MPH2A.6: / MPH2G.6 ADVANCED PHARMACEUTICAL TECHNOLOGY 3 Hrs/Week

THEORY

UNIT - I

1. Formulation Development:

(a) Solid dosage forms:

Improved production techniques for tablets: New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression and computerization for in process quality control of tablets.

(b) Powder dosage forms:

Formulation development and manufacture of powder dosage form for internal and external use including inhalation dosage forms.

(c) Liquid and semi-solid dosage forms:

Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.

(d) Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, manufacture & quality control.

UNIT - II

2. Aseptic processing operation and parenteral dosage form development:

Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation conditions, Theoretical evaluation of aseptic operations. Advances in materials and production techniques for parenteral dosage forms.

UNIT - III

3. Scale-up Techniques:

Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments.

4. Process Validation:

Regulatory basis, Validation of solid dosage forms, Sterile products, Liquid dosage forms, Process validation of raw materials, Validation of analytical methods, Equipment and Process.

UNIT - IV

5. Optimization techniques in pharmaceutical and processing:

Optimization parameters, statistical design and other applications, design, development and optimization of in-vitro test systems to evaluate and monitor the performance of different types dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evolution and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.