

NIMS UNIVERSITY, JAIPUR



SYLLABUS

**PG Diploma in Pharmaceutical Production
Management**

**POST GRADUATE DIPLOMA IN PHARMACEUTICAL
PRODUCTION MANAGEMENT (Duration: 1 Year)**

S.NO	YEAR-1	Theory
1.	Pharmaceutical Industry & Production Planning	100
2.	Product Development	100
3	Regulatory Guidelines	100
4	Human Resources Management	100

(1). Pharmaceutical Industry and Production Planning:

(A). **Pharmaceutical Industry Developments:** Licenses for Formulation Industry, Plant Location- Factors Influencing

(B). **Plant Layout:** Factors Influencing, Special Provisions, Storage space requirements, Sterile and Aseptic area layout

(C) **Pharmaceutical Process Flow and Work Study:** General Flow Patterns, Work Station Design, Process Flow Diagrams, Work Study and Work Measurements

(D) **Production Planning:** General Principles, Production Systems, Calculation of Standard cost, Process Planning, Routing, Loading, Scheduling, Despatching of Records, Production Control.

(E) **Material Management:** Value analysis and Vendor Development

(F) **Maintenance Management:** Corrective maintenance, Scheduled maintenance, Preventive maintenance, Predictive maintenance and Replacement analysis.

(G) **Waste Management:** Solid Waste Management, Effluent Analysis and Treatment

(H) **Industrial Hazards and Plant Safety:** Fire hazards, mechanical hazards and electrical equipments, chemicals and pharmaceuticals, monitoring and preventing systems, Safety Management.

(I) **Time Management:** Time Management Concept, Time Management Generations, Prioritization of Work- Time Allotment, Implementation of Time Management Programme.

(J) **Warehousing:** Design, Construction, Maintenance and sanitation for materials and products, Good warehousing practices.

(2). Product Development:

(A). **Process Variables:** A consideration of Physico-chemical Characteristics of new drug molecules with respect to different dosage form, Solubility Phenomenon in Pharmaceuticals, Enhancement of Solubility, Stability Studies.

(B). **Optimization techniques in pharmaceutical formulation and processing:** Concept of optimization, optimization parameters, Classical optimization, Statistical Designs, Optimization Methods (EVOP, The Simplex and The Lagrangian).

(C). **Bioprocess Technology:** Design and Operation of Fermenters, Fermentation Technology, Fermentation Process Kinetics, General Fermentation Process Economics

(D). **Herbal Technology:** Processing, Equipment and Analytical Profiles of Extract Drugs, Isolation, estimation and Standardization of phytoconstituents (with special emphasis on HPLC and HPTLC).

(E) **Pilot Plant Scale-up Techniques:** Significance of Pilot scale-up Phase to affect and orderly set-up from the laboratory procedures and formulations to routine production procedures, raw materials and process, physical lay-outs, personnel requirements, and reporting responsibilities. Input specifications and in-process and finished product specifications.

(F). **Packaging of pharmaceutical dosage forms:** Introduction, glass- the absolute barrier, elastomeric closures, plastic, metal, paper and board, special packaging, analysis and control of packaging materials, blister and strip packaging and their evaluations.

(G). **Stability testing of pharmaceutical products:** Physicochemical factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Brief review of ICH Guidelines related to stability study.

(H). **Enzyme Technology:** Production, isolation and purification of enzymes, Applications in pharmacy and Immobilized enzymes and its future applications.

(3) Regulatory Considerations:

- (A) US-FDA Guidelines
- (B) ICH Guidelines
- (C) ISO 9000
- (D) Quality Control-Quality Assurance and Validation: Introduction, need of validation, importance, advantages, phases of validation, types of validation, concept of quality assurance, definition/scope, requirements for effective Q.A, quality system validation, Q.A Vs Q.C.
- (E) **Pharmaceutical documentation:** Introduction, objectives of documentation, general requirements, and various types of documentation related to industrial work.
- (F) GMP-cGMP
- (G) WHO Guidelines
- (H) Factories Act 1948: Objectives, Approval licensing and Registration of factories, inspecting staff, health and safety, welfare, working hours, penalties and procedures.
- (I) Intellectual property rights and patents laws, GATT, WTO, TRIPs and TRIMs.

(4) Human Resources Management

- (A) Human Resource Planning
- (B) Job Analysis and Design
- (C) Recruitment
- (D) Personnel selection
- (E) Orientation and Placement
- (F) Training and Development
- (G) Performance Appraisal
- (H) Remuneration and Salaries
- (I) Compensation and Incentives
- (J) Motivation
- (K) Job design
- (L) Computer application in pharmaceutical production and management