

BLDEA's Shri Sanganabasava Mahaswamiji College of Pharmacy And Research Centre Vijayapur - 586 103



PHARMACEUTICAL QUALITY ASSURANCE

About College

BLDE Association's Shri Sanganabasava Mahaswamiji College of Phar- macy and Research Centre was established in the year 1982, to cater to the needs of Pharmacy education in North Karnataka region. Since its inception, the College has earned great respect and reputation among the students and people across the state for imparting quality Pharmaceutical education and has continued to be one of the prominent Pharmacy education institutions of the region.

The BLDE Association is propagating education in Vijayapur and Bagalkot districts, which are recognized as socially, economically and educationally backward areas. The BLDEA was established by visionary and renowned scholar 'Vachana Pitamaha' the late Dr. P. G. Halakatti, with other philanthropists of Vijayapur with a primary objective of reaching out education to all in North Karnataka region.

About Department

Postgraduate course was established in the year 2010. The Department is a recognized research centre for M. Pharm under the Rajiv Gandhi University of Health Sciences, Karnataka. Department is well Equipped with state of the art facilities to undertake academics in Bachelor and Master of pharmacy courses. Presently, the Department has research interests in GMP, GLP, Development and Validation of Analytical methods, pharmaceutical processes and calibration of equipment including important aspects of pharmaceutical quality control and quality assurance in alignment with pharmaceutical industry.





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Department Profile



NAME	DEPARTMENT OF PHARMACEUTICAL QUALITY ASSURANCE	
	THREE MEMBERS:	
FACULTY	Dr. Santosh Karajgi,	
	(Dr.) Shripad Potadar,	
	Dr. Sudha Patil	
YEAR OF APPROVAL	2010-11	
YEAR OF ESTABLISHMENT	2012-13	
ADMISSION APPROVAL	10 SEATS	
No. OF PASSED OUT STUDENTS	12	

Faculty member details



Dr Santosh R Karajgi



Mr Shripad S Potadar



Dr Sudha B Patil

Professor and HOD

M Pharm PhD

Professional Details

Years of experience:- 23 Scientific Publications :- 69 Conferences/seminars Presented:- 10 Book Chapters :- 14 Collaborative Patents Published :-09 Research Grants :-02

Assistant Professor

M Pharm (Ph.D)

Years of experience:- 11 Scientific Publications :- 14 Conferences/seminars Attended:- 24 Book Chapters :- 03 Research Grants :-02

Assistant Professor M Pharm Ph.D

Years of experience:- 01 Scientific Publications :- 07 Conferences/seminars Attended :- 13 Patent Filed :- 01

Vision And Mission Of The Institute

Vision

To provide quality pharmaceutical education, practice and research with global standards and to meet health care needs of the backward region of North Karnataka.





Mission

Empowering graduates in application based knowledge with high degree professional integrity and ethics.

Research & Publications

The department has received research grant of Rs. 1.25 lakh from the Rajiv Gandhi University of Health Sciences Bengaluru & 2.25 Lakh from BLDE(DU) Vijayapur.90 high impact publications have been generated by the researchers of the department using the facility. Staff members of the department carry out consultancy, evaluation, book authors, National & International journal referees, editors etc, because of their competency and contribution in the core knowledge domain.

Quality Policies Of The Department

- To bring continuous reforms in curriculum delivery and deployment
- To enhance the skills and Knowledge of the students through career development programs and skill up-gradation programs.
- To produce quality professionals to meet the emerging Industrial, Social and Economical needs.
- To create research ecosystem in the department to work through thrust areas
- To create a good ambiance to the students for their Academic Excellence through good research publications and presentations.
- To develop industry academic interaction system
- Continuous quality improvement through online webinars and seminars.
- Putting effort towards environment and sustainability.

Department Highlights

SI. No	Activity	Total (Up to 2022)	Last Five Years (2017-2021)
1.	Research Publications	90	60
2.	Presentations	10	04
3.	Book Chapters	14	01
4.	Collaborative Patents Published	09	01
5.	Research Grants	03	02

Curriculum Planning and Delivery

- Course Learning Objectives are set by Affiliating University RGUHS
- Course outcomes are planned by the course in charge of the department
- Effective use of Black board and ICT enabled methods for teaching learning activities
- Must to know, Desirable to know and Nice to know concept
- Blue print for model curriculum and question paper provided by the University

Teaching Learning and Evaluation Process

CLOs and COs

- Well planned Course Learning Objectives and Course Outcomes
- Remedial classes, Special classes, Extra Classes
- Periodical continuous tests, assignments and evaluation
- Identification of slow learners, advanced and medium learners
- Participation in Online webinars
- Plagiarism check for PG dissertations

Research, Innovations and Extension Activities

- Encouragement for students to participate in conferences and
- paper presentations
- Encouragement for students to publish papers
- Sanitizer preparation and distribution to District Hospital in
- Covid-19 times during 2020-21
- Department wise visit to adapted villages
- Awards and Recognitions

Infrastructure

- UV-Visible Spectrophotometer
- Infrared spectrophotometer
- High Performance Liquid Chromatography Instrument
- Dissolution Apparatus
- Flame Photometer
- Fluorometer
- Potentiometer and Conductometer
- Disintigration Apparatus
- Friabilator
- Pilot Plant consisting Industrial scale 16 station tablet punching machine, coating pan etc.











Student Support

- Industrial Visits for students
- Preparation of GPAT and other competitive exams
- Placement assistance
- Webinars by Alumni Students





Participative Activities and Management

- Authorship and Co authorship in Publications
- Authorship and Co authorship in Book chapters
- Principal Investigator and Co investigator positions in Research Grants
- Consultancy activities
- Department Budget Preparation
- Library Books
- Training for Non Teaching Staff
- Online Webinars for Teaching Staff and Students
- Resource Mobilization through BLDE Hygiene and Healthcare Products
- Programs in association with IQAC



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Institutional Values and Best Practices

- Participation in Social Service Activities
- Development of Eco friendly methods of Analysis
- Support to needy students
- Beyond the campus environmental promotion activities

Extension/Extra Curricular Activities



Field Activities





Heritage Walk



Incubation Centre/Entrepreneurship Development Cell/ Patent Cell:

The Institution has established BLDE Hygiene and Healthcare Products which manufactures sanitizer, floor disinfectant, dish wash detergent and a number of other products for in-house use. The unit manufactured thousands litres of sanitizer during COVID-19 pandemic at the request of District Collector and supplied the same to municipality, schools and colleges.

Mr. Shripad Potadar Asst Professor, of Department of Quality Assurance is Unit Incharge of BLDE Hygiene and Healthcare Products. this unit is also utilized practice school for seventh sem students







Scope of Quality Assurance

Quality assurance is an important part of pharmaceutical manufacturing. It assures the quality of the products those are manufactured in manufacturing facility. It is thought that documentation is the main function of quality assurance but it also controls the manufacturing system to manufacture the quality products.

- Quality Assurance Department assures the quality of all the batches manufactured, at every stage of manufacturing/ processing of drug products.
- This is achieved by performing the functions of monitoring as per the laid down QA systems for the following areas:
- Warehousing of incoming components, containers and closures, labels etc.
- Manufacturing process and process checks
- Process monitoring and Process controls Production Record Review
- Final release or rejection of every batch of Drug Products for distribution and sale Stability testing and evaluation of shelf-life of products
- Warehousing of finished products (Drug Products)
- Complaints and product recalls
- Handling of Change Control Systems Out of specification investigations Investigation of deviations
- Returned products (salvage and disposal) Internal Quality Audits and Quality Review Control of non-conforming products
- Reprocessing of non-conforming products
- To achieve the objectives of Quality Assurance, the functions of the department can be classified as follows:
- To plan and manage all the activities of the Quality Assurance to assure the quality of all products manufactured by the Company.
- To coordinate with the manufacturing department in controlling their process and products at every stage of manufacturing to meet the established specifications through testing, auditing and reporting.
- To co-ordinate for development of specifications, the analytical procedure in coordination with the Quality Control and R&D.

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- To review the adequacy and relevance of specifications & analytical procedures in coordination with the Quality Control and R&D.
- To co-ordinate technical audits of the Quality Control Laboratory to determine the analytical Quality Systems are yielding the highest quality information and to ensure that the analytical instrumentation is functioning properly and calibration and servicing is as per schedule.
- To be responsible for the Quality Assurance and records and release functions of the QA Department this shall include:
- Maintenance of Quality Control records of manufacturing procedures for each batch manufactured.
- Records of release, quarantine or rejection of components and finished products, containers, closures and labels based on Quality Control test results.
- Routine "Good Manufacturing Practices Auditing" of the manufacturing process, control and related areas.
- To suggest and organize training programmes for the development of technical and administrative skills of all the employees to meet with cGMP regulations on a continuous basis, which co-coordinating with Plant and Quality Head.
- To establish guidelines and procedures on cGMP and Good Laboratory Practice Standard Operating Procedures of overall Quality Control & Assurance Activities. Protocols related to Method / Process/ Cleaning/ Analytical Method Validation etc.
- To assist Change Control Committee/Technical Committee for overall reviews of non-conformances, failure investigations, analyzing the Quality trends, investigations of market complaints, batch failure investigations, deviations, verifications of change control procedures, updating the specifications, test procedures, manufacturing processes etc.
- To liaison with regulatory authorities for new products manufacturing licenses and renewals of the same and other regulatory requirements.
- To follow the reporting system to the Corporate Quality Head on daily/ weekly/ monthly basis as per the standard procedure. (Reporting System)

-: CONTACT : -

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