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

Paper Code: PS03EPCH01	**Total Credits: 4**
Title Of Paper: Advance Pharmaceutical Chemistry	

Unit	Description in detail	Weightage (%)
1	**Bioavailability and Bioequivalence:** Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.	**25 %**
2	**Water Treatment & Sterilization Process:** Techniques and maintenance – RO, DM, ultra – filtration, WFI. **Sterilization and sterility testing:** Principle, validation of different sterilization processes, methods, industrial sterilizer, air handling unit and sterility testing of different types of dosage form.	**25 %**
3	**Pilot plant design and Large scale synthesis:** Basic requirements for design, facility, equipment selection for tablets, capsules, liquid orals, parentrals and semisolid preparations. **Large-scale Synthesis:** Introduction, scale-up: synthetic strategy, bench-scale, experimentation, scale-up from Bench to Pilot Plant.	**25 %**
4	**Quality Control & Quality Assurance:** Basic concept of quality assurance, functions, source of variation, control of quality – Raw materials, APIs, Packing materials, finished products and environment. **Quality Assurance Systems:** For materials, production, facilities & equipments, packaging & labeling. In-process quality control – importance, inspection, IPQC tests.	**25 %**

Basic Text & Reference Books:

- **Quality assurance of Drugs in Pharmaceuticals**, Author: P.D.Sethi, Vandana Publ, New Delhi.
- **Pharmaceutical statistics,** Author: S.B. Bolton, Vol 80, Marcel Dekker, Inc.
- **Statistical Methodology in Pharmaceutical Science**, Author: D.A. Berry, Marcel Dekker, Inc.
- **How to Practice GLP**, Author: P.D. Sethi, Vandana Publ, New Delhi.
- **Pharmaceutical Production facilities, design and applications**, Author: GC Cole, Publisher: Taylor and Francis.
- **Pharmaceutical Quality Control Lab Library Edition: GMP (Good Manufacturing Practices) Training for Pharmaceutical Manufacturing, Covering FDA Regulations of Standard and OOT (Out of Trend) Results**, Author: Daniel Farb, Publisher: University Of Health Care, ISBN-10: 1594910375, ISBN-13: 978-1594910371.
- **Documentation Basics That Support Good Manufacturing Practices and Quality System Regulations;** Author: Carol DeSain, Publisher: Tamarack Associates, LLC (July 1, 2004), ISBN-10: 097547720X, ISBN-13: 978-0975477205.
- **Good Manufacturing Practices and Inspection (Quality Assurance of Pharmaceuticals);** Author: World Health Organization, Publisher: World Health Organization; 2 Updated edition (June 6, 2007), ISBN-10: 9241547081.
- **The Theory and Practice Of Industrial Pharmacy, Spl Indian Ed, 2009,** Author: Lachman L. ISBN: 8123916973, ISBN-13: 9788123916972, 978-8123916972, Publisher: CBS Publishers & Distributors.