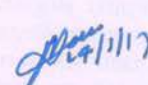


UNIVERSITY OF MUMBAI
No. UG/240 of 2016-17

CIRCULAR:-

The Principals of the affiliated Colleges in Arts, Science & Commerce and the Heads of recognized Institutions concerned are hereby informed that the recommendation made by Ad-hoc Board of Studies in Pharmacy at its meeting held on 30th May, 2016 has been accepted by the Academic Council at its meeting held on 24th June, 2016 **vide** item No. 4.66 and subsequently approved by the Management Council at its meeting held on 18th November, 2016 **vide** item No.29 and that in accordance therewith, in exercise of the powers conferred upon the Management Council under Section 54 (1) and 55 (1) of the Maharashtra Universities Act, 1994 and the Ordinances 6346 and 6347 and Regulations 9068 and 9069 and the syllabus as per the (CBCS) for the M.Voc. (Pharma Analytical Sciences) (Sem. I & II), has been introduced, which is available on the University's web site (www.mu.ac.in) and that the same has been brought into force with effect from the academic year 2016-17.

MUMBAI – 400 032
27th January, 2017


(Dr.M.A.Khan)
REGISTRAR

To,

The Principals of the affiliated Colleges Arts, Science & Commerce and the Heads of Recognized Institutions concerned.

A.C/4.66/24/06/2016
M.C/29/18/11/2016


No. UG/240-A of 2016

MUMBAI-400 032

27th January, 2017

Copy forwarded with Compliments for information to:-

- 1) The Ordinator, Faculties of Arts, Science & Commerce,
- 2) The Professor-cum-Director, Institute of Distance & Open Learning (IDOL)
- 3) The Director, Board of College and University Development,
- 4) The Co-Ordinator, University Computerization Centre,
- 5) The Controller of Examinations.


(Dr.M.A.Khan)
REGISTRAR

AC 24-06-2016
Item No. 4.66

UNIVERSITY OF MUMBAI



Syllabus for Sem I and Sem II, M.Voc

Program: M.Voc

**Course : PHARMA ANALYTICAL
SCIENCES**

(To be Introduced Choice Based Credit System with
effect from the academic year 2016-17)

Preamble:**Indian Pharmaceutical industry:**

India accounts for 7% of the GDP by chemical sector and 11% of the national export. There are about 20000 registered pharmaceutical units in India and there are about 250 large units, 8000 small scale units and 5 central public sector units. Additionally, the size of the Indian diagnostic and lab services is about 160 billion.

Not marred by recession or inflation, the pharma sector has a competitive advantage of prospering steadily and thus attracts lots of young professionals looking at pharmaceutical as their prospective career option. With the expected growth rate of 14% per annum, Indian Pharmaceutical sector is expected to create more jobs in India in near future and add 45,000 fresh openings to its current strength.

Since 2009-10 more than 900 new drug approvals have been given by the Indian drug regulator. The regulatory guidelines have been revised since the Supreme Court directives in 2011-12. Regulatory requirements are increasing in production, quality control and R & D laboratories. Therefore, the regulatory department in a Pharmaceutical company not only needs a very broad understanding of the regulatory requirements but also must understand the chemical processes of production and quality control, the analytical tests, the pre-clinical studies and the clinical trial reports. Further there is an international strategy to harmonize the guidelines using ICH. With about 25 leading pharmaceuticals and about 100 smaller units involved in exports the requirement of regulatory executives is constantly increasing. Some of the top Indian pharmaceuticals have more than 75 executives employed in the regulatory department alone.

The need to develop trained employable human resource:

The Indian Pharmaceutical and Chemical Industry have always been experiencing a dearth of skilled and industrially oriented human resource. The Industry despite employing students from chemistry, biology and pharmacy background always spends 6 months to one year for training the students for general industry needs like Good Laboratory Practices, Good Documentation Practices and regulatory compliances. The important component of knowledge and implementation of quality in laboratory analysis is scarce in the graduates of chemistry and pharmacy. The skilled manpower requirement is in the areas of R & D, quality assurance and intellectual property. The Pharmaceutical industry sector in India is the one of the strong Export oriented sectors that needs to comply with a multitude of regulatory compliances for marketing the drug formulations abroad. In India itself, the sector needs to comply to stringent regulatory compliances and audits before the drug formulations are marketed. The training in practice of GLP as per the current regulatory requirements is missing. This course will provide manpower that is work-ready.

Objectives of the Course

The course will address the requirements of conducting, managing and meeting regulatory requirements for R & D and testing laboratories in pharmaceutical and chemical industries. Major hurdle faced by the R&D centers at various Pharma laboratories is the lack of adequately trained and GLP oriented personnel. This forms a major setback when the application of sophisticated technology especially in the bio analytical field is concerned. The lacunae become more evident when dealing with newer dosage forms and peptide based drugs. This lacunae needs to be addressed very diligently and the proposed programme is a step in this direction

The program will have the following objectives;

- To develop trained manpower in the field of Pharma Analytical Sciences with specific emphasis for instrumentation skills needed for analysis
- To amalgamate knowledge of classical analytical techniques with modern sophisticated instrumentation and provide training in the analysis of chemicals, drugs, food and other products.
- To introduce the training with powerful tools of instrumentation analysis in routine analysis at manufacturing, QC and research
- To provide exposure to National & International regulatory requirements with reference to drugs and chemicals
- To provide training in skills of analysis and develop knowledgeable and employable human resource
- To provide training in soft skills for efficient communication, technical writing, entrepreneurship and basic business management,

O. _____ Eligibility:

- **B.Sc.** in any one of the following subjects: Chemistry, Botany, Zoology, Microbiology, Lifescience, Biochemistry, Biotechnology Bioanalytical Sciences **and** have offered **Chemistry** as one of the subject **till S Y B Sc** (total **5 units**) or equivalent.
- No age bar

R. _____ **Duration:** FOUR semesters (Two Years)

R. _____ **No of Lectures:** 4 theory papers each semester equivalent to 3 credits each.
45 lectures for each paper per semester.

R. _____ **No of Practical periods:** 1 practical paper for the skill component equivalent to 08 credits
and one practical for the general education component equivalent
to 04 credits in each semester.
360 hours for each practical per semester.

R. _____ **No. of credits:** 14 credits of Skill component and 10 credits of general education component
at each semester. Total 24 credits per semester.

University of Mumbai
Credit Based, Semester & Grading System
SYLLABUS IN BRIEF : M.VOC, PHARMA ANALYTICAL SCIENCES :
Semester - I

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS101	Standardization and validation of methods & Pharmacopeial method of analysis	3	45	4
PVPAS102	Total quality management and its practice	3	45	4
PVPASP101	Practical based on Skill Components, Industrial visits and assignments	8	240	10
General Education Component				
PVPAS103	Basic electronics , Basic chromatography and their applications	3	45	4
PVPAS104	Entrepreneurship skill	3	45	4
PVPASP102	Practical based on General Education Components	4	120	5

Semester - II

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS201	Biological methods of testing, Analysis of various formulations & their reporting	3	45	4
PVPAS202	Statistics and its applications	3	45	4
PVPASP201	Practical based on Skill Components Industrial visits and assignments	8	240	10
General Education Component				
PVPAS203	Advanced techniques of instrumental analysis & Basic concepts of laboratory management	3	45	4
PVPAS204	Industrial Training / assignments	3	45	4
PVPAS202	Practical based on General Education Components	4	120	5

Semester - III

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS301	Hyphenated techniques for analysis, Laboratory accreditation and laboratory audits	3	45	4
PVPAS302	Statistical software and their applications	3	45	4
PVPASP301	Practical based on Skill Components Industrial visits and assignments	8	240	10
General Education Component				
PVPAS303	Laboratory data, integrity, security, archival & Special techniques of sample processing (e.g. Proteins)	3	45	4
PVPAS304	Skills of project management and practice of GMP	3	45	4
PVPASP302	Practical based on General Education Components	4	120	5

Semester - IV

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS401	Specialized requirements of analysis (e.g. food and pesticides, stability, laboratory information management etc)	3	45	4
PVPAS402	Analysis of pharmaceutical and cosmetic formulations	3	45	4
PVPASP401	Practical based on Skill Components Industrial visits and assignments	8	240	10
General Education Component				
PVPAS403	Analysis for forensics, water quality, detergents and treatment of laboratory waste water	3	45	4
PVPAS404	Industrial Training // Internship	3	45	4
PVPASP402	Practical based on General Education Components	4	120	5

SYLLABUS IN DETAIL

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS101	Standardization and validation of methods & Pharmacopeial method of analysis	3	45	4
	<ul style="list-style-type: none"> • Basic electronics and applications • Detectors, transducers and sensors • Limits and Range of Detection • Validation of methods • Atomic absorption spectroscopy and applications 			
PVPAS102	Total quality management and its practice	3	45	4
	<ul style="list-style-type: none"> • Theory and Practice of QA and QC • Quality Audits and Compliances • Calibration and Calibration records • Standard Operating procedures and their implementation 			
PVPASP101	Practical based on Skill Components Industrial visits and assignments	8	240	10

Code	Paper	Credits	Lectures	L/Wk
General Education Component				
PVPAS103	Basic electronics , Basic chromatography and their applications	3	45	4
	<ul style="list-style-type: none"> • Types of Instrumental methods • Selection of analytical method • Measurement of uncertainty • Analytical Standards and concept of purity • Basics of Chromatographic Technique 			
PVPAS104	Entrepreneurship skill	3	45	4
	<ul style="list-style-type: none"> • Scope of analytical services • Laboratory design and Laboratory setup • Total Quality Management • Quantitation Techniques and its Reporting • Financial Aspects of Quality Systems 			
PVPASP102	Practical based on General Education Components	8	240	10

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS201	Biological methods of testing, Analysis of various formulations & their reporting	3	45	4
	<ul style="list-style-type: none"> • Biological testing as per IP • Microbiological test for sterility • Capillary Electrophoresis • FTIR • Analysis of powders, creams and lotions • Analysis of Water (Physico Chemical parameters) 			

PVPAS202	Statistics and its applications	3	45	4
	<ul style="list-style-type: none"> • Application of Statistics in Data Analysis • Basic Economics and Business Economics • Start-up Projects & Start-up Financing 			
PVPASP201	Practical based on Skill Components Industrial visits and assignments	8	240	10

Code	Paper	Credits	Lectures	L/Wk
General Education Component				
PVPAS203	Advanced techniques of instrumental analysis & Basic concepts of laboratory management	3	45	4
	<ul style="list-style-type: none"> • Fourier transformation and its application • GLP and its practice • Laboratory Safety • Waste disposal and waste management • Theory and Practical of Electrophoresis • Impurity profiling of Raw Materials • Intellectual Property Rights and Patents • Plastics and Polymers • Perspectives of Society to Technology and Development 			
PVPAS204	Industrial Training / assignments	3	45	4
	<ul style="list-style-type: none"> • Students placement in industry 			
PVPAS202	Practical based on General Education Components	4	120	5

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS301	Hyphenated techniques for analysis, Laboratory accreditation and laboratory audits	3	45	4
	<ul style="list-style-type: none"> • GC-MS • LC-MS • ICP and ICP-MS • NMR and its application 			
PVPAS302	Statistical software and their applications	3	45	4
	<ul style="list-style-type: none"> • Electronic interfaces for data acquisition • SAS and its application • Project Management Skills 			
PVPASP301	Practical based on Skill Components Industrial visits and assignments	8	240	10

Code	Paper	Credits	Lectures	L/Wk
General Education Component				
PVPAS303	Laboratory data, integrity, security, archival & Special techniques of sample processing (e.g. Proteins)	3	45	4
	<ul style="list-style-type: none"> • Laboratory information management systems • Data Integrity and Data Security • Data Archival and Retrieval • Hyphenated techniques and their applications • Dialysis and protein purification • GCP and its practice 			
PVPAS304	Skills of project management and practice of GMP	3	45	4
	<ul style="list-style-type: none"> • Planning and Execution of Data Management • Change Control and its practice • Laboratory accreditations – ISO, NABL etc • Regulatory compliances for GMP and its certification 			
PVPASP302	Practical based on General Education Components	4	120	5

Code	Paper	Credits	Lectures	L/Wk
Skill Component				
PVPAS401	Specialized requirements of analysis (e.g. food and pesticides, stability, laboratory information management etc)	3	45	4
	<ul style="list-style-type: none"> • Analysis of Food and Food products • Pesticide Analysis • Application of ICT in laboratory management • Critical thinking and soft skills 			
PVPAS402	Analysis of pharmaceutical and cosmetic formulations	3	45	4
	<ul style="list-style-type: none"> • Pharmaceutical and Cosmetic Formulations • Financial Management (Including Micro Finance) • Human Resource Management 			
PVPASP401	Practical based on Skill Components Industrial visits and assignments	8	240	10

Code	Paper	Credits	Lectures	L/Wk
General Education Component				
PVPAS403	Analysis for forensics, water quality, detergents and treatment of laboratory waste water	3	45	4
	<ul style="list-style-type: none"> Analytical chemistry in forensics Detergents and Pesticides Environmental Audit and its significance Environmental legislation and acts Waste water treatment and solid waste management Principles and concepts of Green Chemistry Bioremediation and their implementation Stability studies and their significance Conservation of resources and recycling 			
PVPAS404	Industrial Training // Internship	3	45	4
PVPASP402	Practical based on General Education Components	4	120	5

MVoc – Pharma Analytical Sciences

LIST OF PRACTICAL TO BE COVERED IN FOUR SEMESTERS

Orientation Practical : This will include introduction to GLP, IP and regulatory requirements. Basic laboratory skills and instrument calibration.

- Basic laboratory skills
 - Use of analytical balance
 - pH meter
 - Colorimeter
 - Spectrophotometer
 - Safety symbols
 - Fire safety and Safety equipment
 - General Laboratory SOPs and documentations
- Spectroscopy
 - Visible
 - uV
 - IR
 - Calibration, quantitation and preventive maintenance
- Evaluation of Physical characteristics, proximate analysis
 - APIs
 - Medicinal plant raw materials
 - Formulations
- Validation of a pharmacopeial method :
 - HPTLC Method(s)
 - HPLC Method(s)
 - GC Method(s)
- Linearity, LOD, and QC levels
- Accuracy & Precision
- System suitability
- Extraction efficiency
- Stability of Stock solutions
- Bench top stability
- Long and short term stability
- Ruggedness
- Robustness
- Method transfer
- Quality system
 - SOPs
- Structure
- Control of SOPs
- Distribution and Review
- Archival and discard
- SOP training
- Writing and Preparing SOP –
 - HPTLC

- HPLC
 - Column Efficiency
 - GC
- Identification of basic electronic components
 - Diod
 - Transistor
 - Resistance
 - lcs
 - Capacitor etc.
 - Preparing a simple circuit and placing on circuit board.
- Preparing a wired switchboard with switches, fuse and main supply indicators
- Animal handling
 - Weighing
 - Oral Gavage
 - Injections – IV, IM and IP
 - Animal cage cleaning and feeding
 - Recording cage side observations
 - Animal tagging
 - Animal grouping
 - Rats, Mice, guinea pigs, Rabbits
- Test for undue toxicity
- Pyrogen testing using rabbit
- Pyrogen testing using LAL test
- Dermal irritation studies
- From 39 and its usage
- Student t test
- ANOVA with F test, two way, three way etc.
- Chi square test and evaluation
- Practice of basic chromatographic techniques ;
 - TLC
 - HPTLC
 - HPLC
 - GC
 - Extraction – liq-liq and SPE
 - Usage of LV evaporator
 - Column oven
- LC – MS basic instrumentation and control
- LC-MS Quantitaion
- Impurity profiling in MS
- Mass evaluation of components after LC separation
- Mass using quqpdapole
- GC- MS method
- GC-MS library usage
- Head Space GC demonstration
- Method development ;
- HPLC for LC-MS

- GC for GC-MS
- Usage of statistical software like – WinNonLin, SPSS, SAS etc.
- CE and CE analysis of antibiotics, proteins, ascorbic acid and heparin etc.
- Electrophoresis separation of protein mixtures, nucleic acid mixtures
- Evaluation of following formulations for physical and chemical characteristics;
 - Syrups
 - Ointments
 - Creams
 - Gels
 - Sprays etc
- uV protection evaluations for SPF value
- Tablet dissolution studies for immediate release and delayed release
- Water analysis for quality, potability and contaminants
- Analysis of foods, and beverages for pesticide residue, Heavy metals etc.
- Practical in Green chemistry for understanding concepts and applications
- Bioanalysis of analytes from human samples; sweat, blood, plasma etc.
- Waste water analysis
 - BOD
 - COD
 - DO
 - Other physico-chemical parameters
- Analysis of detergents for various standard specifications
- Analysis of oils :
 - Sap value
 - Iodine value
 - Acid value
 - GC analysis of oils for fatty acids, petroleum fractions etc
- Statistics
 - Randomisation
 - DOE
 - Bioequivalence

The Scheme of Examination and Allotment of marks are tabulated below;

M. VOC. (PHARMACEUTICAL ANALYSIS)			
(600 MARKS PER SEMESTER)			
THEORY (FOUR PAPERS)		PRACTICAL (FOUR PAPERS)	
	MARKS		MARKS
SC-1	100	SC-1	50
SC-2	100	SC-2	50
SC-3	100	SC-3	50
GC-1 (GENERAL)	100	GC-1	50
TOTAL MARKS	400		200
GRAND TOTAL			600

NOTE : SC= Skilled Component, GC= General Component