- cancer drugs

BRC302-CLINICAL RESEARCH 60 HOURS

Bioavailability /Bioequivalence Studies

Introduction, terminology, concepts, characteristics and regulatory guidelines in India.

Introduction to GLP and GCP, Declaration of Helsinki

Regulations for pre-clinical and clinical studies and drug regulation:

- DCGI
- Indian Council of Medical Research
- FDA
- OECD

- WHO
- National Institute for Clinical Excellence (NICE), European Medicines Agency

Pharmaceutical marketing - introduction to

- Medico marketing
- Industry scenario
- Pharmaco economics

Special clinical trials and trial related issues - special population, trials on special population, and trials on life threatening diseases (ICH Guidelines).

Micro-dosing - Phase 0 and importance in relation to clinical research

Biomarkers – definitions, importance, surrogate biomarkers

Health Insurance Portability and Accountability Act (HIPAA) - introduction to HIPPA, titles under HIPAA, privacy rule, PHI.

BRC303-CLINICAL RESEARCH
60 HOURS

Clinical Data Management - communication, query process, coding dictionaries, locking of database, process after database locked, publishing, data management: career prospectus

Intellectual Property rights (IPR) - copyright, trademarks, patents: requirement, objectives, patent implications, recent scenario and case studies

Patents Regulations - trade related aspects of intellectual property rights (TRIPS), patent extension rules, implications

Pharmacovigilance:

- Methods of pharmacovigilance, causality assessment
- International Guidelines – US, UK and timelines of ADR reporting

Medical Transcription – introduction, process of transcription in context of clinical

Inspection - introduction, responsibilities of clinical trial staff, and actions: before, during and after completion, action item list

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CONSORT: Consolidated Standards of Reporting Trial

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Trial master file - contents of master file, source document, compilation, documentation, ways and importance

Publishing Research Studies: publication of research paper/report in National and International scientific journals and ethics

Confidentiality and competitiveness in clinical trial guidelines

INTERNSHIP (INTEGRATED PRACTICE) - TOTAL HOURS 1440

- The internship will span1 Year. This will include 6 hours of practice a day, totaling to 1440 hours during internship year. As a part of this, the students will maintain a work logbook which will be duly endorsed by the supervisor or trainer. At the end of internship, the candidate shall submit the work log book along with certificate from the training institute.

- The internship time period provides the students the opportunity to continue to develop confidence and increased skill in clinical delivery of services. Students will demonstrate competence in beginning and intermediate procedures. Students will observe the advanced and specialized procedures. The student will complete the clinical training by practicing all the skills learned in classroom and clinical instruction. The students are expected to work for minimum 6 hours per day and this may be more depending on the need and the healthcare setting.

CODE OF PROFESSIONAL CONDUCT

STANDARD OF PRACTICE AND CARE

Patients are entitled to the highest standard of practice and care. The essential elements of this are professional competence, good relationships with patients and colleagues and observance of professional ethical obligations.

In providing care you must therefore:

- recognize the limits of your professional competence.
- be willing to consult colleagues
- keep clear, accurate and contemporaneous patient records which report the relevant findings.
- keep colleagues informed.
- pay due regard to the efficacy and the prudent use of resources.
- be competent, truthful, and accurate, when reporting on investigations.
- be competent when giving or arranging treatment.

Patients' rights

- treat patients politely and considerately.
- respect patients' privacy and dignity.
- give information to patients in a way they can understand.
- respect the right of patients to be fully involved in decisions about their care.
- respect the right of patients to refuse treatment or to take part in teaching or research, reporting the refusal to the person requesting the procedure.
- respond to complaints promptly and constructively.
- ensure that your views about a patient's life style, culture, beliefs, race, colour, sex, sexuality, age, social status, or perceived economic worth, do not prejudice the service you give.

CONFIDENTIALITY

Patients have a right to expect that you will not pass on any personal information which you learn in the course of your professional duties, unless they agree.

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