SARDAR PATEL UNIVERSITY
Programme: MSC (Pharmaceutical Chemistry)
Semester: IV
Syllabus with effect from: June 2010

Paper Code: PS04CPCH03	**Total Credits: 4**
Title Of Paper: Validation, Documentation and cGMP	

Unit	Description in detail	Weightage (%)
1	**Introduction to pharmaceutical validation:** Definition, Manufacturing process model, Government regulations, Scope and advantage of validation. **Concept and Philosophy of cGMP and GLP.** cGMP guidelines viz. ICH/WHO/USFDA/EDQM/ Schedule M/NDA/AMDA	**25 %**
2	**Analytical method validation:** General principles of analytical method validation, validation of following analytical instruments (HPLC, Dissolution test apparatus, UV/Visible spectrophotometer).	**25 %**
3	**Process validation:** Prospective, concurrent, retrospective and revalidation, Process validation of following formulations (Coated tablets, Capsules, Ampoules & Vials, Ointments/Cream, Liquid orals). **Cleaning validations:** Cleaning of equipments, Clean room technology.	**25 %**
4	**Intellectual Property Rights:** Scope and Objective, Basic terms, concepts of law (Indian legal system) Concepts of property with respect to Intellectual creativity, Tangible and Intangible property. Concepts of IPR, Scope and nature of patents, Copyrights, Trademarks, Geographical Implications. Concepts related to patents, Type of patents, Global perspective of patent system, Role of international organization: WTO, WIPO, EPO in patent practice.Indian Patent Act, Patentability, Patent Application, Revocation of Patent, Infringement and Litigation with few case studies on patent, Commercialization and Licensing	**25 %**

Basic Text & Reference Books:

- **How to Practice GMPs**, Author: P.P.Sharma, Vandna Publications, Agra
- **Pharmaceutical Process Validation**, Author: Ira R. Berry and Robert Nash, Publisher: Marcel Decker Inc.(2nd edition).
- **Validation of Pharmaceutical Processes: Sterile Products, Second Edition, Revised and Expanded**; Auhtor: James P. Agalloco; Publisher: Informa HealthCare; 2nd edition; ISBN-10: 0824793846, ISBN-13: 978-0824793845.
- **Current Good Manucturing Practices**, Author: M.A. Potdar, Pharma-Med Press, Hydreabad.
- **Good Manufacturing Practices and Inspection (Quality Assurance of Pharmaceuticals);** Author: World Health Organization, Publisher: World Health Organization; 2nd Updated edition (2007)ISBN-10: 9241547081, ISBN-13: 978-9241547086.
- **Intellectual Property Rights under WTO: Tasks Before India,** Author: T. Rammappa – New Delhi, Wheeler Publishing, 2000.
- **Intellectual Property Rights: Text & Cases;** Author: Dr. S. Balasubhramanian Dr. R Radhakrishnan, Publisher: Excel Books N Delhi, ISBN: 8174466096, ISBN-13: 9788174466099, 978-8174466099.