4.6 ADVANCED INDUSTRIAL PHARMACY (THEORY)
50 hours ; 2 hours/week

1. **Biopharmaceutical classification systems** and methods to improve the bioavailability of poorly soluble drugs - solid dispersion and complexation techniques.
   4 hours; 5-10 marks
2. **Controlled drug delivery systems**: Principle, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. **5 hours; 8-10 marks**
   Microencapsulation: Definition, applications, air suspension, coacervation and phase separation techniques. **3 hours; 5-7 marks**

3. a) **Novel drug delivery systems**: Concepts, advantages and disadvantages, types of drug delivery systems such as transdermal, nasal, ocular, buccal and implants with suitable examples. **6 hours; 10-12 marks**
   b) **Targeted drug delivery systems**: Concepts and approaches, advantages and disadvantages. Applications of microspheres, liposomes, niosomes, nanoparticles.
   4 hours; 5-10 marks
4. **Pilot Plant scale up**: General considerations - including significance of personnel requirements, space requirements, raw materials and development of Master Formula Records and Batch Manufacturing Records. Pilot plant scale up considerations for tablets.
   6 hours; 10-12 marks

5. **Pharmaceutical Packaging**: Materials used for packaging of pharmaceutical products, advantages, disadvantages and quality control tests. **4 hours; 5-10 marks**

6. **Current Good Manufacturing Practices (cGMP)**: as per D&C Act, USFDA, MHRA and TGA guidelines. **4 hours; 5-10 marks**

7. **Validation**: Definition, types of validation, methods for process validation of pharmaceutical operations – Mixing and compression. **6 hours; 10-12 marks**

8. **Biostatistics**: Introduction, Types of data distribution, Measures describing the central tendency distributions- average, median, mode. Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean. **5 hours; 8-10 marks**

9. **ICH guidelines and QbD**: Introduction to ICH guidelines: Quality, efficacy and safety of drugs. Introduction to the concepts of Quality by Design (QbD).
   3 hours; 5-10 marks

ADVANCED INDUSTRIAL PHARMACY REFERENCE BOOKS

1. Chien YW. Novel drug delivery systems. 2nd ed. New York:Marcel Dekker Inc;2007.
2. Jain NK. Controlled and novel drug delivery. New Delhi: CBS Publishers and Distributors;1997.
3. Nash RA, Berry IR. Pharmaceutical process validation. 2nd ed. New York: Marcel Dekker Inc;1993
4. Robinson JR, Vincent HLL. Controlled drug delivery. 2nd ed. New York: Marcel Dekker Inc;1987.
5. Sharma PP. Validation in pharmaceutical industry. Delhi:Vandana Publications.
6. Subrahmanyam CVS, Thimmasetty J. Pharmaceutical regulatory affairs. 1st ed. New Delhi: VallabhPrakashan;2012.
7. Vyas SP, Khar RK. Controlled drug delivery. Delhi: Vallabh Prakashan; 2002.
8. Yajaman S. Novel drug delivery systems and regulatory affairs. New Delhi:S Chand Publishing.

Websites:

www.ich.org, www.cdsco.nic.in