

REVISED FINAL SYLLABUS FOR M.PHARM (QA)
(15TH MARCH 2013)

M PHARM--QUALITY ASSURANCE

GOALS

To equip a post- graduate in Quality Assurance to:

- Achieve comprehensive understanding and competency in quality assurance systems and regulatory requirements.
- Develop and implement a robust quality assurance system in an organization towards quality excellence

COMPONENTS OF THE PG QUALITY ASSURANCE CURRICULUM

- Theoretical knowledge.
- Practical skills.
- Training in research methodology.
- Training in thesis writing.

SUBJECTS/ CURRICULUM:

M Pharm (Previous):

TITLE OF PAPERS

PAPER I: Modern Pharmaceutical Analysis	(T: 3HRS/WK, P: 6HRS/WK)
PAPER II: Quality Assurance	(T: 2HRS/WK, P: 6HRS/WK)
PAPER III: Pharmaceutical Technology & Validation	(T: 2HRS/WK, P: 6HRS/WK)
PAPER IV: Analytical Assurance	(T: 2HRS/WK, P: 6HRS/WK)

List of Equipment:

- 1) Double beam UV-Visible Spectrophotometer.
- 2) Gas Chromatograph.
- 3) HPLC.
- 4) FTIR.
- 5) Electronic balance (0.01mg sensitivity).

PAPER II: QUALITY ASSURANCE

GOAL:

- To equip student to be professionally competent to achieve global quality standards in the pharmaceutical industry.

OBJECTIVES:

On completion of the course in Quality Assurance, the candidate must be able to:

- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
- Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation.

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. Concept and evolution of Quality Assurance and Quality Control, cGMP, TQM (2hr)
2. **Overview of ICH Guidelines** - QSEM, with special emphasis on Q-series guidelines(2hr)(Unit 1&2-20marks
3. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC) and EMEA covering: (70marks)**
 - a. **Organization and Personnel** : Responsibilities, training, hygiene(2hr)
 - b. **Premises**: Location, design, plan and layout, construction, maintenance and sanitation, environmental control – sterile and non-sterile areas, prevention and containment of contamination.(2hr)
 - c. **Equipment**: Material Make, Selection process through vendor evaluation, purchase specifications, maintenance, Preventive Maintenance Protocol, Automation (2hr)
 - d. **Raw materials**: Purchase specifications, maintenance of stores, vendor qualification and evaluation. (2hr)
 - e. **Manufacture and controls of various dosage forms**: Various tiers of documents pertaining to Manufacturing documents, master formula record, and batch manufacturing

- record, standard operating procedures for various operations - cleaning, filling, drying, compression, coating, disinfection and sterilization. **(3hr)**
- f. **In-process quality controls:** For sterile and non-sterile dosage forms **(2hr)**
 - g. **Packaging material controls:** Packaging materials and control of packaging materials **(1hr)**
 - h. **Quality control laboratory responsibilities:** GLP protocols on non-clinical testing control on animal house, data generation, integration and storage, standard test procedure, retention of sample records. CPCSEA guidelines. **(5hr)**
 - i. **Finished product release:** Quality review and batch release document. **(1hr)**
 - j. **Warehousing:** Good warehousing practices, cold chain management and materials management. **(1hr)**
 - k. **Distribution:** Distribution records, handling of returned goods, recovered materials and reprocessing. **(2hr)**
 - l. **Complaints and recalls:** Evaluation of complaints, recall procedure and documentation. **(2hr)**
 - m. **Waste and scrap disposal:** Storage and management of scrap, recycling practices, Disposal procedures and records. **(1hr)**
 - n. Change management, annual product quality review and parametric release **(2hr)**
 - o. **Audits:** Types of audits, quality audits of manufacturing processes and facilities, audits of quality control **(3hr)**
 - p. **Documentation** - Good documentation practices, root cause analysis, corrective action preventive action (CAPA), out of specifications (OOS) and out of trend (OOT) **(3hr)**
4. **Clinical studies-** ICH GCP (E6) guidelines, post marketing surveillance, pharmacovigilance, BABE (bioavailability and bioequivalence) studies. **(2hr)**
 5. Concepts and management of contract manufacturing (European guidelines) **(2hr)(Unit 4&5-20marks)**
 6. Introduction, scope and importance of IPR. Concept of trade mark, copyright and patents **(2hr)**
 7. Product registration guidelines – CDSCO, USFDA. **(2hr)(Unit 6&7-15marks)**
 8. Concept of ISO 9001:2008, 14000, OSHAS guidelines **(2hr)**
 9. Brief concept of IND, NDA, ANDA, SNDA and PAT **(2hr)(Unit 8&9-15marks)**

PRACTICALS

150hrs (6hrs/wk)

The following exercise to be worked upon along with documentation.

1. Drawing and discussion on plant layouts.
2. Preparation of Master Formula Record.
3. Preparation of Batch Manufacturing Record.
4. Preparation of Quality control records for dosage forms (3Expts)
5. Quality control tests and interpretation of results according to pharmacopoeial specifications and alerts for tablets, capsules, semisolids and parenterals. (6Expts)
6. Standard operating procedures- for operation and calibration of analytical instrument.(5Expts)
7. Standard operating procedures- for operating pharmaceutical machinery. (3Expts)
8. Verification of compendial methods (3Expts)
9. Case studies: IPQA Failure, Deviation OOS, market recalls, complaints investigation, scale up, Corrective action preventive action (CAPA) (any 4Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the internal assessment marks for theory and practicals separately.

FINAL EXAMINATION PRACTICALS:

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment (group discussion/ topic presentation/case study)	Viva-Voce	Total
20	35	25	20	100

REFERENCES :

1. Sharp J. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press; 2005.
2. Chow SC. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.

3. McCormick K. Quality (Pharmaceutical Engineering Series). Butterworth-Heinemann; 2002.
4. Gad SC. Pharmaceutical Manufacturing Handbook: Production and Processes. John Wiley & Sons; 2008.
5. Willig SH, Stoker JR. Good manufacturing practices for pharmaceuticals: a plan for total quality control. Marcel Dekker; 1997.
6. Signore AA, Jacobs T. Good Design Practices for GMP Pharmaceutical Facilities. Taylor & Francis Group; 2005.
7. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
8. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance. St. Lucie Press; 2002.
9. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
10. Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley; 1998.
11. Waller P. An Introduction to Pharmacovigilance. John Wiley & Sons; 2011.
12. Mann RD, Andrews EB. Pharmacovigilance. John Wiley & Sons; 2007.
13. Niazi S. Handbook of Bioequivalence Testing. CRC Press; 2007.
14. Shargel L, Kanfer I. Generic Drug Product Development: Solid Oral Dosage Forms. Marcel Dekker; 2005.
15. Medina C. Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics. CRC Press; 2004.
16. Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare; 2007.
17. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.
18. Hoyle D. ISO 9000 Quality Systems Handbook - updated for the ISO 9001:2008 standard. Routledge; 2012.
19. Edwards AJ. ISO 14001 Environmental Certification Step by Step: Revised Edition. Butterworth-Heinemann; 2003.
20. Mantus D. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics. Informa Healthcare USA; 2008.
21. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.
22. Ganguli P. Intellectual Property Rights. The McGraw.Hill Companies; 2008

Websites:

1. <http://www.ich.org/>
2. <http://www.ich.org/about/organisation-of-ich.html>
3. <http://www.ich.org/about/process-of-harmonisation.html>
4. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
5. [http://cdsco.nic.in/html/gmp/schedulem\(gmp\).pdf](http://cdsco.nic.in/html/gmp/schedulem(gmp).pdf)
6. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=210>
7. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
8. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step_4/E6_R1_Guideline.pdf
9. <http://ori.hhs.gov/documents/WHOHandbookonGCP04-06.pdf>

Journals:

- 1) Indian drugs.
- 2) International Journal of Pharmaceutical Quality Assurance.
- 3) Journal of Pharmaceutical Quality Assurance
- 4) Pharma Pulse.
- 5) The Quality Assurance Journal.
- 6) Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.

PAPER III: PHARMACEUTICAL TECHNOLOGY AND VALIDATION

GOAL:

- To consistently achieve excellence in the field of drugs and pharmaceuticals with a thorough understanding of current global industrial requirements.

OBJECTIVES:

On completion of the course in Pharmaceutical technology and validation, the student must be able to -

- Gain a thorough understanding of all aspects related to development, manufacturing and evaluation of pharmaceuticals.
- Acquire adequate understanding of process design of pharmaceuticals.
- Understand the principles of validation in pharmaceutical industry

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. **Preformulation Studies:** Understanding concepts of physicochemical and biopharmaceutical characteristics in preformulation. Compatibility studies, protocol for product development. **(5hr)(20marks)**
2. **Dissolution Studies:** Biopharmaceutical Classification System (BCS) and its relevance to drug development, Factors affecting dissolution, Pharmacopoeial dissolution testing models, *In vitro* – *in vivo* correlation (IVIVC), Biowavers, Similarity factors. **(5hr)(20marks)**
3. **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. **(5hr)(15marks)**
4. Concepts of Pilot plant scale up and technology transfer, scale up and post approval changes (SUPAC) and bulk active chemicals post approval changes (BACPAC). **(5hr)(15marks)**
5. **Packaging of Pharmaceutical Products (Parenterals and Non - Parenterals):** Objectives, Types of packaging, Containers and closures, Quality control testing of primary and secondary packaging materials. Packaging of solid, semisolid and liquid dosage forms. Innovative packaging technologies. Product-package compatibility. **(5hr)(15marks)**
6. **Validation:** **(25hr)(55 marks)**
 - Introduction to calibration of instruments and its guidelines.
 - Introduction to Qualification and Validation,
 - Importance and scope of Validation.
 - Types of Validation,
 - Validation master plan.

- Process Validation of different dosage forms - solid, semisolids and parenterals
- Qualification of equipment: DQ, IQ, OQ and PQ(Validation of critical equipment - mixer, compression machine, fluidized bed dryer (FBD), filling equipment, sterilization tunnel.)
- Sterile equipment train Validation, Validation of HVAC systems including clean room concepts, air handling equipment and water supply systems (purified, distilled and water for injection).
- Cleaning Validation.
- Understanding of computer system validation (electronic records and digital signature- 21 CFR Part 11) concept of firmware, Commercial off the Shelf (COTS) and GAMP 5

PRACTICALS

150hrs (6hrs/wk)

1. Evaluation of marketed solid, semisolid and liquid dosage form as per Pharmacopeia. (3Expts)
2. Drug - drug and drug - excipients compatibility studies by TLC, FTIR and DSC. (3Expts)
3. Comparative dissolution study with interpretation of similarity factor f1 and f2 for drugs belonging to BCS class I and III drugs. (2Expts)
4. Determination of shelf life for a formulation based on ANCOVA. (Analysis of Covariance).
5. Preparation and execution of stability protocol for a pharmaceutical dosage form as per ICH guidelines.
6. Investigation of a case study based on Pilot plant scale up.
7. Quality control testing of primary and secondary packaging materials.
8. Evaluation of container closure integrity.
9. Determination of compatibility between drug substances and packaging material.
10. Qualification of Pharma Equipment (Tablet compression machine, Stability chamber, Mixer). (3Expts)
11. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester). (3Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESEMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the assessment marks for theory and practicals separately.

FINAL EXAMINATION (PRACTICAL)

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment	Viva-Voce	Total
20	35	25	20	100

REFERENCES:

1. Niazi SK, Niazi S. Handbook of Preformulation: Chemical, Biological and Botanical Drugs. CRC Press; 2007.
2. AbdouHM. Dissolution Bioavailability and Bioequivalence, Mack Publishing Company, Eastern Pennsylvania.
3. Augustijns P, Brewster M. Solvent Systems and their Selection in Pharmaceutics and Biopharmaceutics. Springer; 2010.
4. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
5. Milo Gibaldi, Text book of Bio-Pharmaceuticals and Clinical Pharmokinetics, 3rd Edn, Lea &Febriger, Philadelphia.
6. Chow S-C. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.
7. Dressman JB, Kramer J. Pharmaceutical Dissolution Testing. Taylor & Francis; 2005.
8. Chilukuri DM, Sunkara G, Young D. Pharmaceutical Product Development: In Vitro-In Vivo Correlation. Informa Healthcare; 2007.
9. Niazi S. Handbook of Bioequivalence Testing. CRC Press; 2007.
10. Sunesen VH. Biorelevant Dissolution Media to Simulate in Vivo Dissolution of Poorly Soluble Drugs. Danish University of Pharmaceutical Sciences; 2003.
11. Chow SC. Statistical Design and Analysis of Stability Studies. CRC Press; 2007.

12. Chow SC. Encyclopedia of Biopharmaceutical Statistics. Marcel Dekker; 2003.
13. Paulson DS. Handbook of Regression and Modeling: Applications for the Clinical and Pharmaceutical Industries. CRC Press; 2007.
14. Huynh BK. Handbook of Stability Testing in Pharmaceutical Development: Regulations, Methodologies, and Best Practices. Springer; 2009.
15. Huynh BK. Pharmaceutical Stability Testing to Support Global Markets. Springer; 2010.
16. Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare; 2007.
17. Levin M. Pharmaceutical Process Scale-Up. CRC Press; 2001.
18. Piringer OG, Baner AL. Plastic Packaging: Interactions with Food and Pharmaceuticals. John Wiley & Sons; 2008.
19. Jenke D. Compatibility of Pharmaceutical Solutions and Contact Materials: Safety Assessments of Extractable and Leachable for Pharmaceutical Products. John Wiley & Sons; 2009.
20. Theobald N, Winder B. Packaging Closures and Sealing Systems. John Wiley & Sons; 2009.
21. Bauer E. Pharmaceutical Packaging Handbook. Informa Healthcare; 2009.
22. Dean DA, Evans R, Hall I. Pharmaceutical Packaging Technology. Taylor & Francis; 2000.
23. Calver G. What Is Packaging Design? Rotovision; 2007.
24. Haider SI. Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP and GLP Compliance. St. Lucie Press; 2002.
25. Wrigley GC. Facility Validation: Theory, Practice, and Tools. CRC Press; 2004.
26. Haider SI, Asif ES. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries. CRC Press; 2010.
27. Segalstad SH. International IT Regulations and Compliance: Quality Standards in the Pharmaceutical and Regulated Industries. John Wiley & Sons; 2008.
28. Ekins S. Computer Applications in Pharmaceutical Research and Development. John Wiley & Sons; 2006.
29. Ira R. Berry and Robert A. Nash, Pharmaceutical process validation (Drugs and Pharmaceutical Series), Marcel Dekker Inc. New York.
30. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare; 2007.
31. Agalloco JP, Carleton FJ. Validation of Pharmaceutical Processes. CRC Press; 2008.
32. Qiu Y, Chen Y, Zhang GGZ, Liu L, Porter W. Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice. Academic Press; 2009.

33. Haider SI. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, And Biotech Industries. CRC Press; 2006.
34. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press; 2000.
35. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press; 2000.

Websites:

1. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html> (ICH Stability guidelines Q1A-F)
2. <http://apps.who.int/medicinedocs/documents/s19638en/s19638en.pdf>(WHO Guidelines on packaging for pharmaceutical Products)
3. <http://www.fda.gov/downloads/Drugs/Guidances/UCM070640.pdf> (US FDA, Scale-Up and Post approval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation)
4. <http://www.validation-online.net/pharmaceutical-validation.html> (Sample validation documents)

Journals:

1. Indian Journal of Pharmaceutical Sciences.
2. Indian drugs
3. Journal of Validation Technology.
4. Pharmaceutical Engineering, International Society of Pharmaceutical Engineers.

PAPER IV: ANALYTICAL ASSURANCE

GOAL:

To equip students with comprehensive knowledge on regulatory aspects of analytical techniques.

OBJECTIVES:

On completion of the course in analytical assurance and regulatory compliance, the candidate must be able to-

- Develop and validate analytical and bioanalytical methods for pharmaceuticals vis-a-vis regulatory compliance.
- Understand the latest internationally recognized standards and developments in analytical assurance.

COURSE DESCRIPTION

THEORY

50hrs (2hrs/week)

1. **Analytical method development and validation**- Introduction, method development for assay of API and dosage forms using UV - Visible Spectroscopy, LC and GC. Validation of analytical method as per ICH guidelines and USP.(6hr)(20marks)
2. **Bioanalytical method validation** – Introduction, sample preparation and validation parameters as per USFDA.(3hr)(15marks)
3. **Impurity profiling and validation** – Types and sources - metal impurities, biological impurities, residual solvents and related substances. Identification, characterization and quantification by LC-MS/MS, GC-MS, AAS/ICPMS. Harmonized methods for microbiological limit tests. Validation as per ICH guidelines.(7hr)(20marks)
4. **Stability indicating assay** – Types of stability indicating assay method (SIAM), forced degradation studies, SIAM development and validation.(5hr)(15marks)
5. **Standardization of herbal substances, preparations and products**–As per WHO and EU requirements with special emphasis on microbial, heavy metals and pesticide residues. (5hr)(15marks)
6. **Immunological assay** - Principle, methods and application – Enzyme Linked Immunosorbent Assay and Radio Immunoassay.(2hr)(10marks)

7. **Bioassay** – Overview, types – direct, indirect and assay based on quantal responses, parallel line bioassays, bench top and primary bioassay screening, high-throughput screening, statistical principles in bioassay- randomization, replication and elimination of variation. **(6hr)(15marks)**
8. **Pyrogens** – Production, chemistry and properties of bacterial pyrogens and endotoxin. Bacterial endotoxin challenge testing: IP, BP and USP methods. Interpretation of data comparison with other pyrogen tests. **(3hr)**
9. **Sterility testing**- methodology and interpretation. **(2hr)**
10. Preservative efficacy or antimicrobial effectiveness testing as per USP.**(1hr)(Unit 8,9&10-10marks)**
11. **Advanced techniques**- principles and applications of Near Infra Red spectroscopy, Scanning Electron Microscopy, Transmission Electron Microscopy.**(5hr)(5marks)**
12. **Qualification of analytical instruments** - HPLC, UV-Visible Spectrometer, GC and FTIR. **(5hr)(15marks)**

PRACTICALS

150hrs (6hrs/wk)

1. Analytical method validation for the parameters accuracy, precision, repeatability, specificity, system suitability, selectivity and robustness for the following drugs/formulations by UV-Visible Spectroscopy and HPLC.(7Expts)
 - a. Paracetamol tablets
 - b. Diclofenac sodium gel.
 - c. Cetirizine syrup.
 - d. Metronidazole infusion.
 - e. Chloramphenicol capsules.
 - f. Ibuprofen and Paracetamol tablets
 - g. Paracetamol and Diclofenac sodium tablets.
2. Identification of impurities in drug substances by TLC and LC method - Aspirin, Paracetamol and Ranitidine HCl.(3Expts)
3. Stability indicating assays for Ranitidine HCl and Aspirin by LC method.(2Expts)
4. Limit test for heavy metals of herbal preparations - Arsenic, lead, cadmium and mercury.(2Expts)
5. Determination of residual solvents by GC. (2Expts)

6. Qualification of analytical instruments – UV- Visible spectrometer, FTIR, Colorimeter, pH meter, HPLC. (4Expts)

SCHEME OF EXAMINATION

INTERNAL ASSESEMENT:

There shall be a total of three sessionals conducted in theory and two in practicals for 30 marks separately. The average of best of two sessionals should be considered as the assessment marks for theory and practicals separately.

FINAL EXAMINATION PRACTICALS

Scheme for university practical examination

Synopsis	Major Experiment	Minor Experiment	Viva-Voce	Total
20	35	25	20	100

REFERENCES:

1. Riley CM, Rosanske TW. Development and Validation of Analytical Methods. Elsevier; 1996.
2. Chow S-C. Encyclopedia of biopharmaceutical statistics. Marcel Dekker; 2000.
3. Snyder LR, Kirkland JJ, Glajch JL. Practical HPLC Method Development. Wiley; 1997.
4. Ahuja S, Dong M. Handbook of Pharmaceutical Analysis by HPLC. Elsevier; 2005.
5. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare; 2007.
6. Braithwaite A, Smith FJ. Chromatographic Methods Fifth Edition. Chapman and Hall; 1996.
7. Ermer J, Miller JHM. Method Validation in Pharmaceutical Analysis. John Wiley & Sons; 2006.
8. Chan CC, Lee YC, Lam H, Zhang X-M. Analytical Method Validation and Instrument Performance Verification. John Wiley & Sons; 2004.
9. Bliesner DM. Validating Chromatographic Methods: A Practical Guide. John Wiley & Sons; 2006.
10. Mikkelsen SR, Cortón E. Bioanalytical Chemistry. John Wiley & Sons; 2004.
11. Ahuja S, Scypinski S. Handbook of Modern Pharmaceutical Analysis. Academic Press; 2001.
12. Rhodes CT, Carstensen JT. Drug Stability: Principles and Practices. Marcel Dekker; 2000.

13. Organization WH. Quality Control Methods for Medicinal Plant Materials. World Health Organization; 1998.
14. Chow SC. Encyclopedia of biopharmaceutical statistics. Marcel Dekker; 2000.
15. Rahman A, Choudhary MI, Thomsen WJ. Bioassay Techniques for Drug Development. Harwood Academic Publishers; 2001.
16. Wu G. Assay Development: Fundamentals and Practices. John Wiley & Sons; 2010.
17. IP, BP, USP, latest versions.
18. Williams KL. Endotoxins: Pyrogens, LAL Testing and Depyrogenation. CRC Press; 2007.
19. Agalloco JP, Carleton FJ. Validation of Pharmaceutical Processes. CRC Press; 2008.
20. Morris MD, Matousek P. Emerging Raman Applications and Techniques in Biomedical and Pharmaceutical Fields. Springer; 2010.
21. Ciurczak EW, Drennen JK. Pharmaceutical and Medical Applications of Near-Infrared Spectroscopy. CRC Press; 2002.
22. Swarbrick J. Encyclopedia of Pharmaceutical Technology. Informa Healthcare; 2007.
23. Diamandis EP, Christopoulos TK. Immunoassay. Academic Press; 1996.
24. Deshpande SS. Enzyme Immunoassays: From Concept to Product Development. Springer; 1996.
25. Yalow RS. Radioimmunoassay. Hutchinson Ross Pub. Co.; 1983.

Websites:

1. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q2_R1/Step4/Q2_R1_Guideline.pdf
2. <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
3. http://www.uspbpep.com/usp31/v31261/usp31nf26s1_c51.asp
4. http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
5. <http://www.sciencedirect.com/science/article/pii/S073170850200047X>

Journals:

- 1) Indian drugs.
- 2) Indian Journal of Pharmaceutical Sciences.
- 3) Indian Journal of Chemical Society.
- 4) Journal of Chromatography.
- 5) Journal of Pharmaceutical and Biomedical Analysis.