Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Scheme of Teaching and Examination

Master of Pharmacy (M. Pharm)

(Quality Assurance)

II Semester

S. No.	Board of study	Subject Code	Subject	Periods per week			Scheme of Examination Theory/Practical			Total Marks	Credit L+(T+P) /2
				L	T	P	ESE	CT	TA		
1	Pharmacy	574211(41)	Quality Assurance -I	4	1	-	100	20	20	140	
2	Pharmacy	574212(41)	Quality Assurance -II	4	1	-	100	20	20	140	
3	Pharmacy	574213(41)	Validation & Calibration	4	1	-	100	20	20	140	
4	Pharmacy	574214(41)	DRA & GMP	4	1	-	100	20	20	140	
5	Pharmacy	574221(41)	Quality Assurance -I Lab	-	-	6	100	-	50	150	
6	Pharmacy	574222(41)	Quality Assurance -II Lab	-	-	6	100	-	50	150	
7	Pharmacy	574223(41)	Quality Assurance –III Lab	-		6	100	-	40	140	
Total				**16**	**4**	**18**	**700**	**80**	**220**	**1000**	

L- Lecture, T- Tutorial, P- Practical,

Duration of Theory paper: 3 hours

ESE – End Semester Examination, CT – Class Test, TA- Teacher Assessment

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Semester: **M.Pharm.(QA)** 2nd semester
Branch: Pharmacy
Subject: **Quality Assurance**- I
Subject Code: 574211 (41)
Total Theory period: 50 Hrs
Total Tutorial period: 12
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Unit 1.
Regulatory requirements for import, export, manufacture and sale of drug and formulation. Types of manufacturing licenses. Master Formula and Batch Manufacturing Records.

Unit 2.
Details of GMP requirements for building (premises) for manufacture of drugs, personnel, hygiene, sanitation, waste and disposal.

Unit 3.
Quality of water used in pharmaceutical manufacturing. Process utilized for preparation of water, validation of the processes and evaluation of the water quality.

Unit 4.
Air-handling systems required for pharmaceutical manufacturing. Regulatory requirements and monitoring. Validation of air-handling system.

Unit 5.
Conducting clinical and non-clinical testing, animal house and regulatory aspects related to use of animals. Records to be maintained.

Unit 6.
Finished products release, Quality review, Quality audits, Batch release documents, Complains and recalls, Evaluation of complaints recall procedures, relevant records and documents.

Recommended Books:

- Regulatory guidelines related to GMP by
  - Australian code of GMP for medicinal products, 16th Aug. 2002.
  - 21 Code of Federal Regulation, parts 210, 211 & 58. (USFDA guidelines).
  - MHRA, UK Guidelines on GMP.
  - GMP Guidelines by Medicines Control Council of South Africa.
  - Schedule M of D & C Act.
- Assurance of Quality, Pharmaceutical Total Quality Approach, M. S. P. Khan, Chitgaon, Bangladesh, Signet Press-1990.
- Modern Pharmaceutics II edi. G. S. Banker, C.T. Rhodes.

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Semester: **M.Pharm.(QA)** 2nd semester
Branch: Pharmacy
Subject: **Quality Assurance**- II
Subject Code : 574212 (41)
Total Theory period: 40 Hrs
Total Tutorial period : 12
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Unit 1.

Duties and responsibility of QA department in case of any complaint on Quality of the product marketed. Product recalls, evaluation of controlled samples Documents necessary to handle such complaints and to be maintained.

Unit 2.

Duties of QA department in monitoring the quality of products manufactured under loan license or under third party license. Documents to be maintained.

Unit 3.

Guidelines for Industrial Safety & Health. Materials Safety Data Sheet (MSDS). Procedures for obtaining license for manufacture of narcotic and psychotropic drugs. Records to be maintained for manufacturing alcoholic preparations.

Unit 4.

The Drug Price Control Order,1985. The Medicinal & Toiletry Preparations Act,(Excise Duties Act, 1955 & Rules,1976). Disposal of wastes and scraps, procedures and records.

Unit 5.

Legislation to regulate import, manufacture, sale and distribution of cosmetics. Quality Control and Quality Assurance of cosmetics.

Unit 6.

Legislation to regulate import, manufacture, sale and distribution of herbal drugs and their preparations. Quality Control and Quality Assurance of herbal drugs.

BOOKS RECOMMDNED

- The internal quality audit by Monica Girmaldi and Janet Gough Davis Harwood International Publishing.
- Validation Master plan by Terveeks or Deeks, Davis Harwood International Publishing.
- Validation of Asceptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
- Statistical Design and Analysis in Pharmaceutical Science, by Chow, (Marcel Dekker).
- Automation & Validation of Information in Pharmaceutical Processing, by deSPAUTZ, (Marcel Dekker).
- Guidelines for Laboratory Quality Auditing, by Singer,(Marcel Dekker).
- Pharmaceutical Experimental Design, by Lewis, (Marcel Dekker).
- New Drug approval process, 2nd edition, Vol. 56, by Guarino, Marcel Dekker., New York.
- Hosting a compliance Audit by Janet Gough Davis Harwood International Publishing.

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Semester: **M.Pharm**. **(QA)** 2nd semester Branch: Pharmacy
Subject: **Validation & Calibration** Subject Code: 574213 (41)
Total Theory period: 40 Hrs Total Tutorial period: 12
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Unit 1.
General principles of validation of processes- manufacturing & analytical, and products. Calibration of instruments, equipments, etc. & their validation. Types of validation - prospective, concurrent, retrospective and revalidation.

Unit 2.
Tablets: List of equipments required for tablet manufacturing. Calibration of equipments, machineries and validation systems followed documents to be maintained. Processes involved in-process control tests and their records. Environmental requirements.

Unit 3.
Capsules and Powders: List of equipments required for capsules and powders manufacturing, calibration of equipments, machineries and validation systems followed, documents to be maintained. Processes involved in-process control tests and their records. Environmental requirements.

Unit 4.
Liquids: List of equipments required for liquids manufacturing, calibration of equipments, machineries and validation systems, documents to be maintained. Processes involved in-process control tests and their records. Environmental requirements.

Unit 5.
Sterile products: Basic principles in the validation of sterile products .List of equipments required, processes involved for paranteral and ophthalmic products manufacturing. Calibration of equipments, machineries and validation systems followed documents to be maintained. In-process control tests and their records. Environmental requirements. Process for microbial destruction, D value, Z & F value.

Unit 6.
Semisolids: List of equipments required for semisolid dosage forms manufacturing, calibration and validation systems followed, documents to be maintained. Processes involved, in-process control tests and their records. Environmental requirements.

Unit 7
Types of cleaning situations. Validation & verification of cleaning processes.

Recommended Books:

- Pharmaceutical Process Validation, Second Edition, Ira R. Berry & Robert Nash, Marcel Dekker Inc
- Validation of Pharmaceutical Process (Sterile Products), Second Edition Revised & Expanded, F.J. Carleton and J.P. Agalloco, Marcel Decker Inc.
- Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune.
- Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.

Chhattisgarh Swami Vivekanand Technical University, Bhilai (C.G.)

Semester: **M.Pharm.(QA)** 2nd semester
Branch: Pharmacy
Subject: **DRA & GMP**
Subject Code: 574214 (41)
Total Theory period: 40 Hrs
Total Tutorial period: 12
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Unit 1.
Genesis of Quality control and Quality Assurance. Concept of Total Quality Management, cGMP and GLP, ICH and ISO 9000.

Unit 2.
Classification of pharmaceutical ingredients. Purchase, Inventory and Storage systems followed in pharmaceutical industry in accordance with the GMP. Compendial and Internal standards and specifications of ingredients.

Unit 3.
Selection of vendors for pharmaceutical ingredients. Role of QA dept in these activities. Documentations to be maintained. Storage and issue systems of raw materials used in pharmaceutical industry. Documentations to be maintained. Role of QC and QA.

Unit 4.
Specifications, Standardization and Quality control of packaging materials.

Unit 5.
Statistical Quality control. Types of sampling systems/plans followed and interpretation. Illustrative examples.

Unit 6.
Quality control and Quality assurance in case of loan license and third party license manufacturing. Regulatory requirements and GMP requirements for such manufacturing. Documentations to be maintained.

Recommended Books.

- Forensic Pharmacy by B.S. Kuchekar, A. M. Khadatare and S. C. Jitkar, 6th Ed., Nirali Prakashan.
- Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi.
- Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan.
- James Swarbrick, James C Boylon, Encyclopedia of Pharmaceutical Technology, 2nd Ed. Marcel Dekker Inc.
- Bubuarm N.R, Whatever one should know about patent, 2nd Ed., Pharma Book Syndicate.
- Gnarino Richard A, New Drug Approval Process, 3rd Edition, Marcel Dekker Inc.
- P. Warayan, Intellectual Property Laws, Eastern Law House.
- Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
- Pharmacy Law and Ethics by Dale and Appelbes, the Pharmaceutical Press, Joy Winfield.

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Semester: **M.Pharm.(QA)** 2nd semester
Branch: Pharmacy
Subject: **Quality Assurance**- I
Subject Code: 574221(41)
Total Practical period: 72 Hrs.
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Practicals Recommended

- Complete analysis of formulations, one of each type, as per protocol and comment there on.
- Validation of processes – manufacturing & analytical(at least 3 exercises on each)
- Calibration of at least 3 equipments and 3 instruments.
- Cleaning validation of at least 2 equipments.

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Semester: **M.Pharm.(QA)** 2nd semester
Branch: Pharmacy
Subject: **Quality Assurance**- II
Subject Code: 574222(41)
Total Practical period: 72 Hrs.
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Practical's Recommended

- Exercises on statistical analysis of data using different models (at least 6 exercises).
- Exercises on determination of (1) order of degradation, (2)shelf-life prediction and(3) interpretation of results, based on given data(arbitrary)(at least 3 exercises).
- Exercises on pharmacolegal cases (at least 3).

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Semester **: M.Pharm.(QA)** 2nd semester — Branch: Pharmacy
Subject : **Quality Assurance**- III — Subject Code: 574223 (41)
Total Practical period : 72 Hrs.
Total Marks in the End Semester: 100
Minimum of Class tests to be conducted: 02

Practical's Recommended

- Experiments on dissolution study of at least 3 drugs and their marketed formulations. Interpretation of the results.
- Exercises on co-relation of in-vitro dissolution data and in-vivo plasma concentration-time profile data using different equations(models)(at least 3).
- Exercises on interpretation of market recalls situations for at least 3 different situations.
- Exercises on re-process recommendation for product rejects during manufacturing and after recall (at least 2 types).