

#### 4.1 PHARMACEUTICAL TECHNOLOGY AND BIOPHARMACEUTICS (THEORY) 75 hours ; 3 hours/week

##### 1. **Preformulation:**

- a. Study of physicochemical characteristics of drug substances. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms. **6 hours;6-8marks**

##### **Tablets:**

- b. Classification of tablets. Processing of tablets: Formulation, granulation methods, compression and processing problems. Equipment's and tablet tooling. **5 hours; 5-7 marks**

- c. Tablet coating: Types of coating, coating materials, formulation of coating materials, method of coating, equipment employed and defects in coating. **4 hours; 4-6 marks**

- d. In process quality control, evaluation of tablets and packaging. **2 hours;2-5marks**

##### 2. **Capsules:**

- a) Hard gelatin capsules: Extraction of gelatin and production of hard gelatin capsule shells. Filling, finishing and special techniques of formulation of hard gelatin capsules. Quality control tests for capsules. **5 hours; 5-7 marks**

- b) Soft gelatin capsules: Nature of shell and capsule content, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. **3 hours; 3-5 marks**

3. **Parenteral Preparations:** Definition, types, advantages and limitations, general formulation, vehicles, production procedure, production facilities and controls. Formulation of injections, sterile powders, emulsions and suspensions. Containers and closures pertinent to sterile preparations and quality control tests.

**14 hours;15-20 marks**

4. **Ophthalmic formulations:** Requirements, formulation of eye drops, eye lotion and eye ointments, containers and evaluation. **5 hours; 5-7 marks**

5. **Liquid orals:** Formulation and manufacturing considerations. Filling and packaging methods. **5 hours; 5-7 marks**

6. **Pharmaceutical aerosols:** Definition, propellants, containers, valves, types of aerosol systems, manufacture of aerosols. Evaluation of aerosols: Quality control and stability studies. **6 hours; 5-10 marks**

7. **Cosmetics:** Formulation and preparation of the following cosmetic preparations. Lipsticks, Shampoos, Face and Talcum powders, Nail lacquers, cold cream and vanishing cream, tooth pastes, and hair dyes and sunscreens. **10 hours; 10-15 marks**

##### 8. **A) Biopharmaceutics:**

- a. Definition and applications, Absorption of drugs through GIT: Mechanisms and factors affecting.
- b. Bioavailability and Bioequivalence. Measurement of Bioavailability ( $C_{max}$ ,  $T_{max}$ , AUC).

- B) Pharmacokinetics-Basic concepts:** Blood level curves for I.V, Constant rate infusion, Oral, I.M, and Sustained release dosage forms. **11 hours; 10-15 marks**

**PHARMACEUTICAL TECHNOLOGY & BIO PHARMACEUTICS (PRACTICALS)**  
**75 hours ; 3 hours/week**

- 1. Manufacture of tablets. \*\***
  - a) Tablets prepared by wet granulation.
  - b) Tablets prepared by direct compression.
  - c) Mouth dissolving tablet.
  - d) Chewable tablet.
- 2. Manufacture of sterile products. \*\***
  - a) Ampoules of ascorbic acid injection IP
  - b) Ampoules of calcium gluconate injection IP
  - c) Sodium chloride intravenous infusion IP
  - d) Vials of oxytetracycline injection IP
  - e) Eye drops
- 3. Evaluation of pharmaceutical formulations. (Q.C. tests)\***
  - a) Tablets.
  - b) Capsules.
  - c) Sterile products.
- 4. Formulation of two liquid oral preparations\* and evaluation by assay\*\*.**
  - a) Preparation and evaluation of paracetamol syrup.
  - b) Preparation and evaluation of magnesium hydroxide mixture BP.
- 5. Cosmetic preparations.\***
  - a) Lipsticks
  - b) Cold cream and vanishing cream
  - c) Clear liquid shampoo
  - d) Tooth paste and tooth powders
  - e) Sunscreens
- 6. Tablet coating. (demonstration)**
- 7. Demonstration of microencapsulation technique/ matrix tablets/ transdermal patches.**

**Note: \*\* Denotes major experiments      \* Denotes minor experiments**

**SCHEME OF EXAMINATION**

1. Synopsis	-10 Marks
2. Major experiment (indicated by **)	-30 Marks
3. Minor experiment (indicated by *)	-20 Marks
4. Viva voce	-10 Marks
<b>Total</b>	<hr/> <b>= 70 Marks</b> <hr/>

## **PHARMACEUTICAL TECHNOLOGY & BIO PHARMACEUTICS REFERENCE BOOKS**

1. Aulton ME. *Pharmaceutics, The science of dosage form design*. 2<sup>nd</sup> ed. Edinburgh:Churchill Livingstone;2002.
2. Banker GS, Rhodes CT. *Modern pharmaceutics*. 4<sup>th</sup> ed. New York: Marcel Dekker Inc; 2005.
3. Carter SJ. *Cooper and Gunn's Tutorial pharmacy*. 6<sup>th</sup> ed. New Delhi:CBS Publishers;2000.
4. Gennaro AL. *Remington: The science and practice of pharmacy, Vol I and II*. 20<sup>th</sup> ed. Philadelphia:Lippincott Williams and Wilkins;2000.
5. Lachman L, Lieberman HA, Kanig JL. *Theory and practice of industrial pharmacy*. 3<sup>rd</sup> ed. Bombay: Varghese Publishing House; 1987.
6. Lachman L, Lieberman HA, Kenneth EA. *Pharmaceutical dosage forms: Parenteral medications Vol I,II and III*. New York:Marcel Dekker Inc;1992.
7. Lachman L, Lieberman HA. *Pharmaceutical dosage forms: Tablets Vol I,II and III*. New York:Marcel Dekker Inc;1980.
8. Loyd VA, Nicholas GP, Howard CA. *Ansel's pharmaceutical dosage forms and drug delivery systems*. 8<sup>th</sup> ed. Noida: BI Publications Pvt Ltd;2005.
9. *Pharmacopoeias: I.P., B.P., U.S.P.*
10. Rawlins EA. *Bentley's textbook of pharmaceutics*. 8<sup>th</sup> ed. New Delhi:Reed Elsevier India Pvt Ltd;2010.
11. Shargel L, Andrew BC, Susanna WP. *Applied biopharmaceutics and pharmacokinetics*. 5<sup>th</sup> ed. New York: The McGraw Hill Companies Inc;2005.
12. Sharma PP. *Cosmetics – Formulation, manufacturing and quality control*. 2<sup>nd</sup> ed. Delhi: Vandana Publications; 2001.
13. Subrahmanyam CVS, Thimmasetty J, Vijayendraswamy SM, Shivanand K. *Laboratory manual of industrial pharmacy*. Delhi:Vallabh Prakashan;2009.
14. Venkateswarlu V. *Biopharmaceutics and pharmacokinetics*. Hyderabad:Pharma Book Syndicate;2004.
15. Wilkinson JB, Moore RJ. *Harry's cosmeticology*. 7<sup>th</sup> ed. London:Longman Scientific & Technical;1989.

### **LIST OF MINIMUM EQUIPMENTS REQUIRED**

1. Ampoule filling sealing machine	01 no.
2. Ampoule washing machine	01 no.
3. Capsule filling machine	01 no.
4. Clarity test apparatus	02 nos.
5. Digital thermometers	02 nos.
6. Friability test apparatus	02 nos.
7. Lipstick moulds	10 nos.

8. Magnetic stirrers, 500 ml and 1 liter capacity	05 nos.
9. Mechanical stirrers	03 nos.
10. Monsanto's hardness testers	02 nos.
11. Ointment crimping machine	01 no.
12. Ointment filling machine	01 no.
13. Pfizer type hardness testers	02 nos.
14. Standard granulating sieves	2 sets
15. Tablet coating pan	01 no.
16. Tablet disintegration test apparatus IP	01 no.
17. Tablet dissolution test apparatus	01 no.
18. Tablet punching machine	01 no.
19. Tray dryer	01 no.
20. Vial crimping machine	01 no.