ARIBAS
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ज्ञानेन शीलम् & KNOWLEDGE CONSORTIUM OF GUJARAT

CVM UNIVERSITY

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ARIBAS

Certificate Course in "Analytical Testing in Biopharmaceuticals and Regulatory Affairs"

(Post Graduate Certificate Course)
COURSE STRUCTURE

Subject	Course Code	Course Title	No. of Credits	Theory/ Practical (T/P)	Hours per week	External Exam Duration	Continuous Evaluation	External Evaluation	Total Marks
Core	PGCCATBR01	Analytical Testing and Quality Assurance of Biopharmaceutics	4	T	4	3 hrs	50	50	100
	PGCCATBR02	Quality Audit & Regulatory Affairs for Biopharmaceutics	4	T	4	3 hrs	50	50	100
Lab	PGCCATBR03	Based on PGCCATBR01 & PGCCATBR02	4	P	4	3 hrs	50	50	100
		Total	**12**						300
Project/Industrial Training	PGCCATBR04	xxxx	**08**	P					100+100 =200
		Total	**12+08= 20**						
	Total Examination								500

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Detailed Syllabus

PGCCATBR01: Analytical Testing and Quality Assurance of Biopharmaceuticals

Credits: 4, 4 Hrs Per Week

Unit 1: Quality Control, Quality Assurance and Good Manufacturing Practice

- Introduction to pharmacopoeia, Basic principles of Quality Control (QC) and Quality Assurance (QA),
- Basics of pharmaceutical sectors, Pharmaceuticals, Product Evolution, Importance of R & D
- GMP and regulations: Guide to good manufacturing practice, EU good manufacturing practice, FDA and CFRs, Ten rules GMP
- The role and development of pharmacopoeias
- Role of the company regulatory affairs department
- Documentation

Unit 2: Lab Management, Design and Microbiology Laboratory Techniques

- Pharmaceutical microbiology laboratories, Laboratory management,
- Laboratory design: Sample collections and testing areas, Equipment, Clean air devices and containment
- Microbiology laboratory techniques: Good Laboratory Practice (GLP) and laboratory safety, Aseptic techniques
- Microbiological examination of nonsterile products: Total viable aerobic count, Bioburden determination, Method validation, Media growth promotion, Sample Preparation, Tests for specified organisms, Specification limits
- Environmental Monitoring, Water Analysis

Unit 3: Sterilization and Sterility assurance of Pharmaceutical Products

- Sterilization: D and Z value Determination, Sterilization of Products: Terminal sterilization, Aseptic filling, Blow-fill-seal technology, Factors affecting sterilization effectiveness
- Microbial Testing by Physical and Chemical agents: Physical Methods and Radiation

- Microbial Testing by Chemical agents: Disinfectant—Critical Evaluation, Disinfectant Variants
- Sterility testing: In Vitro and In Vivo Testing for Pyrogens and Endotoxins, LAL Test

Unit 4: Microbiological Assays and Analytical Assays of Pharmaceutical Products

- Microbiological (Microbial) Assays : Antibiotics–Vitamins–Amino Acids: Principle, methodologies, Variants In Assay Profile
- Types of Microbiological (Microbial) Assays: Agar Well Diffusion Assays: One Dimensional Assay, 2d-3d Assay, Measurement of Zone & Calibration, Standard Curve
- Rapid-Reliable-Reproducible Microbial Assay Methods: Luciferase assay, Urease activity and Antibiotic assay: Cylinder plate assay, Turbidimetric Method
- Analytical Methods for Microbial Assays: High Performance Liquid Chromatography [HPLC], Reverse-Phase Chromatography [RPC] and Ion-Pair (or Paired-Ion) Chromatography

References

1. Biopharmaceuticals. Biochemistry and Biotechnology 2nd edition [G. Walsh] Wiley (2003)
2. Pharmaceutical Microbiology by Ashutosh Kar
3. Pharmaceutical Microbiology - Essentials for Quality Assurance & Quality Control by Tim Sandle
4. Microbiological Quality Assurance by Brown & Gilbert
5. Principles of Fermentation Technology by Stanbury, Whittaker & Hall
6. Pharmaceutical Biotechnology by Gary Walsh
7. Quality Assurance of Pharmaceuticals, Vol.2, 2nd Edition

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Detailed Syllabus PGCCATBR02: Quality Audit & Regulatory Affairs for Biopharmaceuticals

Credits: 4, 4 Hrs Per Week

Unit 1: Cleanroom and Environmental mMonitoring

- Introduction, Cleanroom contamination, Cleanroom classification, Isolators, Cleanroom certification, cleanroom testing (Physical Parameters- Air patterns and air movement, Airflows, Air changes, Clean up times, Positive pressure, HEPA filters, Temperature, humidity, lighting and room design)
- Microbiological environmental monitoring: AIR sampling methods (Settle plates, active air samples), Surface sampling methods (contact plates, swabs), Key aspects of the monitoring program, Personnel, Aseptic technique
- Other cleanroom disciplines: Clothing, Grade A areas, Grade C areas, Cleaning

Unit 2: Rapid Microbiological methods

- Introduction, changing world of microbiology, Advantages of rapid methods, Regulatory acceptance,
- Types of rapid microbiological methods: Growth-based methods, direct measurement, cell component analysis, optical spectroscopy, Nucleic acid amplification, Microelectrical-mechanical systems
- Selection of rapid microbiological methods: Key considerations, Internal Company obstacles, validation, method transfer, training, expectations from the vendor

Unit 3: Quality Audit and Bioprocess economics

- SOPs & protocols for various operations
- Production and process, packaging and labeling, IPQC, Finished product release
- Quality review, Quality audit,
- Audits of quality control facilities
- Complaints and recalls, evaluation of complaints, recall procedures, related records and documents, Waste disposal, scrap disposal producers and records, Loan license (contract manufacture) audits, etc.
- Expenses for industrial materials, equipment, product recovery and effluent treatments

- Cost recovery due to waste usages and recycling

Unit 4: Regulatory agencies and IPR

- Drug Regulatory Affairs, Harmonization of regulatory requirements including ICH guidelines
- Regulatory requirements of different regions applicable to pharmaceutical developments,
- Quality control on finished products. Filing of INDA, NDA and ANDA for approval and registration. Review and comparison of each guidelines such as OECD, MHRA, WHO, FDA, ICH, etc.
- IPR and patent process, International harmonization of patent law, Indian scenario
- Patents of biotechnological process and their protection

References

1 Microbiological Quality Assurance by Brown & Gilbert
2 Pharmaceutical Microbiology - Essentials for Quality Assurance & Quality Control by Tim Sandle
3 Hugo and Russell's Pharmaceutical Microbiology 7th edition edited by Stephen P Denyer, Norman A Hodges & Sean P Gorman
4 Biopharmaceuticals. Biochemistry and Biotechnology 2nd edition [G. Walsh] Wiley (2003)
5 Pharmaceutical Microbiology by Ashutosh Kar
6 Bioethics and Biosafety in Biotechnology [V. Sreekrishna] - New Age International Pvt Ltd Publishers (2007)
7 IPR, Biosafety and Bioethics [Deepa Goel, Shomini Parashar] - Pearson Education (2013)

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4 Credits(6 hrs/week)

PGCCATBR03: Practicals based on PGCCATBR01 and PGCCATBR02

- Bioassay of Antibiotics
- MIC Determination
- Microbial Limit Test (MLT)
- Sterility Test
- Bacterial Endotoxin Test
- Phenol Coefficient Test
- Qualitative & Quantitative Analysis of water
- Product analysis by GC/ HPLC

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8 Credits

PGCCATBR04: Project / Dissertation Work Theory

- The candidate is required to show article to faculty in/before commencing his/her experimental work.
- Two typed/computerized bound copies of the dissertation shall be submitted to the University at least fifteen days before the commencement of the final examination.